

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
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Case Number: 181156 Seq: 1 Gender: F

Reported: 07/01/2003 Weight: 79.00 Hospitalisation: Age: 41

Onset Date: 28/11/2002 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Sedation		Excessive sedation, slept for over 15 hours and then extremely drowsy	Patient already in hospital.

Medicine Details:

Medicine Details.					
ZYPREXA (Suspected)			Reason:		
Tablet	2.5	Milligram	Daily		Oral
Batch:	Started:			Stopped:	29/11/2002
TRAMAL (Suspected)			Reason:		
Tablet	50.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	29/11/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:181191Seq:1Gender:MReported:08/01/2003Weight:0.00Hospitalisation:Admitted to hospitalAge:15

Onset Date: 17/08/2002 DOB: 13/03/1987

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Fever, Malaise, Ck was elevated on 27/08/2002 at 402 but unnoticed until his admission in 04/11/2002 when Ck was 1963. Neuroleptic Malignant Syndrome. Myalgia.	Date hospitalised 04/11/02.
Blood creatine phosphokinase incr			
Malaise			
Myalgia			
Neuroleptic malignant syndrome			

Medicine Details:

OLANZAPINE (Suspected)			Reason:	Unspecified ps	sychosis
Tablet	5.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
RISPERIDONE (Suspected)			Reason:	Unspecified ps	sychosis
Tablet	1.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	04/11/2002
SERTRALINE HYDROCHLORIDE (S	uspected)		Reason:	Depression	
Tablet	25.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	04/11/2002

Laboratory Investigations:

L	Date	Type	Range	Date Tested	Result	Details
ſ	08/01/2003	Creatine	CK range	27/08/2002	402	
	08/01/2003	Creatine	CK range	04/11/2002	1963	
	08/01/2003	Creatine	CK range	06/11/2002	3553	

Additional Information:

The dose start and stop date for the drug Olanzapine - 01/02 and 10/02. Dose start date for Risperidone - 01/01 and dose start date for Sertraline - 01/02. Despite 10 days of treatment, patient remains psychotic.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 181205
 Seq: 1
 Gender:
 F

 Reported:
 08/01/2003
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 85

Onset Date: 10/09/2002 DOB: 27/10/1916

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touction Dotaile.			
Preferred Term	Severity	Report Description	Treatment
Pemphigoid		blisters all over body, started at the upper limb, then progressed to whole body	Treated with Topical Eleuphrat to legs and arms, oral Prednisone, Azathioprine and Minomycin.
Dermatitis bullous	Severe		
Pemphigoid	Severe		

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified schizophreniaTablet5.0 MilligramDailyOral

Batch: Started: 08/09/2002 **Stopped:** 10/09/2002 CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
08/01/2003	Histology				

Additional Information:

other drugs - Zocor, Prinivil, Normison and Panadol.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:181218Seq: 1Gender:FReported:08/01/2003Weight:0.00Hospitalisation:Admitted to hospitalAge: 31Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delusion		Delusions, Obsessive-Compulsive Disorder and Creatine Kinase Increased	
Blood creatine phosphokinase incr			
Obsessive-compulsive disorder			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 15.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
08/01/2003	Creatinine				

Additional Information:

Medical history - Drug and Alcohol problems.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 181336 Seq: 1 Gender: U

Reported: 09/01/2003 Weight: 60.00 Hospitalisation: Age: 72

Onset Date: 30/10/2002 **DOB**: 03/10/1930

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Gait disturbance	to Doctor	Suddenly unable or unwilling to walk 2 weeks into Zyprexa. Started walking 2 days after Zyprexa - no obvious neurological deficit	

Medicine Details:

viedicine Details:						
NATRILIX (Other drug)		Rea	son:			
	1.0	Dose Unspecified	Daily			
Batch:	Started:	L TERM		Stopped:		
ZOLOFT (Other drug)		Rea	son:			
	100.0	Milligram	Alternate	days		
Batch:	Started:			Stopped:		
ZYPREXA (Suspected)		Rea	son:			
Tablet	5.0	Milligram	Daily		Oral	
Batch:	Started: 23	/10/2002		Stopped:	19/11/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 181475 Seq: 1 Gender: M

Reported: 13/01/2003 Weight: 0.00 Hospitalisation: Age: 41

Onset Date: 20/11/2002 **DOB**: 13/12/1960

Outcome: Recovered 28/11/2002 Causality: Causality possible

Reaction Details:

toaction Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Coordination abnormal		Ataxia; slow movement, possible extrapyramidal syndrome.	

Medicine Details:

SOLIAN (Interaction)		Reason:		
	200.0 Milligram	Daily		
Batch:	Started: 04/11/2002		Stopped:	
ZYPREXA (Interaction)		Reason:		
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 20/08/2002		Stopped:	
KALMA (Other drug)		Reason:		
Batch:	Started:		Stopped:	
LITHIUM CARBONATE (Other drug)		Reason:		
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

patient was also taking Iron tablets.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 181587 Seq: 1 Gender: U

Reported: 14/01/2003 Weight: 0.00 Hospitalisation: Age: 52

Onset Date: 06/12/2002 **DOB**: 02/07/1950

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		Hyperglycaemia	

Medicine Details:

Medicine Details.			
TOFRANIL (Other drug)		Reason:	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 04/12/2002	Stopped:	07/12/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
14/01/2003	Biochemistry				

Additional Information:

Patient has Type 11 Diabetes monitors BSL, usually well controlled.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Ren	ort	Deta	ils:
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Case Number: 181640 Seq: 1 Gender: F

Reported: 15/01/2003 Weight: 0.00 Hospitalisation: Age: 43

Onset Date: 21/06/2002 DOB: 28/03/1959

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sleep walking	Required Visit to Doctor		Dose reduction from 20mg to 10mg.

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repoi ospitalisat	etails: liber: 181691 rted: 15/01/2003 tion: Admitted to	Seq: 1			Gender: Weight: Age:	0.00 45
Onset D	pate: pme: Unknown				DOB:	Causality possible
eaction D					oudounty.	caddanty possible
	eferred Term	Severity	Repo	rt Description		Treatment
	se increased	Caused or prolonged inpatient hospitalisation	Blood sugar incre			
/ledicine						
ZYPREXA (S			Reas	son:	01	
Table		Otented			Oral	
Bate	ы.	Started:		Stoppe	ed:	
				Stoppe	ed:	
	ry Investigatio	ons:	ed Result	Stoppe	ed: Detai	Is
Laborato		ons:	ed Result	Stoppe		ls

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:						
Reported: ´ lospitalisation: Onset Date: ´	5/01/2003	Seq: 1			Gender: Weight: Age: DOB:	0.00
Outcome: \	Jnknown				Causality:	Causality possible
eaction Details		_	_			
Preferred	l Term	Severity		oort Description		Treatment
Sepsis		Caused or prolonged inpatient hospitalisation		hrombocytopenia	а.	
Thrombocytopenia	ı	Caused or prolonged inpatient hospitalisation				
Medicine Deta GINSENG (Other dro			Re	ason:		
Batch:		Started:	Stopped:			
MINIPRESS (Other of	lrug)			eason:		
Tablet		1.0 Milligram		Daily Oral		
Batch:		Started:		Stop	oed:	
TEMAZEPAM (Other	drug)	40.0		ason:		
Batch:		Started:	Milligram	Daily Stop	and:	
ZYPREXA (Suspecte	ed)	Started.	Re	ason:	Jeu.	
Tablet	, _ ,	2.5	Milligram	Daily	Oral	
Batch:		Started:	3 '	Stop		
-l				1		
Laboratory Inv	ype Ran	ge Date Test	ted Result		Deta	ils

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 181695
 Seq: 1
 Gender: M

 Reported:
 15/01/2003
 Weight: 0.00

Hospitalisation: Admitted to hospital Age: 51
Onset Date: 29/10/2002 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

100.01.01. = 0100.			
Preferred Term	Severity Report Description		Treatment
Orthostatic hypotension		Postural Hypotension - orthostatic hypotension	dose of olanzapine may be reduced to 2.5mg/day

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

Tablet 5.0 Milligram Daily Oral

Batch: Started: Stopped: 30/10/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of postural hypotension, anxiety, epilepsy

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 181730
 Seq: 1
 Gender:
 F

 Reported:
 16/01/2003
 Weight:
 3.90

 Hospitalisation:
 Age: 28D

Onset Date: DOB:
Outcome: Unknown Causality: Causality possible

Reaction Details:

<u>leaction Details.</u>	dotion betails:						
Preferred Term	Severity	Report Description	Treatment				
Cerebral haemorrhage neonatal		Acute haemorrhage in left basal ganglia of brain.					
Infantile apnoeic attack	Required Visit to Doctor	Apnoea and desaturation requiring ventilation for 1st p days of life.	Phenobarbitone for seizures; ventilation; hyperbilirubinaemia requiring phototherapy				
Congenital foot malformation		Baby dysmorphic - long, thin digits and overlapping 4th toes.					
Hyperbilirubinaemia		Conjugated hyperbilirubinaemia					
Weight decrease neonatal		Feed intolerance (weight dropped by 10% until day 20)					

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspec	cified psychosis	
Tablet			Oral	
Batch:	Started:	Sto	pped:	
ZYPREXA (Suspected)		Reason:		
Batch:	Started:	Sto	pped:	
ZUCLOPENTHIXOL DECANOATE	(Suspected)	Reason: Unspec	cified psychosis	
Injection			Intramuscular	
Batch:	Started:	Stopped:		
EPILIM (Suspected)		Reason:		
Tablet	1.2 Gram	Daily	Oral	
Batch:	Started:	Sto	pped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
16/01/2003	Electroencephalog				EEG - seizure from right temporal region.
16/01/2003	Other data				Acute haemorrhage determined by cerebral ultrasound and MRI scan

Additional Information:

Epilim 1200mg started in 1991 (first trimester of pregnancy), then 1500mg/day (at 20 weeks gestation age) and continues. Clozaril, zyprexa and zuclopenthixol started in 1991.

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DOB:

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 181730
 Seq: 1
 Gender:
 F

 Reported:
 16/01/2003
 Weight:
 3.90

 Hospitalisation:
 Age: 28D

Outcome: Unknown Causality: Causality possible

Reaction Details:

Onset Date:

Caction Details.	ouotion Botano.							
Preferred Term	Severity	Report Description	Treatment					
Hepatosplenomegaly neonatal		Liver distrubances and hepato-splenomegaly.						
Convulsion		Seizures from day 8 onwards						
Hyperammonaemia		Transient hyperammonemia.						
Vomiting		Vomiting						
Hypoxia								

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified psychosis	
Tablet		Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL DECANOATE	(Suspected)	Reason: Unspecified psychosis	
Injection		Intramuscular	
Batch:	Started:	Stopped:	
EPILIM (Suspected)		Reason:	
Tablet	1.2 Gram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Epilim 1200mg started in 1991 (first trimester of pregnancy), then 1500mg/day (at 20 weeks gestation age) and continues. Clozaril, zyprexa and zuclopenthixol started in 1991.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 182677 Seq: 1 Gender: U

Reported: 11/02/2003 Weight: 42.00 Hospitalisation: Age: 77

Onset Date: 31/10/2002 **DOB:** 21/09/1925

Outcome: Recovered 03/02/2003 Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Gait disturbance		Parkinson's like change in tone with rigidity, cogwheel, tremor and shuffley gait.		
Parkinsonism		Parkinson's like change in tone with rigidity, cogwheel, tremor and shuffley gait.		
Tremor		Parkinson's like change in tone with rigidity, cogwheel, tremor and shuffley gait.		

Medicine Details:

ZYPREXA (Suspected)		Reason:	Paralysis agitans
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 26/11/2001		Stopped: 21/11/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	no	rt	De	tai	ls:
	\sim		-	u	

Case Number: 182708 Seq: 1 Gender: F

Reported: 11/02/2003 Weight: 82.00 Hospitalisation: Age: 34

Onset Date: DOB: 07/07/1968

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
Α	bdominal distension		Felt "bloated".	Olanzaipine ceased.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 20/11/2002 Stopped: 03/01/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 182815 Seq: 1 Gender: F

Reported: 12/02/2003 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 62

Onset Date: 20/01/2003 **DOB**: 21/09/1940

Outcome: Recovered 28/02/2003 Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Liver function test abnormal	Abnormal LFTs after commencement of olanzapine.		

Medicine Details:

FEXOFENADINE HYDROCHLORIDE	(Other drug)	Reason:	Chronic nasopharyngitis	
Oral application	30.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	
OLANZAPINE (Suspected)		Reason:	Unspecified psychosis	
Oral application	5.0 Milligram	Daily	Oral	
Batch:	Started: 10/01/2003		Stopped: 20/01/2003	
OLANZAPINE (Suspected)		Reason:	Unspecified psychosis	
Oral application	10.0 Milligram	Daily	Oral	
Batch:	Started: 17/01/2003		Stopped: 20/01/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/02/2003	ALT = SGPT				
	GGT = SGGT =				
	SAP = ALP				

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 183825 Seq: 1 Gender: M

Reported: 07/03/2003 Weight: 0.00 Hospitalisation: Age: 30Y

Onset Date: 30/05/2002 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Overdose		Overdose and convulsions	
	Grand mal convulsion			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 30.0 Milligram Daily Oral

Batch: Started: Stopped: contin

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Previous treatment with Clozapine years ago from which he developed seizures. No family history of seizures. Drug induced seizures.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 183857 Seq: 1 Gender: U

 Reported:
 10/03/2003
 Weight:
 0.00

 Hospitalisation:
 Age:
 99U

 Onset Date:
 25/11/2002
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Glucose tolerance impaired		Glucose intolerance	

Medicine Details:

CLOZAPINE (Suspected)		Reason:	Schizophrenia		
Tablet	400.0 Milligram	Daily		Oral	
Batch:	Started: 18/11/2002		Stopped:		Contin
OLANZAPINE (Suspected)		Reason:	Schizophrenia		
Tablet	10.0 Milligram	Daily		Oral	
Batch:	Started: 09/10/2002		Stopped:	26/11/2002	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 183966 Seq: 1 Gender: M

 Reported:
 06/02/2003
 Weight:
 0.00

 Hospitalisation:
 Age:
 16Y

Onset Date: 22/11/2002 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Required Specialist Consultation	Mild neutropenia	

Medicine Details:

Medicine Details.		
ZYPREXA (Suspected)		Reason: Manic-depression psycho,manic
Tablet	12.5 Milligram	Daily Oral
Batch:	Started: 04/07/2002	Stopped: 22/11/2002
EPILIM (Suspected)		Reason: Manic-depression psycho,manic
Tablet	800.0 Milligram	Daily Oral
Batch:	Started: 27/07/2002	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
06/02/2003	Neutrophils		15/10/2002	2.38	
06/02/2003	Neutrophils		22/11/2002	1.53	
06/02/2003	Neutrophils		27/12/2002	1.52	
06/02/2003	Neutrophils		06/12/2002	1.63	
06/02/2003	Neutrophils		15/01/2003	1.58	
06/02/2003	Neutrophils		12/12/2002	1.49	
06/02/2003	Neutrophils		02/12/2002	1.47	

Additional Information:

182488 is a duplicate

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 183966 Seq: 1 Gender: M

 Reported:
 06/02/2003
 Weight:
 0.00

 Hospitalisation:
 Age:
 16Y

 Onset Date:
 22/11/2002
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.		
ZYPREXA (Suspected)		Reason: Manic-depression psycho,manic
Tablet	12.5 Milligram	Daily Oral
Batch:	Started: 04/07/2002	Stopped: 22/11/2002
EPILIM (Suspected)		Reason: Manic-depression psycho,manic
Tablet	800.0 Milligram	Daily Oral
Batch:	Started: 27/07/2002	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/02/2003	White blood cells		15/10/2002	4.5	
06/02/2003	White blood cells		22/11/2002	3.8	
06/02/2003	White blood cells		02/12/2002	3.8	
06/02/2003	White blood cells		06/12/2002	3.8	
06/02/2003	White blood cells		13/12/2002	3.6	
06/02/2003	White blood cells		27/12/2002	3.4	
06/02/2003	White blood cells		15/01/2003	3.6	

Additional Information:

182488 is a duplicate

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 184372 Seq: 1 Gender: F

Reported: 25/03/2003 Weight: 0.00 Hospitalisation: Age: 89

Onset Date: 03/12/2002 DOB: 12/10/1913

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
			parkinsonism type tremor in hands and arms (more noticable at rest).	

Medicine Details:

OLANZAPINE (Suspected) Reason: Otr spec symp psychopathol nec

Tablet 7.5 Milligram Daily Oral

Batch: Started: Stopped: 25/12/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Increased Olanzapine from 5 mg to 7.5mg one month ago, tremor noticed since then,

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:184905Seq: 1Gender:MReported:11/04/2003Weight:0.00Hospitalisation:Admitted to hospitalAge: 22Y

Onset Date: 01/09/1999 **DOB**:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Schizophrenia		Catatonic type schizophrenia,	Carbamazepine, Clonazepam 0.5mg daily and a reduction in the dose of Zyprexa to 7.5mg daily.
Convulsion		Convulsions generalized, tremulousness, hypotensive, myoclonus, sleep excessive, withdrawn, sluggishness, electroencephalogram abnormal, amnesia, confusion.	
Amnesia			
Confusional state			
Electroencephalogram abnormal			

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified schizophrenia10.0MilligramDailyOral

Batch: Started: 01/01/1996 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Electroencephalog Other data				

Additional Information:

At the age of one year he had status epilepticus and was treated with anticonvulsants for one year. He had a single seizure at age seven. History: Velo-cardio-facial syndrome (Digeorge's syndrome).

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number:184905Seq: 1Gender:MReported:11/04/2003Weight:0.00Hospitalisation:Admitted to hospitalAge: 22Y

Onset Date: 01/09/1999 **DOB**:

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Hypersomnia			
Hypotension			
Myoclonus			
Sluggishness			
Social avoidant behaviour			
Tremor			

Medicine Details:

ZYPREXA (Suspected)

Reason: Unspecified schizophrenia

10.0 Milligram Daily Oral

Batch: Started: 01/01/1996 Stopped:

Laboratory Investigations:

Additional Information:

At the age of one year he had status epilepticus and was treated with anticonvulsants for one year. He had a single seizure at age seven. History: Velo-cardio-facial syndrome (Digeorge's syndrome).

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:184938Seq: 1Gender:MReported:14/04/2003Weight:0.00Hospitalisation:Admitted to hospitalAge: 55

Onset Date: 02/09/2002 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	Neuro leptic malignant syndrome.	Gentle hydration iv, neuro obs, Nofree water ck levels and uec monitoring.
Altered state of consciousness	Life threatening		
Hyponatraemia	Life threatening		
Muscle rigidity	Life threatening		
Pneumonia aspiration	Life threatening		

Medicine Details:

Medicine Details.					
DIAZEPAM (Other drug)	Reason:				•
Tablet	10.0	Milligram	Daily		Oral
Batch:	Started:		L TERM	Stopped:	
OLANZAPINE (Suspected)			Reason:	Unspecified so	hizophrenia
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	04/09/2002

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
	14/04/2003	Creatine		04/09/2002	151956	
	14/04/2003	Other data				
	14/04/2003	Sodium		04/09/2002	117	
Į	14/04/2003	Urine osmolality		04/09/2002	251	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

ty 10.0 Milli d: 20.0 Milli	gram L TI		С	Oral	0.00 55 Causality prob Treatme	
10.0 Milli	gram L TI	Reason: Daily ERM Reason:	scription Stopped:	DOB: ausality:	Causality prob	
10.0 Milli	gram L TI	Reason: Daily ERM Reason:	scription Stopped:	Oral	Treatme	
10.0 Milli	gram L TI	Reason: Daily ERM Reason:	scription Stopped:	Oral	Treatme	
10.0 Milli	gram L TI	Reason: Daily ERM Reason:	Stopped:			nt
10.0 Milli	gram L TI	Reason: Daily ERM Reason:	Stopped:			
d: 20.0 Milli	L TI	Daily ERM Reason:			1	
d: 20.0 Milli	L TI	Daily ERM Reason:			1	
d: 20.0 Milli	L TI	Daily ERM Reason:			ı	
d: 20.0 Milli	L TI	ERM Reason:			1	
20.0 Milli		Reason:		hizophrenia	l	
	gram				•	
	J	Daily	·	Oral		
		,	Stopped:	04/09/2002	>	

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Num		C					
		-	: 1			ender: F	
-	ted: 07/05/2003	3			W	eight: 0.00	
ospitalisat						Age: 72Y	
	Date: 20/01/2003					DOB:	
	me: Not yet rec	overed			Cau	sality: Causality poss	ible
eaction D							
	eferred Term		everity	•	rt Description	Treatmer	nt
	nic normocytic a	naemia	C	count low	mia, white blood cell		
hrombocyt	openia		0	Thrombocytoper decreased.	ia and lymphocyte cou	unt	
	count decrease cell count decre						
l adicina	Dotails:						
				Rea	son:		
	er drug)			Rea Dose Unspecified	son: Or	ral	
ATIVAN (Oth	e r drug) et	s	C Started:			ral	
ATIVAN (Oth Table Bate	e r drug) et	s			Or Stopped:	ral	
ATIVAN (Oth Table Bate TEMAZEPAN	er drug) et ch:	s	Started:	Oose Unspecified	Or Stopped:		
ATIVAN (Oth Table Bate TEMAZEPAN	er drug) et ch: // (Other drug) application		Started:	Oose Unspecified	Or Stopped:		
ATIVAN (Oth Table Bate TEMAZEPAN Oral Bate	er drug) et ch: (Other drug) application		Started:	Oose Unspecified	Stopped: Or Stopped: Or Stopped:		
ATIVAN (Oth Table Bate TEMAZEPAN Oral Bate EFEXOR (Oth	er drug) et ch: (Other drug) application		Started:	Pose Unspecified Rea Pose Unspecified	Stopped: Or Stopped: Or Stopped:	ral	
ATIVAN (Oth Table Bate TEMAZEPAN Oral Bate EFEXOR (Ot Oral Bate	er drug) et ch: (Other drug) application ch: her drug) application ch:	s	Started:	Pose Unspecified Rea Pose Unspecified Rea	Stopped: Or Stopped: Or Stopped:	ral	
ATIVAN (Oth Table Bate TEMAZEPAN Oral Bate EFEXOR (Ot Oral Bate	er drug) et ch: (Other drug) application ch: her drug) application	s	Started: Started:	Pose Unspecified Rea Pose Unspecified Rea Pose Unspecified Rea Rea	Stopped: Stopped: Stopped: Stopped: Or Stopped:	ral	
ATIVAN (Oth Table Bate TEMAZEPAN Oral Bate Oral Bate OLANZAPIN	er drug) et ch: // (Other drug) application ch: her drug) application ch: E (Suspected)	s	Started: Started: Started:	Pose Unspecified Rea Pose Unspecified Rea Pose Unspecified	Stopped: Stopped: Stopped: Stopped: Stopped: Stopped:	ral	
ATIVAN (Oth Table Bate TEMAZEPAN Oral Bate EFEXOR (Ot Oral	er drug) et ch: // (Other drug) application ch: her drug) application ch: E (Suspected)	s	Started: Started:	Pose Unspecified Rea Pose Unspecified Rea Pose Unspecified Rea Rea	Stopped: Stopped: Stopped: Stopped: Or Stopped:	ral	
ATIVAN (Oth Table Bate Oral Bate EFEXOR (Ot Oral Bate OLANZAPIN	er drug) et ch: // (Other drug) application ch: her drug) application ch: E (Suspected)	s	Started: Started: Started:	Pose Unspecified Rea Pose Unspecified Rea Pose Unspecified Rea Rea	Stopped: Stopped: Stopped: Stopped: Stopped: Stopped:	ral	
TEMAZEPAN Oral Bato Oral Bato Oral Bato OLANZAPIN Bato	er drug) et ch: // (Other drug) application ch: her drug) application ch: E (Suspected)	s	Started: Started: Started:	Rea Oose Unspecified Rea Oose Unspecified Rea Oose Unspecified Rea Oose Unspecified	Stopped: Stopped: Stopped: Stopped: Stopped: Stopped:	ral	

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	185586	Seq: 1				Gender:	F	
	07/05/2003					Weight:		
Hospitalisation:						Age:		
Onset Date:	20/01/2003					DOB:		
	Not yet recovered	I			C	ausality:	Causality possible	•
Reaction Detai	ls:							
Medicine Deta	aile							
CLOZARIL (Suspe				Reason:	Schizophrenia			
Tablet	,	225.0	Milligram	Daily		Oral		
Batch:		Started: 05		,	Stopped:		Contin	
Laboratory In	vestigations:							
Additional Inf	ormation:							
Auditional IIII	omanom.							

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 185614 Seq: 1 Gender: F

Reported: 07/05/2003 Weight: 100.00 Hospitalisation: Age: 56

Onset Date: 08/04/2003 **DOB**: 31/07/1946

Outcome: Recovered Causality: Causality probable

Reaction Details:

٠,	todotion botano			
	Preferred Term	Severity	Report Description	Treatment
	Urinary incontinence	Required Visit to Doctor	Urinary incontinence.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 2.5 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Zoloft, Marevan and Karvea.

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Case Number: 185798

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

				.ge : 70Y : OB:
				lity: Causality possible
			Judou	inty: Gaddanty possible
Se	verity	Report D	escription	Treatment
			•	
	dı	riving his car and wa	as involved in an	
		Danasa		
		Reason:	Oral	
Sta	arted: 15/04/	/2002	Stopped:	
ns:	Date Tested	Result		Details
P ns: Range	Date Tested	Result		Details
	Date Tested	Result		Details
	Date Tested	Result		Details
	Date Tested	Result		Details
	Date Tested	Result		Details
	Date Tested	Result		Details
	Date Tested	Result		Details
	Date Tested	Result		Details
Range	Date Tested	Result		Details
Range	Date Tested	Result		Details
Range	Date Tested	Result		Details
Range	Date Tested	Result		Details
Range	Date Tested	Result		Details
		a		Patient experienced a seizure whilst driving his car and was involved in an accident. Reason: Oral



Hospitalisation:

Case Number: 186199

Reported: 26/05/2003

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

Age: 99u

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Onset Da	ate:					DOB:		
Outcon	ne: Recovered		Causality: Causality possible					ble
Reaction De	etails:							
Pre	ferred Term	Severity	Repo	ort Desc	ription		Treatmen	t
Circulatory co	ollapse	Caused or prolonged inpatient hospitalisation	Collapse, drama diarrhoea, very l	tic drop i ow temp	in platelets, erature	needed Mirtaza	ed unconscion respiratory a pine and apine ceased	assistance.
Body tempera	ature decreased	Caused or prolonged inpatient hospitalisation						
Diarrhoea		Caused or prolonged inpatient hospitalisation						
Medicine [
OLANZAPINE	(Suspected)		Rea	son:				
Batch	1:	Started:			Stopped:			
MIRTAZAPINE	(Suspected)		Rea	son:				
Tablet	:	60.0	Milligram	Daily	Or	al		
Batch	n:	Started:			Stopped:			
	y Investigațio							
Date	Туре	Range Date Test	ed Result			Details		
Additional	Information	:						
eport Run: 04/0	6/2007 05:12PM	Database: pusime02	A	DRS004			Page 30	of 530



Case Number: 186199

Reported: 26/05/2003

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

ospitalisation:		Age: 99u				
Onset Date:		DOB:				
Outcome: Recovered			Causality:	Causality possible		
eaction Details: Preferred Term	Severity	Report Descrip	otion T	Treatment		
Thrombocytopenia	Caused or prolonged inpatient hospitalisation	Nepolt Descrip	JUOIT	rreaunent		
Medicine Details:						
OLANZAPINE (Suspected)		Reason:				
	-					
Batch:	Started:	Reason:	Stopped:			
MIRTAZAPINE (Suspected) Tablet	60.0 Milligram	Reason: Daily	Oral			
Batch:	Started:		Stopped:			
aboratory Investigations	S:					
Additional Information:						
04/02/2227		ADDCCC				
ort Run: 04/06/2007 05:12PM Da	atabase: pusime02	ADRS004		Page 31 of 530		



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 186262 Seq: 1 Gender: F

Reported: 26/05/2003 Weight: 45.50 Hospitalisation: Age: 82

Onset Date: DOB: 28/11/1920

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

daction Botano.			
Preferred Term	Severity	Report Description	Treatment
		Hyperextension of neck - difficulty with swallowing.	
		Hyperextension of neck - difficulty with swallowing.	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

5.0 Milligram Daily

Batch: Started: 24/09/2002 Stopped: 04/05/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History: Principal diagnosis = Dementia. Allergies to Penicillin, Tetracycline and Sulphur. On concomitant antidepressant therapy (Aropax) and anti-epileptic (Valproate).

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:186276Seq: 1Gender:UReported:28/05/2003Weight:0.00Hospitalisation:Admitted to hospitalAge: 47

Onset Date: 08/03/2003 DOB: 23/02/1956

Outcome: Recovered 09/03/2003 Causality: Causality possible

Reaction Details:

touction botaile:			
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatraemia, polydypsia, consciousness fluctuating, drowiness, writing movements.	Fluid restriction.
Consciousness fluctuating			
Dysgraphia			
Polydipsia			
Somnolence			

Medicine Details:

Medicine Details.					
METFORMIN HYDROCHLORIDE (Othe	r drug)		Reason:	Diabetes mellitus	
Tablet	400.0	Milligram	Daily	Oral	
Batch:	Started:		L TERM	Stopped:	
OLANZAPINE (Suspected)			Reason:	Unspecified neurosis	
	40.0	Milligram	Daily		
Batch:	Started: 08/	/03/2003		Stopped:	

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
	28/05/2003	Serum glucose		08/03/2003	10.8	
	28/05/2003	Serum glucose		09/03/2003	5.1	
	28/05/2003	Sodium		08/03/2003	123	
L	28/05/2003	Sodium		09/03/2003	141	

Additional Information:

History: Chronic schizophrenia and NIDDM controlled with Amisulpride and Metformin. Amisulpride ceased and Olanzapine commenced 1 week ago. H2O consumption - 1/2 cup every 20mins. Patient began during compulsivety after switched from Amisulpride to Olanzapine (due to poor tolerance/weight gain.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:186541Seq: 1Gender:MReported:03/06/2003Weight:0.00Hospitalisation:Admitted to hospitalAge: 77Y

Onset Date: 25/02/2003 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion botanoi			
Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		71	Decreased dose, changed to Madopar 50/12.5 tds. Celecoxib ceased.

Medicine Details:

LEVODOPA-CARBIDOPA (Suspected)		Reason:	Paralysis agita	ans
Tablet	3.0	Dose Unspecified Dail	у	Oral
Batch:	Started:		Stopped:	28/02/2003
CELECOXIB (Suspected)		Reason:	Pain	
Capsule	400.0	Milligram Dail	у	Oral
Batch:	Started:		Stopped:	27/02/2003
OLANZAPINE (Suspected)		Reason:	Unspecified p	sychosis
Tablet	0.5	Dose Unspecified Dail	у	Oral
Batch:	Started:		Stopped:	03/03/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Sertraline, Gliclazide and Pizotifen. Standing blood pressure had improved.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 186562
 Seq: 1
 Gender:
 F

 Reported:
 03/06/2003
 Weight:
 80.00

Hospitalisation: Age: 57

Onset Date: 08/05/2003 **DOB**: 02/04/1946

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	to Doctor	Bilateral lower legs and ankles oedema, redness and burning sensation both lower legs and ankles.	
	to Doctor	Bilateral lower legs and ankles oedema, redness and burning sensation both lower legs and ankles.	
	to Doctor	Bilateral lower legs and ankles oedema, redness and burning sensation both lower legs and ankles.	

Medicine Details:

ZYPREXA (Suspected)		Reason:	Unspecified psychosis
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 22/04/2003		Stopped: 14/05/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Clonazepam, Epilium, Temazapam, Sezoquel, panadol.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 186583
 Seq: 1
 Gender:
 M

 Reported:
 04/06/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 82Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Details.	AUGION DOGGIO.								
Preferred Term	Severity	Report Description	Treatment						
Tremor		Unilateral tremors of hand, rigidity, frequent falls	Stopped Efexor XR						
Fall									
Muscle rigidity									

Medicine Details:

Medicine Details.			
EFEXOR-XR (Suspected)		Reason: Depression	
Capsule	75.0 Milligram	Daily	Oral
Batch:	Started: 21/11/2002	Stopped:	19/12/2002
OLANZAPINE (Suspected)		Reason:	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started: 21/11/2002	Stopped:	16/01/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Renitec, Zyloprim, Aspirin.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 186590 Seq: 1 Gender: F

Reported: 04/06/2003 Weight: 0.00 Hospitalisation: Age: 42Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

ouotion botano.							
Preferred Term	Severity	Report Description	Treatment				
Dyskinesia		Abnormal movements of thumb and fingers - tardive dyskinesia. Withdrawal dyskinesia.					

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 2.5 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Lithium, Epilim, Zoloft, Lipitor. Zyprexa symptoms went when dose increased to 5mg again, because of breakthrough psychotic symptoms. Zyprexa dose was was reduced to 2.5mg sometime in August 2002. Symptoms occurred sometime in September 2002.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 186595 Seq: 1 Gender: M

Reported: 04/06/2003 Weight: 0.00 Hospitalisation: Age: 23

Onset Date: 21/05/2003 **DOB**: 02/07/1979

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Dotano			
Preferred Term	Severity	Report Description	Treatment
Stevens-Johnson syndrome		Stevens-Johnson syndrome: oral mucosa / penile mucosa / conjunctiva nasal mucosa involvement.	Topical steroids/mouthwash/iv fluids support.

Medicine Details:

ZYPREXA (Suspected) Reason: Depression

Tablet 10.0 Milligram Daily Oral

Batch: Started: 20/05/2003 Stopped: 24/05/2003

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient was also taking Mirtazapine, Valium. Previous 3/12 course of Zyprexia last year-apparently developed mild oral ulceration at time. No erythema multiforme.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 186674 Seq: 1 Gender: M

Reported: 06/06/2003 Weight: 80.00 Hospitalisation: Admitted to hospital Age: 36

Onset Date: 16/04/2003 **DOB**: 23/06/1966

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetic ketoacidosis		Diabetic ketoacidosis	Commenced on insulin.

Medicine Details:

DIAZEPAM (Other drug)		Reason:			
	5.0 Milligram	As necessary			
Batch:	Started:	Stopped:			
OLANZAPINE (Suspected)		Reason: Schizophrenia			
	00.0 14:11:	Deile			

20.0 Milligram Daily

Batch: Started: Stopped: 16/04/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Olanzapine commenced Oct 2002. In retrospect had raised BSLs prior to discharge from psychiatric ward several weeks after Olanzapine commenced. Not followed.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 186687 Seq: 1 Gender: F

Reported: 06/06/2003 Weight: 0.00 Hospitalisation: Age: 94

Onset Date: 23/05/2003 DOB: 29/04/1909

Outcome: Recovered 02/06/2003 Causality: Causality possible

Reaction Details:

todetion betails.			
Preferred Term	Severity	Report Description	Treatment
Hypothermia	prolonged inpatient hospitalisation	Hypothermia and confusion. Recent confusion and wandering outdoor in cold/wet, detected pesticides containing carbaryl in drug screen.	Olanzapine ceased, bear hugger.
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected) Reason: Hallucinations

2.5 Milligram Daily

Batch: Started: 19/05/2003 Stopped: 26/05/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Fusemide, Thyroxine, Aspirin, pantoprazole, caltrate, Slow k, metoclopramide, Spirondactone, Trimethoprim.

History of Hypothyrodism.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 186770
 Seq: 1
 Gender:
 M

 Reported:
 10/06/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 43

 Onset Date: 24/02/2003
 DOB: 13/09/1959

Outcome: Not yet recovered Causality: Causality probable

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		Hyperglycaemia	Ceased Olanzapine.
Hyperlipidaemia		Hyperglycaemia	Ceased Olanzapine.

Medicine Details:

Medicine Details.					
FLUVOXAMINE MALEATE (Interaction)			Reason:		
Batch:	Started:			Stopped:	
OLANZAPINE (Interaction)			Reason:	Depression	
	10.0	Milligram	Daily		
Batch:	Started:	ST	ERM	Stopped:	27/02/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
10/06/2003	Serum glucose		24/02/2003	38.1	

Additional Information:

Patient was also taking Sodium Valproate, Acdactone, Luvox, Mycrogynon ED.

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Report Details:

Case Number: 186880

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 12/06/2003			W	eight: 0.00			
ospitalisation:		Age: 23Y					
Onset Date:				DOB:			
Outcome: Unknown		Causality: Causality possib					
eaction Details:		T -		 			
Preferred Term	Severity		Description	Treatment			
lepatitis		Hepatitis nos, Alar increased	nine aminotransferas	e Ceased Epilim and Olanzapine.			
Nanine aminotransferase inc	rease						
ledicine Details: OLANZAPINE (Suspected)		Reaso	n:				
Batch:	Started:		Stopped: 29	0/05/2003			
EPILIM (Suspected)		Reaso	n:				
Tablet	400.0	Milligram [Daily Oral				
Batch:	Started: 19/0	05/2003	Stopped: 29	0/05/2003			
_aboratory Investigatio	P ns: Range Date Test	ed Result		Details			
Additional Information:							
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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

ospitalisation Onset Dat Outcome	e: e: Not yet re tails:	ecovered					DOB	99U : : Causality possible
	erred Term		Severity	NUDDM	Report De	escription	D:	Treatment
Diabetes melli	ius insulin-ae	epender		NIDDM			dia	et which believes manag abetes.
Weight increas	sed			weight in	creased			
Medicine Do					Reason:			
Tablet					Daily		Oral	
Batch:			Started:		D	Stopped:		
ZYPREXA (Sus) Tablet	pectea)		10.0	Milligram	Reason: Daily	Depression	Oral	
Batch:			Started:		TERM	Stopped:	Olai	Contin
.aboratory	Investigat	tions:						
Date	Туре	Range	Date Tes	ted Re	sult		Deta	ils
	ner data							
16/06/2003 Oth								

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Details:
--------	----------

 Case Number:
 186915
 Seq: 1
 Gender:
 M

 Reported:
 16/06/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 23Y

Onset Date: 15/05/2003 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Stevens-Johnson syndrome		Stevens Johnson Syndrome	Zyprexa was ceased, treated with Xylocain, Lignocain, Steroid, Antibiotic eye drops, Chlorhexadine mouth wash, IV fluid support.

Medicine Details:

AVANZA (Other drug)		Reason:		
Batch:	Started:		Stopped:	contin
ZYPREXA (Suspected)		Reason: L	Jnspecified schizophrenia	
Tablet	10.0 Millig	ram Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Zyprexa was started and stopped sometime in may 2003.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 187019 Seq: 1 Gender: M

Reported: 18/06/2003 Weight: 0.00 Hospitalisation: Age: 44

Onset Date: DOB: 06/01/1959

Outcome: Recovered Causality: Causality probable

Reaction Details:

toaction Botanoi			
Preferred Term	Severity	Report Description	Treatment
Depressed mood	l. <u></u> ' .	Patient associates onset of depressed mood.	

Medicine Details:

ZYPREXA (Suspected)		Reason: Schizopl	hrenia
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started:	Stop	ped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient strongly associates onset of depressed mood with increased Zyprexa use. His underlying schizo-affective disorder make the association difficult to discern.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 187137
 Seq: 1
 Gender:
 M

 Reported:
 20/06/2003
 Weight:
 0.00

 Hospitalisation:
 Age:
 99u

 Onset Date:
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

veaction petans.			
Preferred Term	Severity	Report Description	Treatment
		non-insulin-dependent and feeling unwell.	Diet to control weight and blood sugar levels and oral hypolycaemics.
Diabetes mellitus non-insulin-depe	Required Specialist Consultation		
Malaise	Required Specialist Consultation		

Medicine Details:

EPILIM (Other drug)		Reason:			
Oral application		Dose Unspec	ified	Oral	
Batch:	Started:			Stopped:	
EFEXOR-XR (Other drug)			Reason:		
Oral application		Dose Unspec	ified	Oral	
Batch:	Started:			Stopped:	
ZYPREXA (Suspected)			Reason:	Schizo-affective type psychos	
Tablet	30.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	Contin

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Onset date: 2003. Medical history: Inclueds chronic pyschosis and a history of obesity.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 187692
 Seq: 1
 Gender: M

 Reported:
 25/06/2003
 Weight: 72.50

Hospitalisation: Age: 52

Onset Date: 10/06/2003 **DOB**: 27/03/1951

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Gynaecomastia	Required Visit to Doctor	Diffuse soft lump under right nipple.	

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started: 11/12/2002	Stopped:	: Contin
OLANZAPINE (Suspected)		Reason: Schizophrenia	a
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started: 27/02/2003	Stopped:	: 02/05/2003
OLANZAPINE (Suspected)		Reason: Schizophrenia	a
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 02/05/2003	Stopped:	: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 187726 Seq: 1 Gender: F

Reported: 25/06/2003 Weight: 121.00 Hospitalisation: Age: 30

Onset Date: 15/07/2001 **DOB**: 26/02/1971

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
		Diabetes mellitus and mild hyperglycaemia.	Metformin. Zyprexa ceased.
	' .	Diabetes mellitus and mild hyperglycaemia.	

Medicine Details:

 ZYPREXA (Suspected)
 Reason:
 Schizophrenia

 Tablet
 20.0 Milligram
 Daily
 Oral

 Batch:
 Started: 15/05/2001
 Stopped: 26/05/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Thyroxine, Sodium Valproate and Fluoxetine.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188147 Seq: 1 Gender: M
Reported: 03/07/2003 Weight: 0.00
Hospitalisation: Age: 30

Onset Date: 25/05/2003 **DOB**: 02/05/1973

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	. = .	Peripheral oedema bilaterally, skin hot and red.	Oral antibiotics. Olanzapine ceased.
	Required Visit to Doctor		

Medicine Details:

Medicine Details.		
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia
Wafer	30.0 Milligram	Daily Oral
Batch:	Started: 15/05/2003	Stopped: 05/06/2003
CLONAZEPAM (Suspected)		Reason: Otr spec symp psychopathol nec
Tablet	6.0 Milligram	Daily Oral
Batch:	Started: 15/05/2003	Stopped: 20/06/2003

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
Г	03/07/2003	Echocardiogram				

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 188198
 Seq: 1
 Gender:
 F

 Reported:
 02/07/2003
 Weight:
 0.00

Hospitalisation: Age: 99U
Onset Date: DOB:

Outcome: Recovered 19/09/0600 Causality: Causality possible

Reaction Details:

i toaction Botaile.			
Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Hyponatraemia, peripheral oedema, elevated LFT's.	Ceased Olanzapine and replaced with Risperidone.
Hepatic enzyme increased	Required Visit to Doctor		
Hyponatraemia	Required Visit to Doctor		

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

7.5 Milligram Daily

Batch: Started: 14/04/2003 Stopped: 05/06/2003

Laboratory Investigations:

	<u>,</u>				
Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Paroxetine, Clonazepam, Ranitidine, Spronolactone, Felodepine.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 188210
 Seq: 1
 Gender: M

 Reported:
 07/07/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 56

Onset Date: 06/05/2003 **DOB**: 27/08/1946

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u>teaetion Betails.</u>			
Preferred Term	Severity	Report Description	Treatment
Jaundice cholestatic	Caused or prolonged inpatient hospitalisation	Obstructive jaundice.	
Hepatitis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Zolpidem Sandoz (Suspected)			Reason:		
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	12/05/2003
OLANZAPINE (Suspected)			Reason:		
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	12/05/2003

Laboratory Investigations:

I	Date	Туре	Range	Date Tested	Result	Details
07/0	07/2003	ALT = SGPT		07/05/2003	1030	
07/0	07/2003	ALT = SGPT		12/05/2003	1260	
07/0	07/2003	ALT = SGPT		09/05/2003	1300	
07/0	07/2003	ALT = SGPT		15/05/2003	915	
07/0	07/2003	ALT = SGPT		16/05/2003	905	
07/0	07/2003	AST = SGOT		07/05/2003	1000	
07/0	07/2003	AST = SGOT		09/05/2003	1340	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188210 Seq: 1 Gender: M

Reported: 07/07/2003 Weight: 0.00 Hospitalisation: Age: 56

Onset Date: 06/05/2003 **DOB**: 27/08/1946

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Zolpidem Sandoz (Suspected)		Reason:			
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	12/05/2003
OLANZAPINE (Suspected)			Reason:		
Tablet	20.0	Milligram	Daily		Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2003	AST = SGOT		12/05/2003	1080	
07/07/2003	AST = SGOT		16/05/2003	662	
07/07/2003	AST = SGOT		15/05/2003	682	
07/07/2003	Bilirubin		07/05/2003	153	
07/07/2003	Bilirubin		09/05/2003	189	
07/07/2003	Bilirubin		12/05/2003	122	
07/07/2003	Bilirubin		16/05/2003	72	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 188210
 Seq: 1
 Gender: M

 Reported:
 07/07/2003
 Weight: 0.0

Reported: 07/07/2003 Weight: 0.00 Hospitalisation: Age: 56

Onset Date: 06/05/2003 **DOB**: 27/08/1946

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.					
Zolpidem Sandoz (Suspected)			Reason:		
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	12/05/2003
OLANZAPINE (Suspected)			Reason:		
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	12/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2003	Bilirubin		15/05/2003	82	
	GGT = SGGT =		07/05/2003	586	
	GGT = SGGT =		09/05/2003	624	
07/07/2003	GGT = SGGT =		12/05/2003	562	
	GGT = SGGT =		16/05/2003	620	
07/07/2003	GGT = SGGT =		15/05/2003	542	
07/07/2003	Liver biopsy				

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 188210
 Seq: 1
 Gender: M

 Reported:
 07/07/2003
 Weight:
 0.00

Hospitalisation: Age: 56

Onset Date: 06/05/2003 **DOB**: 27/08/1946

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Micalcinic Details.					
Zolpidem Sandoz (Suspected)			Reason:		
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started:		St	topped:	12/05/2003
OLANZAPINE (Suspected)			Reason:		
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started:		St	topped:	12/05/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
07/07/2003	SAP = ALP		07/05/2003	335	
07/07/2003	SAP = ALP		09/05/2003	366	
07/07/2003	SAP = ALP		12/05/2003	349	
07/07/2003	SAP = ALP		15/05/2003	327	
07/07/2003	SAP = ALP		16/05/2003	363	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188258 Seq: 1 Gender: F

Reported: 09/07/2003 Weight: 0.00 Hospitalisation: Age: 76

Onset Date: 25/08/2002 **DOB**: 14/03/1926

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Admitted to hospital for investigation of pancytopenia associated with fevers and diarrhoea.	Treated empirically with Timentin and Ciprofloxacin. G-CSF 300mcg given as a single dose, with patient responding readily with a rise in WCC. Clopidogrel and Olanzapine ceased.
Anaemia			
Diarrhoea			
Platelet count decreased			
Pyrexia			

Medicine Details:

Micalcine Details.			
OLANZAPINE (Suspected)		Reason:	
Tablet	2.5 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	25/08/2002
CLOPIDOGREL (Suspected)		Reason:	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2002	Stopped:	25/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/07/2003	Haemoglobin		14/08/2002	101	
09/07/2003	Haemoglobin		23/08/2002	103	
09/07/2003	Haemoglobin		25/08/2002	92	
09/07/2003	Haemoglobin		26/08/2002	95	
09/07/2003	Haemoglobin		30/08/2002	124	
09/07/2003	Haemoglobin		02/09/2002	127	
09/07/2003	Platelets		14/08/2002	258	

Additional Information:

Patient also taking Metoprolol, Tradolopril, Simvastatin, Aspiring, Timolol 0.5% eye drops and Carbechol eye drops.



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188258 Seq: 1 Gender: F

Reported: 09/07/2003 Weight: 0.00 Hospitalisation: Age: 76

Onset Date: 25/08/2002 **DOB:** 14/03/1926

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

MEGICINE DETAILS.			
OLANZAPINE (Suspected)	F	Reason:	
Tablet	2.5 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	25/08/2002
CLOPIDOGREL (Suspected)	F	Reason:	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2002	Stopped:	25/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/07/2003	Platelets		23/08/2002	190	
09/07/2003	Platelets		26/08/2002	210	
09/07/2003	Platelets		02/09/2002	315	
09/07/2003	Platelets		30/08/2002	227	
09/07/2003	Platelets		25/08/2002	101	
09/07/2003	White blood cells		14/08/2002	6.11	
09/07/2003	White blood cells		23/08/2002	0.84	

Additional Information:

Patient also taking Metoprolol, Tradolopril, Simvastatin, Aspiring, Timolol 0.5% eye drops and Carbechol eye drops.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188258 Seq: 1 Gender: F

Reported: 09/07/2003 Weight: 0.00 Hospitalisation: Age: 76

Onset Date: 25/08/2002 DOB: 14/03/1926

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.			
OLANZAPINE (Suspected)		Reason:	
Tablet	2.5 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	25/08/2002
CLOPIDOGREL (Suspected)	1	Reason:	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2002	Stopped:	25/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/07/2003	White blood cells		25/08/2002	0.46	
09/07/2003	White blood cells		26/08/2002	0.92	
09/07/2003	White blood cells		30/08/2002	2.02	
09/07/2003	White blood cells		02/09/2002	13.4	

Additional Information:

Patient also taking Metoprolol, Tradolopril, Simvastatin, Aspiring, Timolol 0.5% eye drops and Carbechol eye drops.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188333 Seq: 1 Gender: F

Reported: 09/07/2003 Weight: 0.00 Hospitalisation: Age: 37

Onset Date: 09/03/2003 DOB: 08/09/1965

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Betails.	dotton Botano.							
Preferred Term	Severity	Report Description	Treatment					
Hypersensitivity		Hypersensitivity						
Liver function test abnormal		Hypersensitivity with rash, fever and rasied LFT's.						
Pyrexia		Hypersensitivity with rash, fever and rasied LFT's.						
Rash		Hypersensitivity with rash, fever and rasied LFT's.						

Medicine Details:

PHENYTOIN SODIUM (Suspected) Reason: Epilepsy

400.0 Milligram Daily

Batch: **Started**: 15/02/2003 **Stopped**: 10/03/2003

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Tablet 2.5 Milligram Alternate days Oral

Batch: Started: Stopped: 10/03/2003

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ	09/07/2003	ALT = SGPT				
	09/07/2003	Albumin				
		GGT = SGGT =		10/03/2003	215	
Į		Other data				

Additional Information:

Other drugs: Methadone, Baclofen, Thiamine, Sorbitol and Coloxyl.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188553 Seq: 1 Gender: M

Reported: 17/07/2003 Weight: 68.00 Hospitalisation: Age: 15

Onset Date: 04/11/2002 **DOB:** 13/03/1987

Outcome: Recovered 18/11/2002 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
		malaise, fevers, delerium, muscles aches, creatine kinase increased.	Ceased Risperidone and Olanazapine.
	Caused or prolonged inpatient hospitalisation		
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.			
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started:	Stopped: 25/10/2002	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
17/07/2003	Creatine				

Additional Information:

History of intellectual and global speeches delay.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188553 Seq: 1 Gender: M

Reported: 17/07/2003 Weight: 68.00 Hospitalisation: Age: 15

Onset Date: 04/11/2002 **DOB**: 13/03/1987

Outcome: Recovered 18/11/2002 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Micalcinic Details.			
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started:	Stopped: 25/10/2002	

Laboratory Investigations:

Additional Information:

History of intellectual and global speeches delay.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188596 Seq: 1 Gender: F

Reported: 14/07/2003 Weight: 60.00 Hospitalisation: Age: 26

Onset Date: 03/04/2003 **DOB**: 25/01/1977

Outcome: Recovered 10/04/2003 Causality: Causality probable

Reaction Details:

٠,	todotion Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Generalised oedema	Required Visit to Doctor	Generalised oedema.	

Medicine Details:

ZYPREXA (Suspected) Reason: Otr spec symp psychopathol nec

 Tablet
 5.0 Milligram
 Daily
 Oral

 Batch:
 Started: 18/03/2002
 Stopped: 06/04/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Cipramil and Epilim.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188676 Seq: 1 Gender: M
Reported: 21/07/2003 Weight: 0.00
Hospitalisation: Age: 84

Onset Date: 27/05/2003 **DOB**: 22/06/1918

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	to Doctor	Severe extrapyramidal symptoms, with tremor - generalized, including jaw, tongue, rendering speach unintelligible. Had been coming on for months, severe by 27.5.03.	Zyprexa ceased.
	Required Visit to Doctor		
Tremor	Required Visit to Doctor		

Medicine Details:

ZYPREXA (Suspected) Reason: Otr spec symp psychopathol nec

 Tablet
 5.0 Milligram
 Daily
 Oral

 Batch:
 Started: 15/07/2001
 Stopped: 31/05/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Efexor, Lithicarb, Epilim and Losec.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188982 Seq: 1 Gender: F

Reported: 29/07/2003 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 84

Onset Date: 27/06/2003 **DOB**: 25/05/1919

Outcome: Unknown Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Delirium		Acute delirium, increased confusion, aggression and disorientation.	Zyprexa ceased. Haloperiol injection and tablets were prescribed.
Aggression			
Confusional state			
Disorientation			

Medicine Details:

ZYPREXA (Suspected)Reason: Unspecified schizophrenia

Tablet

Daily

Oral

Batch: Started: 16/06/2003 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Avapro, Noten, Zqntac, Pulmicort and Oxis.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:188990Seq: 1Gender:FReported:28/07/2003Weight:0.00Hospitalisation:Admitted to hospitalAge: 61

Onset Date: 16/02/2003 **DOB**: 15/04/1941

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Grand Mal Seizure , Liver Enzyme Abnormal , Anorexia.	Zyprexa and Haloperidol ceased.
Weight decreased		Weight loss of 14kg over 5 months.	
Anorexia			
Liver function test abnormal			
Red blood cell sedimentation rate i			
Somnolence			

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)		Reason: Otr spec symp psychopathol nec	
	10.0 Milligram	Daily Oral	
Batch:	Started: 05/09/2002	Stopped:	
HALOPERIDOL (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	1.2 Milligram	Daily Oral	
Batch:	Started: 02/06/2002	Stopped: 16/02/2003	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
2	28/07/2003	ALT = SGPT		18/02/2003	246	
2	28/07/2003	Erythrocyte		18/02/2003	114	
2		GGT = SGGT =		18/02/2003	127	
2		SAP = ALP		18/02/2003	350	

Additional Information:

Patient also taking sustagen.

History included: Early onset dementia and agitation.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 189063 Seq: 1 Gender: F

Reported: 01/08/2003 Weight: 0.00 Hospitalisation: Age: 46

Onset Date: 03/07/2003 **DOB**: 24/08/1956

Outcome: Recovered 18/07/2003 Causality: Causality probable

Reaction Details:

eaction betails.							
Preferred Term	Severity	Report Description	Treatment				
Rash		Blotchy skin					
Vision blurred		Severe blurr vision.	Ceased Zyprexa.				
Oedema peripheral		Swelling of extremities.					

Medicine Details:

ZYPREXA (Suspected) Reason: Otr spec symp psychopathol nec

 Tablet
 5.0 Milligram
 Daily
 Oral

 Batch:
 Started: 02/07/2003
 Stopped: 07/07/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No previous history of allergy.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 189091
 Seq: 1
 Gender:
 F

 Reported:
 30/07/2003
 Weight:
 70.00

 Hospitalisation:
 Age: 54

Onset Date: 10/07/2003 **DOB**: 20/05/1949

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caction betails.			
Preferred Term	Severity	Report Description	Treatment
	Required Visit to Doctor	Blurred vision, dry mouth.	
	Required Visit to Doctor		

Medicine Details:

SEROQUEL (Interaction)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 26/05/2003	Stopped:	
PROTHIADEN (Interaction)		Reason:	
Capsule	25.0 Milligram	Daily	Oral
Batch:	Started: 27/02/2003	Stopped:	
PROTHIADEN (Interaction)		Reason:	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 10/07/2003	Stopped:	
RISPERDAL (Interaction)		Reason:	
Tablet	2.0 Milligram	Daily	Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation: Onset Date: Outcome: Reaction Detai	30/07/2003 10/07/2003 Not yet recovered Is:	Seq: 1		Weig A D	der: F ght: 70.00 ge: 54 OB: 20/05/1949 lity: Causality possible	
Medicine Deta	ails:		_			
ZYPREXA (Interact	tion)	40.5 Millians	Reason:	0		
Tablet		12.5 Milligram	Daily	Oral	/0000	
Batch:		Started: 02/09/2002		Stopped: 03/06	12003	
Laboratory In	vestigations:					
Additional Inf	ormation:					

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 189185
 Seq: 1
 Gender:
 F

 Reported:
 05/08/2003
 Weight:
 96.00

Hospitalisation: Admitted to hospital
Onset Date: 20/06/2003
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
		precipitated, body weight increased	Insulin Metrormin on discharge form hospital.
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Rea	ason: Depression	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/02/2002	Stopped:	20/06/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 189263 Seq: 1 Gender: F

Reported: 07/08/2003 Weight: 50.00 Hospitalisation: Age: 48

Onset Date: 31/07/2003 **DOB**: 12/09/1954

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash	Severe	Severe skin eruption	

Medicine Details:

Medicine Details.				
FLUVOXAMINE MALEATE (Suspected)		Reason: Depres	sion	
Tablet	50.0 Milligram	Daily	Oral	
Batch:	Started: 02/07/2003	Sto	pped: 28/07/2003	
OLANZAPINE (Suspected)		Reason: Depres	sion	
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started: 09/07/2003	Sto	pped: 28/07/2003	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 189489
 Seq: 1
 Gender:
 M

 Reported:
 14/08/2003
 Weight:
 0.00

Hospitalisation: Age: 70

Onset Date: 18/03/2003 **DOB**: 30/03/1932

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspraxia		Olanzapine dose increased from 2.5mg nocte to 5mg nocte (approx. 1 month after surgery) by psychiatrist as patient	Olanzapine ceased. Benztropine commenced - 0.5mg bd. Maxolon and Stemetil to be avoided.
Depression			
Tardive dyskinesia			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecifid affective psychosis

Tablet 5.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Euboratory investigations.						
	Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Other drugs used: Clonazepam, Heparin, Thyroxine, Lamotrigine, Lactulose, Docusate and Senna, Glycerin, Hyoscine.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Detail	s:				
Case Number: Reported: Hospitalisation: Onset Date:	189528 12/08/2009 Recovered			V	Sender: F Veight: 67.00 Age: 73 DOB: 16/03/1930 usality: Causality probable
	ed Term	Severity	Repo	ort Description	Treatment
Rash		Required Visi to Doctor	t Facial rash		
Medicine Det		5.0	Rea Milligram	son: Unspecified schi Daily	zophrenia
Laboratory Ir	rype	Ons: Range Date Te	sted Result		Details
Bate	Турс	runge Bute 16	result		Detaile
Additional In	formation	n:			

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 189773 Seq: 1 Gender: F

Reported: 22/08/2003 Weight: 70.00 Hospitalisation: Age: 59

Onset Date: 12/08/2003 **DOB**: 17/04/1944

Outcome: Death Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Life threatening	Death	
	Life threatening		Found dead at home - autorpsy pending.

Medicine Details:

icalcine Details.					
ZYPREXA (Suspected)			Reason:		
Tablet	3.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
BENZTROPINE MESYLATE (Suspected)			Reason:		
	2.0	Milligram	Daily		
Batch:	Started:			Stopped:	
LOSEC (Suspected)			Reason:		
Oral application	20.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
MAGNESIUM NOS (Suspected)			Reason:		
	1.0	Dose Unspec	cified Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Long term use of all suspected drugs.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 189773 Reported: 22/08/2003 Hospitalisation: Onset Date: 12/08/2003 Outcome: Death Reaction Details:	Seq: 1			70.00
Medicine Details:		D		
VALIUM (Suspected) Oral application	5.0 Milligram	Reason: Daily	Oral	
Batch:	Started:	Stoppe		
		Сторр		
Laboratory Investigations:				
Additional Information: Long term use of all suspected drugs.				

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:189796Seq: 1Gender: MReported:25/08/2003Weight: 0.00Hospitalisation:Admitted to hospitalAge: 25Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

١,	caction Betails.			
	Preferred Term	Severity	Report Description	Treatment
	Pancreatitis acute	Caused or prolonged inpatient hospitalisation	Acute pancreatitis.	
	Blood cholesterol increased		High cholesterol.	
	Weight increased		Weight gain.	

Medicine Details:

		Reason:	Obsessive compulsive neurosis	
10.0	Milligram	Daily	Oral	
Started:			Stopped:	
		Reason:	Obsessive compulsive neurosis	
200.0	Milligram	Daily	Oral	
Started:			Stopped:	
	Started: 200.0	200.0 Milligram	10.0 Milligram Daily Started: Reason: 200.0 Milligram Daily	10.0 Milligram Daily Oral Started: Stopped: Reason: Obsessive compulsive neurosis 200.0 Milligram Daily Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recommended sertraline hydrochloride at 25mg/day. The reporter believes the events of weight gain and high cholesterol could possibly be related to olanzaphine and does not know if the pancreatitis was related to the olanzaphine treatment. Date of onset July 2003. Therapy with zyprexa started in April 2003

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 189818 Seq: 1 Gender: F

Reported: 25/08/2003 Weight: 0.00 Hospitalisation: Age: 38Y

Onset Date: 15/07/2003 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Body temperature increased		Neuroleptic malignant syndrome, body temperature increased, muscle stiffness, joint stiffness, leukocytosis, tachypnoea, sweating	Treatment in hospital included intravenous fluids, intravenous antibiotics and further investigations
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Joint stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)			Reason:			
Oral application	10.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		contin
ZOLOFT (Suspected)			Reason:	Depression		
ZOLOFT (Suspected) Tablet	200.0	Milligram	Reason: Daily	Depression	Oral	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

About 12 months after taking Olanzapine consistently the patient has experienced Neuroleptic Malignant Syndrome or Serotonergic Syndrome.

Patient was discharged and is under the care of a cardiologist for Myocarditis. The patient is continuing on Olanzapine treatment.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 189818 Seq: 1 Gender: F

Reported: 25/08/2003 Weight: 0.00 Hospitalisation: Age: 38Y

Onset Date: 15/07/2003 **DOB**:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		
Tachypnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

inearcine Detailer						
ZYPREXA (Suspected)			Reason:			
Oral application	10.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		contin
ZOLOFT (Suspected)			Reason:	Depression		
Tablet	200.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		contin

Laboratory Investigations:

Additional Information:

About 12 months after taking Olanzapine consistently the patient has experienced Neuroleptic Malignant Syndrome or Serotonergic Syndrome.

Patient was discharged and is under the care of a cardiologist for Myocarditis. The patient is continuing on Olanzapine treatment.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 190386
 Seq: 1
 Gender: M

 Reported:
 10/09/2003
 Weight:
 75.00

Hospitalisation: Admitted to hospital **Age**: 34

Onset Date: 20/08/2003 DOB: 27/12/1968
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation	Weight increased from 80 kg to 110kg, found to have IDDM.	Mixtard 30/70
Diabetes mellitus	Caused or prolonged inpatient hospitalisation		
Polydipsia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Batch: Started: 01/05/2001 **Stopped:** 28/08/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking sandomigran, vioxx.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:	Re	po	rt	De	tai	ls:
------------------------	----	----	----	----	-----	-----

 Case Number:
 190386
 Seq: 1
 Gender:
 M

 Reported:
 10/09/2003
 Weight:
 75.00

Hospitalisation: Admitted to hospital Age: 34
Onset Date: 20/08/2003
DOB: 27/12/1968

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		

		ne		

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Batch: Started: 01/05/2001 **Stopped:** 28/08/2003

Laboratory Investigations:

Additional Information:

Patient also taking sandomigran, vioxx.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 190481
 Seq: 1
 Gender:
 F

 Reported:
 15/09/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 55Y

Onset Date: DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
, , , , , , , , , , , , , , , , , , , ,	Caused or prolonged inpatient hospitalisation	Acute myocarditis	

Medicine Details:

SEROQUEL (Suspected)		Reason: Unspecified schizophrenia
		Oral
Batch:	Started:	Stopped:
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia
T	00.0 14:11:	D 11

Tablet 20.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
15/09/2003	Other data				

Additional Information:

The patient had no history of cardiac problems.



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 190620
 Seq: 1
 Gender: M

 Reported:
 18/09/2003
 Weight:
 70.00

 Hospitalisation:
 Age: 23

Onset Date: 10/09/2003 **DOB**: 20/10/1979

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	to Doctor	Gynaecomastia of the right nipple and another breast lump found in the left breast upper, medial quad.	
Breast mass	Required Visit to Doctor		

Medicine Details:

vicaicine Details.				
ZOLOFT (Suspected)			Reason:	Depression
Tablet	100.0	Milligram	Daily	Ora
Batch:	Started:			Stopped:
ZYPREXA (Suspected)			Reason:	Unspecified neuros
	5.0	Milligram	Daily	Ora
Batch:	Started:			Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
18/09/2003	Other data				

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 190758 Seq: 1 Gender: U

Reported: 23/09/2003 Weight: 0.00 Hospitalisation: Age: 56

Onset Date: 20/08/2003 **DOB**: 27/10/1946

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	I. =' .	Early tardive movements of tongue and lips.	

Medicine Details:

 OLANZAPINE (Suspected)
 Reason:
 Unspecified schizophrenia

5.0 Milligram Daily

Batch: Started: 01/06/2003 Stopped: 04/09/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Olanzapine 5mg day. Had been as high as 15mg. Worsening on cessation now improved largely resolved in 3 weeks. Other drugs taken: Valproate, Nitrazepam.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 190793 Seq: 1 Gender: F

Reported: 23/09/2003 Weight: 100.00 Hospitalisation: Age: 44

Onset Date: 04/09/2003 DOB: 04/02/1959

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Oedema	Required Visit to Doctor	Oedema limbs, increased LFT, felt unwell.	
Liver function test abnormal	Required Visit to Doctor		
Malaise	Required Visit to Doctor		

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: 19/08/2003 **Stopped:** 02/09/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Other drugs taken: Efexor XR, Xanax, Triphasil, Avapro.

First exposure to an antipsychotic.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	<u> </u>		
Case Number:	191134	Seq: 1	Gender: M
Reported:	07/10/2003		Weight: 0.00
Hospitalisation:			Age: 53
Onset Date:	28/08/2003		DOB : 14/05/1950

Outcome: Recovered Causality: Causality possible

Reaction Details:

Report Details:

TOUCH	on Botano.			
	Preferred Term	Severity	Report Description	Treatment
Conditi	ion aggravated		QT interval on ECG	Olanzapine was ceased and his concomitant haloperidol was reduced from 2.5mg tds to treatment as needed.

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MEGICINE DELANS.			
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	s	Stopped:
HALOPERIDOL (Suspected)		Reason:	
	75.0 Milligram	Daily	
Batch:	Started:	s	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/10/2003	Creatine kinase				
07/10/2003	Electrocardiograph				
07/10/2003	Troponin				

Additional Information:

Patient also administered: Clozaril, Imipramine, Benztropine Mesylate, Atenolol, Clopidogrel.

Prior to recommencing Clozaril, an echocardiogram was performed on 28 Aug 2003 due to his cardiac and hypertension history. This echocardiogram showed features of moderate ischaemic dilated cardiomyopathy, a left ventricular ejection fraction of approximately 35%, and regional wall motion abnormalities consistent with previous extensive anterior, anteroseptal and apical mvocardial infarcts. The dilated cardiomyopathy was considered most likely pre-existing, and Clozaril was not suspected to have

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 191267 Seq: 1 Gender: F

Reported: 14/10/2003 Weight: 67.00 Hospitalisation: Age: 26

Onset Date: DOB: 03/11/1976

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

	todotion Botanoi			
Preferred Term		Severity	Report Description	Treatment
		to Doctor	Galactorrhoea, following commencement of zyprexa- continued with change to seroquel	

Medicine Details:

Medicine Details.					
CIPRAMIL (Other drug)			Reason:	Depression	
Tablet	20.0	Milligram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	contin
ZYPREXA (Suspected)			Reason:	Unspecified psychosis	S
Tablet	5.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred sometime in 2002. Zyprexa was started sometime in 2002 and stopped sometime in March 2003.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 191350 Seq: 1 Gender: F

Reported: 16/10/2003 Weight: 0.00 Hospitalisation: Age: 49

Onset Date: DOB: 31/05/1954

Outcome: Recovered 01/09/2003 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment		
	to Doctor	Addition of Olanzepine to Efexor XR and Lithium in a patient in a depressed phase of bipolar disorder (depression present for some years) led to immediate cycling to hypomania. Increase of the Olanzepine worsened her condition.	Changed drug to Thioridazine, increased Lithium, stopped Efexor.		

Medicine Details:

Medicine Details.			
OLANZAPINE (Suspected)		Reason: Depression	
	5.0 Milligram	Daily	
Batch:	Started: 20/05/2003	Stoppe	d: 04/07/2003
LITHIUM CARBONATE (Suspected)		Reason: Depression	
Tablet	900.0 Milligram	Daily	Oral
Batch:	Started: 21/01/2003	Stoppe	d:
EFEXOR-XR (Suspected)		Reason: Depression	
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 15/06/2002	Stoppe	d: 28/08/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Last hypomanic during 1996. Since then depressed. Long past history of anorexia nervosa, normal weight since 1996.

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Report Details:

Case Number: 191441

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reporte	d: 20/10/2003	3				V	Veight:	0.00	
lospitalisatio	n:						Age:		
Onset Dat	e:						DOB:		
Outcome	e: Unknown					Ca	usality:	Causality poss	ible
eaction Det									
Prefe	erred Term	Se	everity	Rep	ort Desc	ription		Treatmer	nt
ntentional dru	g misuse		Pre	escribed over	dose, se	izure.			
Convulsion									
Medicine D									
ANTIDEPRESS	ANT NOS (Suspe	cted)		Rea	son:				
Batch:		Sí	tarted:			Stopped:			
ZYPREXA (Sus	pected)			Rea	son: S	chizophrenia			
Tablet			25.0 Milli	gram	Daily	(Oral		
Batch:		Sf	tarted:			Stopped:			
_aboratory Date	Investigati Type	ons: Range	Date Tested	Result			Detai	İs	
Additional l	Information	ı :							
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Rep



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 191490
 Seq: 1
 Gender: M

 Reported:
 22/10/2003
 Weight:
 0.00

Hospitalisation: Age: 43

Onset Date: 10/10/2003 **DOB**: 27/01/1960

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Priapism		TREMOR, CARPAL TUNNEL SYNDROME, CONSTIPATION	Ceased Olanzepine and changed to Clozapine.
Carpal tunnel syndrome			
Constipation			
Tremor			

Medicine Details:

VENLAFAXINE HYDROCHLORIDE	(Other drug)	Reason:		
Tablet	450.0 Milligram	Daily	Oral	
Batch:	Started: 23/01/2002	•	Stopped:	
DIAZEPAM (Other drug)		Reason:		
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started: 23/01/2002	•	Stopped:	
OLANZAPINE (Suspected)		Reason:		
Tablet	20.0 Milligram	Daily	Oral	
Batch:	Started: 08/03/1999	•	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Tremor increases if Olanz increase from 20 to 25mg

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DOB: 19/04/1956

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 191671
 Seq: 1
 Gender:
 F

 Reported:
 28/10/2003
 Weight:
 0.00

Hospitalisation: Age: 47

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Onset Date: 21/10/2003

Preferred Term	Severity	Report Description	Treatment
Freieneu reini	Seventy	Report Description	Healineill
Diabetes mellitus	Caused or prolonged inpatient hospitalisation	Diabetes mellitus	

Medicine Details:

 OLANZAPINE (Suspected)
 Reason:
 Unspecified schizophrenia

 Tablet
 10.0
 Milligram
 Daily
 Oral

Batch: Started: 19/10/2003 **Stopped:** 22/10/2003

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 191716 Seq: 1 Gender: M

Reported: 29/10/2003 Weight: 90.00 Hospitalisation: Age: 22

Onset Date: 28/10/2003 **DOB**: 14/02/1981

Outcome: Recovered 01/10/2002 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal	Treated in outpatient department only	Poverty of thought.	
Somnolence	Treated in outpatient department only	Severe somnolence, akathisia, weight gain, blurred vision, dry mouth,	Changed to Risperdal
Akathisia			
Dry mouth			
Vision blurred			
Weight increased			

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Tablet 20.0 Milligram Daily Oral

Batch: Started: 01/01/2002 **Stopped:** 01/10/2002

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Weight loss, now 82kg, not sleeping 20hours a day.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:			
Case Number: 191758 Reported: 30/10/2009 ospitalisation: Onset Date: 06/08/2009 Outcome: Recovered	3	We	ight: 75.00 Age: 20 DOB: 05/04/1983 ality: Causality possible
eaction Details:			,
Preferred Term	Severity	Report Description	Treatment
Neutropenia	Required Visit to Doctor	Neutropenia x 6 daily treatment.	
Weight increased	Required Visit to Doctor	Weight gain - 65kg at commencement - 75kg at cessation.	
Medicine Details: OLANZAPINE (Suspected)		Reason:	
D 4.1		Dose Unspecified Daily	
Batch: RISPERIDONE (Suspected)	Started:	Stopped:	
LINDUITE (UUSPEULEU)		1303011.	
` ' '		Dose Unspecified Daily	
Batch:	Started:	Dose Unspecified Daily Stopped:	
Batch:	Started:	Stopped:	Details
Batch: Laboratory Investigati	Started:	Stopped:	Details

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 191911 Seq: 1 Gender: F

Reported: 06/11/2003 Weight: 70.00 Hospitalisation: Age: 28

Onset Date: 06/10/2003 DOB: 11/10/1974

Outcome: Recovered 21/10/2003 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Required Visit to Doctor		Zyprexa ceased. Frusemide 10mg daily x 3 days.

Medicine Details:

ZYPREXA (Suspected)

Reason:

2.5 Milligram Daily

Batch: Started: 03/10/2003 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No previous exposure to Zyprexa. Symptoms appeared after 3 days. Allergic to MSG.

Other drugs taken: Cipramil, Valium.

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DOB:

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 191997
 Seq: 1
 Gender:
 M

 Reported:
 10/11/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 75Y

Outcome: Recovered Causality: Causality possible

Reaction Details:

Onset Date:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome.	
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Leukocytosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.				
ZYPREXA (Suspected)		Reason:	Otr spec symp psychopathol nec	
Tablet	5.0 Milli	gram Daily	Oral	
Batch:	Started:		Stopped:	
HALOPERIDOL (Suspected)		Reason:	Otr spec symp psychopathol nec	
Tablet	1.0 Milli	gram Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History included: Agitation and dementia.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 192448
 Seq: 1
 Gender:
 F

 Reported:
 24/11/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 29Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome neonate		exposure during pregnancy.	Dextrose infusion, antibiotic therapy
Drug exposure during pregnancy	Caused or prolonged inpatient hospitalisation		
Hypertonia neonatal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.			_		
PAROXETINE HYDROCHLORIDE (S	uspected)		Reason:		
Tablet	40.0	Milligram	Daily	Oral	
Batch:	Started:	LT	ERM	Stopped:	
OLANZAPINE (Suspected)			Reason:		
	10.0	Milligram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
24/11/2003	Other data				
24/11/2003	Other data				

Additional Information:

Jaiswal S et al. Paroxetine withdrawal in a neonate with historical and laboratory confirmation. Eur J. Pediatr, 2003, 162, 723-724 Nordeng H and Spigest O. Treatment with selective serotonin re-uptake inhibitors in the thrid trimester of pregnancy. Drug Safety 2005; 28(7):556-581

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Detail	s:			
Case Number:	192448	Seq: 1	Gender:	F
Reported:	24/11/2003		Weight:	0.00
Hospitalisation:			Age:	29Y
Onset Date:			DOB:	
Outcome:	Unknown		Causality:	Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoglycaemia neonatal	Caused or prolonged inpatient hospitalisation		
Opisthotonus	Caused or prolonged inpatient hospitalisation		
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.					
PAROXETINE HYDROCHLORIDE (Sus	pected)		Reason:	_	
Tablet	40.0	Milligram	Daily	Oral	
Batch:	Started:	LT	ERM	Stopped:	
OLANZAPINE (Suspected)			Reason:		
	10.0	Milligram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

Additional Information:

Jaiswal S et al. Paroxetine withdrawal in a neonate with historical and laboratory confirmation. Eur J. Pediatr, 2003, 162, 723-724 Nordeng H and Spigest O. Treatment with selective serotonin re-uptake inhibitors in the thrid trimester of pregnancy. Drug Safety 2005; 28(7):556-581

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:	
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 Case Number:
 192448
 Seq: 1
 Gender:
 F

 Reported:
 24/11/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 29Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

1000	on Dotano			
	Preferred Term	Severity	Report Description	Treatment
Tremo	or neonatal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.					
PAROXETINE HYDROCHLORIDE (Sus	pected)		Reason:	_	
Tablet	40.0	Milligram	Daily	Oral	
Batch:	Started:	LT	ERM	Stopped:	
OLANZAPINE (Suspected)			Reason:		
	10.0	Milligram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

Additional Information:

Jaiswal S et al. Paroxetine withdrawal in a neonate with historical and laboratory confirmation. Eur J. Pediatr, 2003, 162, 723-724 Nordeng H and Spigest O. Treatment with selective serotonin re-uptake inhibitors in the thrid trimester of pregnancy. Drug Safety 2005; 28(7):556-581

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 192453 Seq: 1 Gender: U

Reported: 23/10/2003 Weight: 0.00 Hospitalisation: Age: 83

Onset Date: 24/06/2003 **DOB**: 10/07/1919

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Miosis		Pin- point pupils	Ceased Olanzapine.

Medicine Details:

OLANZAPINE (Suspected) Reason: Reactive confusion

Tablet 10.0 Milligram Daily Oral

Batch: Started: 18/06/2003 Stopped: 24/06/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Digoxin. History of hypothyroidism.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 192469
 Seq: 1
 Gender:
 F

 Reported:
 25/11/2003
 Weight:
 0.00

Hospitalisation: Age: 50

Onset Date: DOB: 03/11/1953
Outcome: Not yet recovered Causality: Causality possible

Outcome: Not yet recovered

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus	prolonged inpatient	Symptoms of polydypsia, polyuria, nocturia for over 6 months and weight gain. BGL 36.5	Insulin and diabetes eduration
Nocturia	Caused or prolonged inpatient hospitalisation		
Polydipsia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason:			
	Tablet	15.0 Milli	gram Daily		Oral
	Batch:	Started:		Stopped:	18/11/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
25/11/2003	Other data				

Additional Information:

Other drugs used: Epilim, Oroxine, Somac and Lithicarb.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 192469
 Seq: 1
 Gender:
 F

 Reported:
 25/11/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 50

Onset Date: DOB: 03/11/1953

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Polyuria	Caused or prolonged inpatient hospitalisation		
Weight increased	Caused or prolonged inpatient hospitalisation		

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ш	vi	-(1	 	-	.,	eta	-

ZYPREXA (Suspected)			
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	18/11/2003

Laboratory Investigations:

Additional Information:

Other drugs used: Epilim, Oroxine, Somac and Lithicarb.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 192477
 Seq: 1
 Gender:
 F

 Reported:
 25/11/2003
 Weight:
 45.00

Hospitalisation: Admitted to hospital Age: 64

Onset Date: 19/10/2003 **DOB**: 27/04/1939

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome.	Rehydrate.Cease olanzapine. Diazepam 2mg tds iv prn. W/h lithium. Icu r/v, supportive Rx. Forced Na diuresis.
Agitation	Caused or prolonged inpatient hospitalisation		
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Interaction)	Rea	ason:	Unspecified psychosis
10.0 M	Milligram	Daily	

Batch: Started: 17/10/2003 **Stopped:** 20/10/2003

LITHIUM CARBONATE (Interaction) Reason:

500.0 Milligram Daily

Batch: Started: Stopped: 20/10/2003

DIAZEPAM (Other drug)Reason: Otr spec symp psychopathol nec

15.0 Milligram Daily

Batch: Started: 10/07/2003 Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/11/2003	Creatine		27/10/2003	2107	
25/11/2003	Creatine		26/10/2003	1955	
25/11/2003	Creatine		26/10/2003	2133	
25/11/2003	Creatine		24/10/2003	800	
25/11/2003	Creatine		21/10/2003	1107	
25/11/2003	Creatine		05/11/2003	91	
25/11/2003	Creatine		02/11/2003	628	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 192477 Seq: 1 Gender: F

Reported: 25/11/2003 Weight: 45.00 Hospitalisation: Admitted to hospital Age: 64

Onset Date: 19/10/2003 **DOB**: 27/04/1939

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		
	Caused or prolonged inpatient hospitalisation		
	Caused or prolonged inpatient hospitalisation		

Medicine Details: OLANZAPINE (Interaction)

	10.0 Milligram	Daily	
Batch:	Started: 17/10/2003	;	Stopped: 20/10/2003
LITHIUM CARBONATE (Interaction)		Reason:	
	500.0 Milligram	Daily	

Reason:

Unspecified psychosis

Batch: Started: Stopped: 20/10/2003

DIAZEPAM (Other drug) Reason: Otr spec symp psychopathol nec

15.0 Milligram Daily

Batch: Started: 10/07/2003 Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/11/2003	Creatine		31/10/2003	1385	
25/11/2003	Creatine		29/10/2003	2957	
25/11/2003	Creatine		28/10/2003	2222	
25/11/2003	Creatine		30/10/2003	2983	
25/11/2003	Creatine		01/11/2003	1413	
25/11/2003	Creatine		03/11/2003	375	
25/11/2003	Creatine		07/11/2003	54	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 192477
 Seq: 1
 Gender:
 F

 Reported:
 25/11/2003
 Weight:
 45.00

Hospitalisation: Admitted to hospital **Age:** 64

Onset Date: 19/10/2003 **DOB**: 27/04/1939

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased	Caused or prolonged inpatient hospitalisation		
Fall	Caused or prolonged inpatient hospitalisation		
Hyperreflexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Interaction)		Reason: Unspecified psychosis	
	10.0 Milligram	Daily	
Batch:	Started: 17/10/2003	Stopped: 20/10/2003	
LITHIUM CARBONATE (Interaction)		Reason:	
	500.0 Milligram	Daily	
Batch:	Started:	Stopped: 20/10/2003	
DIAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec	
	15.0 Milligram	Daily	
Batch:	Started: 10/07/2003	Stopped: contin	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/11/2003	Creatine		23/10/2003	656	
25/11/2003	Creatine		25/10/2003	632	
25/11/2003	Serum drug level				

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	port	Deta	ails:
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 Case Number:
 192477
 Seq: 1
 Gender:
 F

 Reported:
 25/11/2003
 Weight:
 45.00

Hospitalisation: Admitted to hospital **Age**: 64

Onset Date: 19/10/2003 DOB: 27/04/1939
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia	Caused or prolonged inpatient hospitalisation		
Incoherent	Caused or prolonged inpatient hospitalisation		
Palpitations	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Interaction)		Reason: Unspecified psychosis	
	10.0 Milligram	Daily	
Batch:	Started: 17/10/2003	Stopped: 20/10/2003	
LITHIUM CARBONATE (Interaction)		Reason:	
	500.0 Milligram	Daily	
Batch:	Started:	Stopped: 20/10/2003	
DIAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec	
	15.0 Milligram	Daily	
Batch:	Started: 10/07/2003	Stopped: contin	

Laboratory Investigations:

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
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Gender: F Case Number: 192477 Seq: 1 **Weight:** 45.00 Reported: 25/11/2003

Hospitalisation: Admitted to hospital **Age:** 64

Onset Date: 19/10/2003 DOB: 27/04/1939 Causality: Causality possible

Outcome: Not yet recovered

Reaction Details:

veaction Details.			
Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Interaction)		Reason: Unspecified psychosis	
	10.0 Milligram	Daily	
Batch:	Started: 17/10/2003	Stopped: 20/10/2003	
LITHIUM CARBONATE (Interaction)		Reason:	
	500.0 Milligram	Daily	
Batch:	Started:	Stopped: 20/10/2003	
DIAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec	
	15.0 Milligram	Daily	
Batch:	Started: 10/07/2003	Stopped: co	ontin

Laboratory Investigations:

Additional Information:

Report Run: 04/06/2007 05:13PM Database: pusime02 ADRS004 Page 103 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 192552
 Seq: 1
 Gender:
 F

 Reported:
 27/11/2003
 Weight:
 0.00

Hospitalisation: Age: 87Y
Onset Date: 21/08/2003 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence	Caused or prolonged inpatient hospitalisation	Very drowsy gradual deterioration now doesn't recognise, hypothermia.	Zyprexa ceased.
Cognitive disorder	Caused or prolonged inpatient hospitalisation		
Hypothermia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

 ZYPREXA (Suspected)
 Reason:
 Unspecified psychosis

 Tablet
 2.5 Milligram
 Daily
 Oral

 Batch:
 Started: 13/08/2003
 Stopped: 22/08/2003

Batch: Started: 13/08/2003 **Stopped:** 22/08/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
27/11/2003	Other data				

Additional Information:

Patient also administered: Pepcidine, Nitrodur Patch, Aspirin, Tenormin, Coloxyl & Senna.

Report Run: 04/06/2007 05:13PM Database: pusime02 ADRS004 Page 104 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 192757 Seq: 1 Gender: M

 Reported:
 02/12/2003
 Weight:
 0.00

 Hospitalisation:
 Age:
 56Y

 Onset Date:
 15/11/2003
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Cachon Details.			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		Olanzapine has discontinued.

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Other drugs used: Atorvastatin and Efexor.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 192760 Seq: 1 Gender: F

Reported: 02/12/2003 Weight: 0.00 Hospitalisation: Age: 76Y

Onset Date: 27/06/2003 DOB:

Outcome: Recovered 11/07/2003 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Life threatening	Acute deterioration in glycaemic conrol resulting in hyperosmolar come and seizure generalised tonic clonic.	Intubated, ventilated, benzodiazepines for seizure. ICU admission - noradrenaline and actrapid infusion. Olanzapine ceased - changed to amisulpride
Diabetic coma	Life threatening	Hyperosmolar (non-ketonic) coma	
Blood glucose increased	Life threatening		

Medicine Details:

ZYPREXA (Suspected) Reason: Paranoia

1.0 Dose Unspecified Daily

Batch: Started: 23/06/2003 Stopped: 27/06/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
02/12/2003	Lactate		27/06/2003	7.9	
02/12/2003	Other data				
02/12/2003	Serum glucose		27/06/2003	75.6	
02/12/2003	Serum osmolality		27/06/2003	379	

Additional Information:

Patient also administered: Panamax, Novorapid, Protaphane, Coversyl, Vioxx, Transiderm Nitro, Zocor, Celebrex.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 193140
 Seq: 1
 Gender:
 F

 Reported:
 15/12/2003
 Weight:
 0.00

Hospitalisation:
Onset Date:

DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Type II diabetes mellitus	Prescribed metformin and blood sugar levels have been well controlled. Ceased Zyprexa.

Medicine Details:

Tablet Reason: Unspecified schizophrenia

Oral

Batch: Started: L TERM Stopped:

Laboratory Investigations:

	<u> Luboi atoi</u>	y ilivostigai				
	Date	Туре	Range	Date Tested	Result	Details
ı [

Additional Information:

Patient had been taking Olanzapine for several years and about 12 months ago she developed Type 11 diabetes. Zyprexa was stopped sometime in Sep 2003.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 193175 Seq: 1 Gender: M
Reported: 16/12/2003 Weight: 0.00
Hospitalisation: Age: 27

Onset Date: 27/09/2002 DOB: 07/10/1974

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Polyserositis	Caused or prolonged inpatient hospitalisation	Polyserositis and pericardial effusion.	Pericardial drain was inserted, transferred to ICU, antibiotics. Clozapine and Olanzapine ceased
Cardiac tamponade	Caused or prolonged inpatient hospitalisation		
Cardiomegaly	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Other drug)	F	Reason:	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 18/08/2002	Stopped:	11/10/2002
OLANZAPINE (Suspected)	F	Reason:	
	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	08/10/2002

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
Ī	16/12/2003	Echocardiogram				
	16/12/2003	Other data				

Additional Information:

Patient also administered: Clozapine, Sodium Valproate, Lithium SR, Salbutamol MDI, Frusemide. Patient was re-admitted. Increased shortness of breath. Had been taking Olanzapine 10mg nocte since discharge.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 193175 Seq: 1 Gender: M
Reported: 16/12/2003 Weight: 0.00
Hospitalisation: Age: 27

Onset Date: 27/09/2002 DOB: 07/10/1974

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation		
Chills	Caused or prolonged inpatient hospitalisation		
Cough	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Other drug)			
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 18/08/2002	Stopped:	11/10/2002
OLANZAPINE (Suspected)		Reason:	
OLANZAPINE (Suspected)	5.0 Milligram	Reason: Daily	Oral

Laboratory Investigations:

Additional Information:

Patient also administered: Clozapine, Sodium Valproate, Lithium SR, Salbutamol MDI, Frusemide. Patient was re-admitted. Increased shortness of breath. Had been taking Olanzapine 10mg nocte since discharge.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 193175 Seq: 1 Gender: M
Reported: 16/12/2003 Weight: 0.00
Hospitalisation: Age: 27

Onset Date: 27/09/2002 DOB: 07/10/1974

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depressed level of consciousness	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Other drug)			
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 18/08/2002	Stopped:	11/10/2002
OLANZAPINE (Suspected)		Reason:	
OLANZAPINE (Suspected)	5.0 Milligram	Reason: Daily	Oral

Laboratory Investigations:

Additional Information:

Patient also administered: Clozapine, Sodium Valproate, Lithium SR, Salbutamol MDI, Frusemide. Patient was re-admitted. Increased shortness of breath. Had been taking Olanzapine 10mg nocte since discharge.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 193175 Seq: 1 Gender: M
Reported: 16/12/2003 Weight: 0.00
Hospitalisation: Age: 27

Onset Date: 27/09/2002 DOB: 07/10/1974

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophilia	Caused or prolonged inpatient hospitalisation		
Pericardial effusion	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Other drug)			
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 18/08/2002	Stopped:	11/10/2002
OLANZAPINE (Suspected)		Reason:	
OLANZAPINE (Suspected)	5.0 Milligram	Reason: Daily	Oral

Laboratory Investigations:

Additional Information:

Patient also administered: Clozapine, Sodium Valproate, Lithium SR, Salbutamol MDI, Frusemide. Patient was re-admitted. Increased shortness of breath. Had been taking Olanzapine 10mg nocte since discharge.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 193478
 Seq: 1
 Gender:
 M

 Reported:
 23/12/2003
 Weight:
 0.00

Hospitalisation: Age: 26Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

veaction Details.			
Preferred Term	Severity	Report Description	Treatment
Intentional overdose	Caused or prolonged inpatient hospitalisation	Intentional overdose, delirium.	
Delirium	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified septicemia

10.0 Milligram Daily

Batch: Started: Stopped: Contin

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient took an intentional overdose 200mg of Olanzapine.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report I	Details:
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 Case Number:
 193596
 Seq: 1
 Gender: M

 Reported:
 06/01/2004
 Weight:
 0.00

 Hospitalisation:
 Age: 77

Onset Date: 11/12/2003 **DOB:** 25/03/1926

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation	Increased Confusion,	Saw psychiologist for Olanzapine.
Hallucination, visual	Caused or prolonged inpatient hospitalisation	Increased visual hallucination.	
Paradoxical drug reaction	Caused or prolonged inpatient hospitalisation	Paradoxical effect, GI Bleed.	

Medicine Details:

OLANZAPINE (Suspected)			Reason:	
Tablet	5.0	Milligram	Daily	Oral
Batch:	Started:	ST	ERM	Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Report Details:

Case Number: 193596

Reported: 06/01/2004

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Hospitalisation:			Αç	ge: 77	
Onset Date: 11/12/2003			DC	DB : 25/03/1926	
Outcome: Not yet recover	ed		Causali	ty: Causality possible	
Reaction Details:					
Preferred Term	Severity	Report Des		Treatment	
Gait disturbance	Caused or prolonged inpatient hospitalisation	Very stiff and unsteady	shuffling gait.		
Gastrointestinal haemorrhage	Caused or prolonged inpatient hospitalisation				
Medicine Details:					
OLANZAPINE (Suspected)		Reason:			
Tablet	5.0	Milligram Daily	Oral		
Batch:	Started:	S TERM	Stopped:		
Laboratory Investigations	:				
Additional Information:					
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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

		Com							
ospitalisatio Onset Da	A. 09/01/20	Seq	: 1					Gend	ler: M
Onset Da	30. 00/01/20	04						Weig	ht: 0.00
	n:								ge : 76
Outcom	te: 15/12/20	03						DO	OB : 15/02/1927
	ie: Unknowr	า					C	ausal	ity: Causality possible
eaction De				ı					
	erred Term		everity			ort Desc			Treatment
Oedema perip	oheral	Requ to Do		periph	eral oede	ma (swe	lling of the	eg)	cessation of olanzapine & commencement of Lasix 40mg bd; (N.B. This patient was already in the hospital when peripheral oedema occurred. He had been waiting for nursing home placement for weeks & therefore, the ADR may not be associated with prolonged hospital stay.)
Medicine D						ason:			
Tablet		_		Milligra	m	1 time		Oral	
Batch			tarted:				Stopped:		
	LE (Other drug	1)				ason:			
Tablet		_		Milligra	m	1 time		Oral	
Batch			started:		Day		Stopped:		
	HYDROBROMI	DE (Other drug)	00.0	N 4:11:		ason:		01	
Tablet	_	_		Milligra	m	1 time	04	Oral	
Batch		3	started:		Dec		Stopped:		
HALOPERIDO	L (Otner arug)		0.5	N 4:11:		ason:		01	
Tablet		_		Milligra	m	1 time	04	Oral	
Batch	:		started:				Stopped:		
_aboratory	Investiga	tions:							
Date	Туре	Range	Date Test	ed	Result				Details
Date									

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: Reported: ospitalisation: Onset Date:	08/01/2004	Seq: 1		Gender Weight: Age:	0.00
Outcome:					: Causality possible
eaction Detai	ils:			_	
ledicine Det			Posser		
THIAMINE (Other of Tablet	urug)	100.0 Milligram	Reason: 1 time	Oral	
Batch:		Started:	i uiile	Stopped:	
OLANZAPINE (Sus	spected)		Reason:	отъррош.	
Tablet		5.0 Milligram	1 time	Oral	
Batch:		Started: 17/11/2003		Stopped: 16/12/200	3
Daten.		Otalled: 1771172000		Otopped. 10/12/200	<u> </u>
aboratory In	vestigations	:			
dditional Inf	formation:				
Maitionai IIII	ormanon.				
ort Pun : 04/06/20/	07 05:13PM Dat	tahasa: nusima02	ADPSOOA		Dogo 116 of E20

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 193766 Seq: 1 Gender: M

Reported: 09/01/2004 Weight: 0.00 Hospitalisation: Age: 60

Onset Date: 04/10/2003 **DOB**: 19/01/1943

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction betains.			
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	prolonged	Admitted unable to swallow and history of mask like facies 12/12, dribbling 3/12, festinating gait 6/12, dry mouth 9/12.	

Medicine Details:

OLANZAPINE (Suspected)

7.5 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient also administered: Seretide and Salbutamol.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 193779 Seq: 1 Gender: M

Reported: 09/01/2004 Weight: 0.00 Hospitalisation: Age: 32

Onset Date: 09/11/2003 **DOB**: 18/10/1971

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia			AB's commenced as sepsis - no benefit.

Medicine Details:

Medicine Details.			
OLANZAPINE (Suspected)		Reason: Otr spec symp psychopa	hol nec
Wafer	30.0 Milligram	Daily Oral	
Batch:	Started: 06/11/2003	Stopped: 08/11/200	3
OLANZAPINE (Suspected)		Reason: Unspecified neurosis	
Wafer	15.0 Milligram	Daily Oral	
Batch:	Started: 08/11/2003	Stopped: 13/11/200	3

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Bisacodyl, Paracetamol, Ranitidine, Metoclopramide, Morphine/Midazolom, Insulin infusion, Propofol infusion, Timentin, Clexane, Methadone.

A spinal injury patient in ICU. No other obvious source of fevers e.g. sepsis found. Olanzapine commenced 06/11/2003. Temps peaked at 40.4 degrees celcius on 13/11/2003. Olanzapine ceased 13/11/2003 am. Active cooling ceased 14/11/2003 am as temps back down to 37 degrees celcius.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
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Case Number: 194066 Seq: 1 Gender: M

Reported: 23/01/2004 Weight: 71.00 Hospitalisation: Age: 79Y

Onset Date: 11/01/2004 DOB:

Outcome: Unknown Causality: Causality probable

Reaction Details:

١,	caction Betans.			
	Preferred Term	Severity	Report Description	Treatment
	Oedema peripheral	Required Specialist Consultation	Bilateral pedal oedema	not known yet

Medicine Details:

OLANZAPINE (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: 09/01/2004 Stopped: 23/01/2004

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Report Details:

Hospitalisation:

Case Number: 194237

Reported: 03/02/2004

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Age: 99U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Outcome: Recovered			D	OB:	
			Causal	ity: Causality possil	ble
action Details:					
Preferred Term	Severity	Repor	t Description	Treatment	t
Suicidal ideation	Caused or prolonged inpatient hospitalisation	·	withdrawal reaction.		
rug withdrawal syndrome	Caused or prolonged inpatient hospitalisation				
ledicine Details:					
PROZAC (Suspected)		Reas	on:		
		Dose Unspecified			
Batch:	Started:		Stopped:		
ZYPREXA (Suspected)		Reas	on:		
		Dose Unspecified			
Batch:	Started:		Stopped:		
		ted Result	[Petails	
_aboratory Investigations: Date Type Ra		ed Result	[Petails	
		ted Result	[Petails	



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 194415 Seq: 1 Gender: M

Reported: 09/02/2004 Weight: 0.00 Hospitalisation: Age: 32

Onset Date: 22/01/2004 DOB: 27/09/1971

Outcome: Recovered 31/01/2004 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancreatitis acute	Caused or prolonged inpatient hospitalisation	Acute Pancreatitis	

Medicine Details:

OLANZAPINE (Suspected)Reason:SchizophreniaTablet5.0MilligramDailyOral

Batch: Started: Stopped:

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Dose start - 12/03. Other drugs: Amisulpride, Litheum SR and Venlafaxine.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 194510
 Seq: 1
 Gender: M

 Reported:
 11/02/2004
 Weight: 80.00

Hospitalisation: Age: 39

Onset Date: DOB: 10/08/1964

Outcome: Recovered 03/02/2004 Causality: Causality possible

Reaction Details:

Veaction Details.	1	T	
Preferred Term	Severity	Report Description	Treatment
Restlessness	prolonged	Restlessness, agitated, anxious, pallor, hyperventilation, shaking (limbs and trunk).	
Agitation	Caused or prolonged inpatient hospitalisation		
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected) Reason: Schizophrenia

10.0 Milligram Daily

Batch: Started: 22/10/2002 Stopped: 25/11/2003

EFEXOR-XR (Suspected) Reason: Depression

Capsule 75.0 Milligram Daily

Batch: Started: 07/10/2003 **Stopped:** 25/11/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Lovan tabs, Alprazolam, Valium.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 194510 Seq: 1 Gender: M

Reported: 11/02/2004 Weight: 80.00 Hospitalisation: Age: 39

Onset Date: DOB: 10/08/1964

Outcome: Recovered 03/02/2004 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperventilation	Caused or prolonged inpatient hospitalisation		
Pallor	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected) Reason: Schizophrenia

10.0 Milligram Daily

Batch: **Started**: 22/10/2002 **Stopped**: 25/11/2003

EFEXOR-XR (Suspected) Reason: Depression

Capsule 75.0 Milligram Daily

Batch: Started: 07/10/2003 Stopped: 25/11/2003

Laboratory Investigations:

Additional Information:

Patient also administered: Lovan tabs, Alprazolam, Valium.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 194544
 Seq: 1
 Gender:
 F

 Reported:
 12/02/2004
 Weight:
 76.00

Hospitalisation: Age: 61

Onset Date: 02/02/2004 DOB: 27/12/1942

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano				
Preferred Term	Severity	Report Description	Treatment	
Rash pustular		Pustular skin eruption and petechies on both legs.	Rofecoxib, dexamethasone, olanzapine stopped.	
Petechiae	Caused or prolonged inpatient hospitalisation			

Medicine Details:

OLANZAPINE (Suspected)			Reason:		
Liquid, multipurpose	2.5	2.5 Milligram		ssary	
Batch:	Started:			Stopped:	
ROFECOXIB (Suspected)			Reason:		
	25.0	Milligram	Daily		
Batch:	Started:			Stopped:	
DEXAMETHASONE (Suspected)			Reason:		
	0.5	Milligram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Other drug therapy pantoprazole, paracetamol, morphine, gabapentin, ketamine, venlafaxine, temazepam.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Hospitalisati Onset Da				Wei	nder: M ight: 70.00 Age: 80Y DOB: ality: Causality possible
eaction D		,0vc1cu		Oddo	unty: Oddodnity possible
	eferred Term	Severity	Reg	ort Description	Treatment
Liver function	n test abnormal		Elevated LFT's	·	
Medicine I					
OLANZAPINE	(Suspected)	7.5		ason:	
Batcl	. .	7.5 Started: 2	Milligram	Daily Stopped : 02/0	2/2004
<u>Laborator</u> Date	y Investigati Type	Range Date Te	ested Result		Details
	71	- J. J.			
Additiona	l Informatior	1:			
eport Run: 04/0	06/2007 05:13PM	Database: pusime02		ADRS004	Page 125 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 194867 Seq: 1 Gender: M

Reported: 24/02/2004 Weight: 0.00
Hospitalisation: Age: 16Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure	

Medicine Details:

ZYPREXA (Suspected)

Reason: Unspecified psychosis

Tablet

Dose Unspecified

Oral

Batch: Started: Stopped:

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Onset 2004. Dose start date: 2004. Medical condition: Eating disorder.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 194881 Seq: 1 Gender: M

Reported: 25/02/2004 Weight: 70.00 Hospitalisation: Age: 65

Onset Date: 09/01/2004 **DOB**: 26/11/1938

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
Eosinopenia		Required Visit to Doctor	Eosinophilia	Ceased Olanzapine

Medicine Details:

 OLANZAPINE (Suspected)
 Reason:
 Unspecified schizophrenia

 Tablet
 20.0
 Milligram
 Daily
 Oral

 Batch:
 Started:
 Stopped:
 30/01/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
25/02/2004	Eosinophils	(0.02-).50)	09/01/2004	5.9	
25/02/2004	Eosinophils	(0.02-).50)	06/02/2004	0.66	

Additional Information:

Patient was also taking Sodium Valproate, Lithium Carborate, Aspirin, Simvastatin. Patient asymptomatic no other causes apparent.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

eport Details:	Seq: 1		Ganda	v. C	
Case Number: 195196 Reported: 08/03/2004		Gender: F Weight: 0.00			
ospitalisation:		_	e: 99u		
Onset Date:		DO			
Outcome: Recovered				y: Causality possible	
eaction Details:				,	
Preferred Term	Severity	Report Descript	tion	Treatment	
Diabetes mellitus	Caused or prolonged inpatient hospitalisation	Diabetes mellitus, diabetic co	oma.		
Diabetic coma	Caused or prolonged inpatient hospitalisation				
		Reason:			
ZYPREXA (Suspected)		Reason: Dose Unspecified	Oral		
Madiaina Dataila					
Medicine Details: ZYPREXA (Suspected) Batch:	Started:	Dose Unspecified	Oral topped:		
ZYPREXA (Suspected)	Started:	Dose Unspecified St	topped:	tails	

Additional Information:

No history of diabetes. It is not known if the patient received corrective treatment for the event. Olanzapine was discontinued and the patient was discharged from hospital with no other medications. The event is not continuing and the patient has fully recovered.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 195198
 Seq: 1
 Gender:
 F

 Reported:
 08/03/2004
 Weight:
 0.00

Hospitalisation: Treated in outpatient department only. **Age:** 51

Onset Date: DOB: 12/03/1952
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Overdose	Required Specialist Consultation	Prescribed overdose, neutrophil count decreased.	Treatment changed to Quetiapine 900mg/daily.
Neutrophil count decreased	Required Specialist Consultation		

Medicine Details:

ZYPF	REXA (Suspected)			Reason:	Schizophrenia	ì
	Tablet	40.0	Milligram	Daily		Oral
	Batch:	Started:		L TERM	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/03/2004	Neutrophils		18/06/2003	1.5	
08/03/2004	Neutrophils		25/07/2003	1.6	
08/03/2004	Neutrophils		15/08/2003	1.9	
08/03/2004	Neutrophils		01/10/2003	1.9	

Additional Information:

Onset date 1999. Dose start and stop date: 1999 and 06/2003. History: Schizophrenia. Patient prescribed Zyprexa 40mg/daily normal dose is 20mg/daily. The patient was seen by a haematologist on 09/07/03 who believed the neutropenia may have been a dose dependant effect. The patient has not yet recovered. Treatment with Olanzapine was discontinued and treatment changed to Quetiapine 900mg/day but neutropenia persisted, described as unrelated to the Quetiapine treatment.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 195243
 Seq: 1
 Gender:
 F

 Reported:
 10/03/2004
 Weight:
 0.00

Hospitalisation: Age: 57

Onset Date: 21/02/2004 **DOB**: 05/11/1946

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caotion Details.								
Preferred Term	Severity	Report Description	Treatment					
Delirium	Caused or prolonged inpatient hospitalisation	Delirium, acute confusional state.	3 lots of ECT treatment both sides.					
Confusional state	Caused or prolonged inpatient hospitalisation							

Medicine Details:

Medicine Details.				
STILNOX (Suspected)			Reason:	Specific disorders of sleep
Tablet	20.0	Milligram	Daily	
Batch:	Started:			Stopped:
OLANZAPINE (Suspected)			Reason:	Unspecified psychosis
	10.0	Milligram	Daily	
Batch:	Started:			Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Efexor, Lithium.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:195245Seq: 1Gender:FReported:10/03/2004Weight:0.00Hospitalisation:Admitted to hospitalAge: 99U

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caction betains.								
Preferred Term	Severity	Report Description	Treatment					
Electrocardiogram QT prolonged	threatening	Electrocardiogram QT prolonged, hypokalemia, infarction (near fatal), ventricular tachyarrythmia.						
Hypokalaemia	Life threatening							
Myocardial infarction	Life threatening							
Ventricular tachycardia	Life threatening							

Medicine Details:

ZYPREXA (Suspected)		Reason:			
	10.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
10/03/2004	Potassium	(3.5 - 5.3)			

Additional Information:

The infarct and hypokalemia were life threatening events.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 195537 Seq: 1 Gender: F

Reported: 16/03/2004 Weight: 0.00 Hospitalisation: Age: 35Y

Onset Date: 17/01/2003 DOB:

Outcome: Recovered 15/07/2003 Causality: Causality probable

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Rash		Severe skin burn, blisters in hair line, forehead, cheeks, eyes. Bright yellow blisters which took 5 months to resolve.	Drug ceased by patient.
Blister	Required Visit to Doctor		
Photosensitivity reaction	Required Visit to Doctor		

Medicine Details:

ZYPREXA (Suspected)		Reason: Unspe	cified neurosis
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Sto	opped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zyprexa was started and stopped sometime in January.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 195725 Seq: 1 Gender: M

 Reported:
 19/03/2004
 Weight:
 0.00

 Hospitalisation:
 Age:
 99u

 Onset Date:
 04/03/2004
 DOB:

Outcome: Not yet recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased		Neutrophil count decreased.	Zyprexa ceased.

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified psychosisTablet10.0 MilligramDailyOralBatch:Started:Stopped:

Laboratory Investigations:

<u>Lubol atol</u>	y ilivostigat				
Date	Туре	Range	Date Tested	Result	Details
19/03/2004	Neutrophils		04/03/2004	1.0	
19/03/2004	Neutrophils		29/02/2004	3.1	

Additional Information:

History of anorexia; Patient very malnourished, weight less then 40kg. Lowest neutrophil count 1 E9/L. Suspected drug discontinued, event continuing

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 196158
 Seq: 1
 Gender:
 F

 Reported:
 02/04/2004
 Weight:
 0.00

Hospitalisation:
Onset Date: 19/03/2004

Age: 68Y

DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Value: Detaile:								
Preferred Term	Severity	Report Description	Treatment					
Convulsion		Convulsion, gait abnormal, Drug ineffective.						
Drug ineffective								
Gait disturbance								

Medicine Details:

Medicine Details.				
ZOLOFT (Other drug)		Reason:	Depression	
Tablet	50.0	Milligram		Oral
Batch:	Started:		Stopped:	
EPILIM (Suspected)		Reason:		
	1.5	Gram Dai	ly	Oral
Batch:	Started:		Stopped:	
ZYPREXA (Suspected)		Reason:		
Tablet	7.5	Milligram Dai	ly	Oral
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
02/04/2004	Serum drug level				

Additional Information:

Valproate was reduced to 1000mg on 17/03/04 due to development of unsteady gait. History: Tumor, depression.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 196230 Seq: 1 Gender: F

Reported: 05/04/2004 Weight: 0.00 Hospitalisation: Age: 89

Onset Date: DOB: 21/06/1914

Outcome: Recovered 31/03/2004 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Colonic pseudo-obstruction	Caused or prolonged inpatient hospitalisation	Pseudo-obstruction of "large bowel", abdominal discomfort, sleeping more, constipation.	Required a visit to doctor. Treated by Agarol.
Abdominal distension	Caused or prolonged inpatient hospitalisation		
Constipation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

 OLANZAPINE (Suspected)
 Reason:
 Unspecified psychosis

 Tablet
 5.0 Milligram
 Daily
 Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Onset date: 11/2003. Other drugs: Tritace, Natrilix, Caltrate and Coversyl & Senna.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:196438Seq: 1Gender:FReported:13/04/2004Weight:0.00Hospitalisation:Admitted to hospitalAge: 35

Onset Date: 15/03/2004 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pleural effusion	prolonged inpatient	Patient experienced bilateral pleural effusion, ascites and extended widespread oedema from legs up to sacrum, fingers and face.	Zyprexa ceased.
Ascites	Caused or prolonged inpatient hospitalisation		
Oedema	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected) Reason:

10.0 Milligram Daily Oral

Batch: Started: 01/03/2004 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient already in hospital.

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DOB:

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 196478 Seq: 1 Gender: M

 Reported:
 15/04/2004
 Weight:
 60.00

 Hospitalisation:
 Age:
 46Y

Outcome: Unrelated death Causality: Causality possible

Reaction Details:

Onset Date: 15/05/2003

Preferred Term	Severity	Report Description	Treatment	
	Required Visit to Doctor		Lopinavir/Ritonavir bd, Lamivudine 150g bd	l

Medicine Details:

OLANZAPINE (Suspected) Reason: Depression

10.0 Milligram Daily

Batch: Started: L TERM Stopped:

AMITRIPTYLINE HYDROCHLORIDE (Suspected) Reason: Depression

25.0 Milligram Daily

Batch: Started: L TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient died from HIV 9/12/03. Patient was also taking Valaciclovir, Abacavir, Bactrim and Gabapentin.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:196641Seq: 1Gender: MReported:20/04/2004Weight: 70.00Hospitalisation:Admitted to hospitalAge: 55Y

Onset Date: 11/01/2004 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		Prolonged QTc syndrome, hyponatraemia, 6 min unconsious, collapse.	
Circulatory collapse	Life threatening		
Hyponatraemia	Life threatening		
Loss of consciousness	Life threatening		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	St	topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
20/04/2004	Sodium	(137-145)			

Additional Information:

Patient was also taking trandilopril, Atenolol, Oxazepime, Aspirin, Thiamine. past history of prolonged SVT.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:196826Seq: 1Gender:FReported:27/04/2004Weight:0.00Hospitalisation:Admitted to hospitalAge: 56

Onset Date: 21/04/2004 **DOB**: 26/01/1948

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Life threatening	undetectable phosphate levels and cardiac	ICU admission for 5 days, CPR, phosphate suplementation.
Anxiety	Life threatening		
Blood phosphorus decreased	Life threatening		
Cardiac arrest	Life threatening		
Hyperventilation	Life threatening		

Medicine Details:

ALPRAZOLAM (Suspected)		Rea	son:			
Tablet		Dose Unspecified			Oral	
Batch:	Started:			Stopped:		Ongoing
OLANZAPINE (Suspected)		Rea	son:			
		Dose Unspecified				
Batch:	Started:			Stopped:		Ongoing
EFEXOR-XR (Suspected)		Rea	son:	Depression		
Capsule	300.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		Ongoing

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
27/04/2004	Phosphate	0.88 - 1.46	10/04/2004	<0.3	

Additional Information:

Patient hospitalised due to circulatory collapse. Other drug therapy taken: nilstat, aspirin, zyprexa, clexane. Phosphate level decreased with hyperventylation (anxiety), but not sufficient to explain phosphate levels <30.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repor Hospitalisati Onset D	ate: me: Unknown	Seq:	1				0.00	
	eferred Term	Se	verity	Rep	ort Description		Treatment	
Drug ineffec	tive			rogression of s		Ola	anzapine ceased.	
Medicine	Details:							
	E (Suspected)			Rea	son:			
Batc	h:	Si	tarted:		Stoppe	Stopped:		
	y Investigat							
Date	Туре	Range	Date Tested	Result		Detai	ls	
Additiona	I Informatio	n:						

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 196954
 Seq: 1
 Gender:
 M

 Reported:
 03/05/2004
 Weight:
 0.00

 Hospitalisation:
 Age: 15Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Weight increased			Risperdal ceased and given Olanzapine.

Medicine Details:

Medicine Details.					
OLANZAPINE (Suspected)			Reason:	Unspecified psychosis	
Batch:	Started:			Stopped:	
RISPERDAL (Suspected)			Reason:	Unspecified psychosis	
Tablet	2.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

On an unspecified date the patient gained 15kg. He was taken off Risperidal and dropped 10kg quickly. He was then put on Olanzapine due to need for an antipsychotic and gained 23kg in 5 weeks.

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Additional Information:

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the same.

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report D							
Case Num	nber: 197003	Seq: 1			Ge	ender: M	
Repo	rted: 04/05/2004		Weight: 0.00				
ospitalisa						Age: 27	
Onset I	Date: 26/02/2000					DOB : 15/01/	
Outco	ome: Death		2	26/02/2000	Caus	sality: Causal	ity possible
action [Details:						
Pı	referred Term	Severity	/	Rep	oort Description	Т	reatment
eath			Ola	nzapine tox	icity.		
FLUVOXAM Bat		drug) Started:			ason: Stopped:		
FLUVOXAM Bat CLOZAPINE	INE MALEATE (Other ch: : (Other drug)	Started:			Stopped: ason:		
FLUVOXAM Bat CLOZAPINE Bat	INE MALEATE (Other ch: : (Other drug) ch:	Started: Started:		Re	Stopped: ason: Stopped:		
FLUVOXAM Bat CLOZAPINE Bat	INE MALEATE (Other ch: : (Other drug)	Started: Started:		Re	Stopped: ason:		
FLUVOXAM Bat CLOZAPINE Bat	INE MALEATE (Other ch: : (Other drug) ch: LPROATE (Other dru	Started: Started:	:	Re	Stopped: ason: Stopped:		
Bat CLOZAPINE Bat SODIUM VA	INE MALEATE (Other ch: : (Other drug) ch: LPROATE (Other dru	Started: Started: g) Started:	:	Re Re	Stopped: ason: Stopped: ason:		
Bat CLOZAPINE Bat SODIUM VA	ch: Cher drug) ch: LPROATE (Other druch: Ch: Ch: Ch: Ch: Ch: Ch: Ch: Ch: Ch: C	Started: Started: g) Started:	:	Re Re	Stopped: ason: Stopped: ason:		
Bat CLOZAPINE Bat SODIUM VA Bat ZUCLOPEN	ch: Cher drug) ch: LPROATE (Other druch: Ch: Ch: Ch: Ch: Ch: Ch: Ch: Ch: Ch: C	Started: Started: g) Started: ther drug)	:	Re Re	Stopped: ason: Stopped: ason: Stopped:		
Bat CLOZAPINE Bat SODIUM VA Bat ZUCLOPEN	ch: (Other drug) ch: LPROATE (Other dru ch: THIXOL ACETATE (O	Started: Started: g) Started: ther drug) Started:	:	Re Re	Stopped: ason: Stopped: ason: Stopped:	Details	

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His treatment included electro-convulsive therapy. The patient was prescribed Olanzapine at the rate of 20mg at night. His port-mortem level was 0.5mg per litre, or 580 nonograms per millilitre. The only other time the patient's blood was tested for Olanzapine was on 24 Nov 1999 when the level was 46 nanograms per millilitre. The combination of drugs he was receiving was



the same.

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:			
Case Number: 197003 Reported: 04/05/2004 Hospitalisation: Onset Date: 26/02/2000 Outcome: Death	Seq: 1		0.00
Reaction Details:	20/02/20	Causanty.	Causality possible
Reaction Details.			
Medicine Details: OLANZAPINE (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
Laboratory Investigations:			
Additional Information: His treatment included electro-convul port-mortem level was 0.5mg per litre Olanzepine was on 24 Nov 1999 whe	. or 580 nonograms per millilitre	 e. The only other time the patient 	's blood was tested for

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 197094 Seq: 1 Gender: F

Reported: 07/05/2004 Weight: 58.00 Hospitalisation: Age: 26Y

Onset Date: 08/04/2004 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia	

Medicine Details:

EPILIM (Suspected)		Reason:	Neuroses
Tablet	600.0 Milligram	Daily	oral Oral
Batch:	Started: 05/04/2004		Stopped: 08/04/2004
DOXYLIN (Suspected)		Reason:	Other acne of sebaceous glands
Tablet	100.0 Milligram	Daily	oral Oral
Batch:	Started: 24/03/2004		Stopped: 12/04/2004
ZYPREXA (Suspected)		Reason:	Unspecified psychosis
Tablet	20.0 Milligram	Daily	oral Oral
Batch:	Started: 29/03/2004		Stopped: 08/04/2004
PAXAM (Suspected)		Reason:	
Tablet	1.5 Milligram	Daily	oral Oral
Batch:	Started: 30/03/2004		Stopped: 19/04/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
07/05/2004	Neutrophils		08/04/2004	1.46	
07/05/2004	Neutrophils		11/04/2004	1.27	
07/05/2004	Neutrophils		21/04/2004	3.81	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 197180
 Seq: 1
 Gender: M

 Reported:
 10/05/2004
 Weight:
 0.00

 Hospitalisation:
 Age: 78Y

Onset Date: 31/01/2004 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		Mirtazapine and Olanzapine ceased.
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.			
MIRTAZAPINE (Suspected)		Reason: Depression	
Tablet	30.0 Milligram	Daily Oral	
Batch:	Started: 27/01/2004	Stopped: 30/01/2004	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	1.2 Milligram	Daily Oral	
Batch:	Started: 30/01/2004	Stopped : 30/01/2004	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
10/05/2004	Other data				

Additional Information:

Patient was also taking Venlafaxine, Aspirin, Lactulose, Coloxyl with Senna, Ostelin, Caltrate, Diamicron, Diabex, Ranitidine, Keflex, Captopril.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 197290 Seq: 1 Gender: F

Reported: 12/05/2004 Weight: 50.00 Hospitalisation: Age: 42

Onset Date: 25/04/2004 **DOB**: 13/09/1961

Outcome: Recovered 06/05/2004 Causality: Causality probable

Reaction Details:

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	·	Zyprexa ceased

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified schizophreniaTablet10.0 MilligramDailyOralBatch:Started: 23/04/2004Stopped: 29/04/2004

Laboratory Investigations:

	. <u>,</u>	• • .			
Date	Туре	Range	Date Tested	Result	Details
12/05/2004	Neutrophils	6.6	25/04/2004	4.5	
12/05/2004	Neutrophils	6.6	25/04/2004	1.4	
12/05/2004	Neutrophils	6.6	03/05/2004	0.9	

Additional Information:

Patient was also taking Losec and Clexane.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 197409
 Seq: 1
 Gender:
 F

 Reported:
 17/05/2004
 Weight:
 0.00

 Hospitalisation:
 Age: 88Y

Onset Date: DOB:

Outcome: Death Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphagia	Caused or prolonged inpatient hospitalisation	Swallowing difficult, tardive dyskinesia, widespread rash	Olanzapine was discontinued, treted with Cogentin, benzodiazepines and Narcotics.
Rash generalised	Caused or prolonged inpatient hospitalisation		
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

 ZYPREXA (Suspected)
 Reason:
 Unspecified psychosis

 Tablet
 5.0 Milligram
 Daily
 Oral

 Batch:
 Started: 25/01/2000
 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Zoloft, Prednisolone, Losec. Patient died 12/04/04.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 197410 Seq: 1 Gender: F

Reported: 17/05/2004 Weight: 0.00 Hospitalisation: Age: 73Y

Onset Date: 29/01/2004 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		Electrocardiogram QT prolonged and cardiac arrest.	Resuscitation and Olanzapine ceased.
Cardiac arrest	Life threatening		
Electrocardiogram QT prolonged	Life threatening		

Medicine Details:

ZYPREXA (Suspected)

Injection, powder for

10.0 Milligram

3 times

Intramuscular

Batch: Started: Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 197453 Seq: 1 Gender: M
Reported: 18/05/2004 Weight: 68.00
Hospitalisation: Age: 62

Onset Date: DOB: 29/12/1941

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Cardiac murmur		Heart murmur - systolic ejection murmur, syncope, hands blue, hypotension.	
Cyanosis			
Hypotension			
Syncope			

Medicine Details:

ilculcine Details.		
COVERSYL (Other drug)	Reason:	
Tablet	4.0 Milligram Daily Oral	
Batch:	Started: Stopped:	
OLANZAPINE (Suspected)	Reason: Unspecified psychosis	
	2.5 Milligram Daily	
Batch:	Started: 22/06/2000 S TERM Stopped: 12/10/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was taking Olanzapine 1.25mg daily for 6 weeks before the dosage was increased to 2.5mg daily. He was taking Coversyl 4mg daily for 6 weeks before he was decreased to 1mg daily.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 197456
 Seq: 1
 Gender:
 M

 Reported:
 19/05/2004
 Weight:
 0.00

 Hospitalisation:
 Age: 25

Onset Date: 13/04/2004 **DOB**: 28/11/1978

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Blood albumin increased, ALT increased.	
Sinus tachycardia			Epilim and Lovan were ceased and Olanzapine was decreased to 20mg/day.
Leukocytosis			
White blood cell count increased			

 cu	1611	Detai	13.

EPILIM (Suspected)		Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
LOVAN (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	225.0 Milligram	Daily Oral	
Batch:	Started: 06/04/2004	Stopped:	Contin

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
19/05/2004	Albumin	35-45	19/04/2004	51	
19/05/2004	Electrocardiograph		13/04/2004	Serial ECG's	
	GGT = SGGT =	7-64	19/04/2004	42	
	Haemoglobin	120-180	19/04/2004	170	
19/05/2004	Platelets	150-450	19/04/2004	251	
19/05/2004	SAP = ALP	30-120	19/04/2004	30	

Additional Information:

Medically significant.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation Onset Date	d: 21/05/2004 : Admitted to ho e: : Not yet recove			Ago DO	t: 0.00 e: 78Y
	rred Term	Severity	Repo	ort Description	Treatment
Tardive dyskine	esia	Caused or prolonged inpatient hospitalisation	Tardive dyskines	·	
Medicine De			Rea	son:	
,	<u>.</u>				
Batch:		Started:		Stopped:	
FRUSEMIDE (Ot Batch: ASPIRIN (Other		Started:		Stopped:	
Batch:		Started:		Stopped:	
CLEXANE (Other	r drug)		Rea	son:	
Batch:		Started:		Stopped:	
Laboratory	Investigations				
Date	Investigations Type F	Range Date Test	ed Result	De	tails
Additional l i Patient also takir		oxin, Frusemide, A	spirin and Clexan	e.	

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	197507	Seq: 1				Gender:	F	
Reported:	21/05/2004					Weight:	0.00	
Hospitalisation:	Admitted to hospi	tal				Age:	78Y	
Onset Date:						DOB:		
Outcome:	Not yet recovered	i			С	ausality:	Causality possible	
Reaction Detai	ils:							
Madiaina Dat	oilo							
Medicine Det				Reason:				
02/11/2/11 11/2 (04/	spootou,			110000111				
Batch:		Started:			Stopped:			
Batch: EFEXOR (Suspect	ed)	Started:		Reason:	Stopped:			
Batch: EFEXOR (Suspect Tablet	ed)		Milligram	Reason: Daily	Stopped:	Oral		
EFEXOR (Suspect	ed)				Stopped:	Oral	Continuing	
EFEXOR (Suspect	ed)	412.0		Daily		Oral	Continuing	
EFEXOR (Suspect	ed)	412.0		Daily		Oral	Continuing	
EFEXOR (Suspect	ed)	412.0		Daily		Oral	Continuing	
EFEXOR (Suspect	ed)	412.0		Daily		Oral	Continuing	
EFEXOR (Suspect	ed)	412.0		Daily		Oral	Continuing	
EFEXOR (Suspect	ed)	412.0		Daily		Oral	Continuing	
EFEXOR (Suspect Tablet Batch:		412.0		Daily		Oral	Continuing	
EFEXOR (Suspect Tablet Batch:	ed)	412.0		Daily		Oral	Continuing	
EFEXOR (Suspect Tablet Batch:		412.0		Daily		Oral	Continuing	
EFEXOR (Suspect Tablet Batch:		412.0		Daily		Oral	Continuing	
EFEXOR (Suspect Tablet Batch:		412.0		Daily		Oral	Continuing	
EFEXOR (Suspect Tablet Batch:		412.0		Daily		Oral	Continuing	
EFEXOR (Suspect Tablet Batch:		412.0		Daily		Oral	Continuing	
EFEXOR (Suspect Tablet Batch:		412.0		Daily		Oral	Continuing	
EFEXOR (Suspect Tablet Batch:	vestigations:	412.0		Daily		Oral	Continuing	
EFEXOR (Suspect Tablet Batch: Laboratory In	evestigations:	412.0 Started:	L	Daily TERM		Oral	Continuing	
EFEXOR (Suspect Tablet Batch: Laboratory In	vestigations:	412.0 Started:	L	Daily TERM		Oral	Continuing	
EFEXOR (Suspect Tablet Batch: Laboratory In	evestigations:	412.0 Started:	L	Daily TERM		Oral	Continuing	
EFEXOR (Suspect Tablet Batch: Laboratory In	evestigations:	412.0 Started:	L	Daily TERM		Oral	Continuing	

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 197670 Seq: 1 Gender: M

Reported: 27/05/2004 Weight: 100.00

Hospitalisation: Age: 44
Onset Date: DOB: 27/01/1960

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	outpatient	Priapism and increased tremor (extrapyramidal side effect) if olanzapine is increased from 20 to 25mg.	Reduction in olanzapine dose. Augmentation with aripiprazole
	outpatient	Priapism and increased tremor (extrapyramidal side effect) if olanzapine is increased from 20 to 25mg.	Reduction in olanzapine dose. Augmentation with aripiprazole

Medicine Details:

Medicine Details.				
DIAZEPAM (Other drug)		Reason:		
	2.5 Milligram	2 times	Oral	
Batch:	Started: 23/01/2002		Stopped:	
VENLAFAXINE HYDROCHLORIDE	(Other drug)	Reason: Dep	pression	
	450.0 Milligram	Daily	Oral	
Batch:	Started: 23/01/2002 L TE	ERM	Stopped:	
OLANZAPINE (Suspected)		Reason: Sch	izophrenia	
	20.0 Milligram	Daily	Oral	
Batch:	Started: 08/03/1999 L TE	ERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

symptoms alleviated when olanzapine reduced from from 25 mg to 20 mg

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 197714 Seq: 1 Gender: F

Reported: 31/05/2004 Weight: 0.00 Hospitalisation: Age: 43

Onset Date: 14/04/2004 **DOB**: 02/10/1960

Outcome: Recovered 13/05/2004 Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia.	Ceased Zyprexa

Medicine Details:

Medicine Details.			
SOLIAN (Other drug)		Reason: Unspecified psychosis	
Tablet	120.0 Milligram	Daily Oral	
Batch:	Started: 14/01/2004	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started: 14/11/2003	Stopped: 14/04/2004	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
31/05/2004	Neutrophils		16/03/2004	1.55	
31/05/2004	Neutrophils		13/04/2004	1.32	
31/05/2004	Neutrophils		13/05/2005	4.2	
31/05/2004	White blood cells		16/03/2004	3.0	
31/05/2004	White blood cells		13/04/2004	2.8	
31/05/2004	White blood cells		13/05/2004	6.0	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 197740
 Seq: 1
 Gender:
 F

 Reported:
 31/05/2004
 Weight:
 0.00

Hospitalisation: Age: 75

Onset Date: 15/12/2003 **DOB:** 23/10/1928

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u>tcaction Details.</u>			
Preferred Term	Severity	Report Description	Treatment
Optic neuropathy			Computerised tomography, numerous blood tests and electrophysiological test.
Visual acuity reduced			
Visual field defect			

Medicine Details:

ZYPREXA (Suspected)Reason: Unspecified neurosis

10.0 Milligram Daily

Batch: Started: 01/01/1999 L TERM Stopped:

Laboratory Investigations:

Laborato	ıy ilivestiya	uona.			
Date	Туре	Range	Date Tested	Result	Details
31/05/2004	Other data				The patient could only see two out of 15 Ishihara colour test plates in the left eye and none in the right. Goldmann visual fields demonstrated marked constriction. An electrophysiological test was conducted, which demonstrated markedly slower small check visual evoked response and also very low amplitudes in the visual evoked response, indicating delayed optic nerve conduction.

Additional Information:

History: Blindness in the right eye from reported Glaucoma, having had bilateral iridencleisis operations approximately 38 years ago. The patient has been blind since that time and had a very dense cataract, which prevented the reporter from commenting on the state of the right optic nerve. The patient developed a cataract in the left eye and had it removed via an intracapsular cataract extraction precedure approximately 35 years ago.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198141 Seq: 1 Gender: M

Reported: 15/06/2004 Weight: 0.00 Hospitalisation: Age: 21Y

Onset Date: 15/05/2004 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Creatine Kinase increased and blood lactate dehydrogenase increased.	Olanzapine discontinued.
Blood lactate dehydrogenase incre			Olanzapine discontinued.

Medicine Details:

ZYPREXA (Suspected)Reason:SchizophreniaTablet15.0 MilligramDailyOralBatch:Started: 01/05/2004Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
15/06/2004 15/06/2004	Creatine kinase				

Additional Information:

History: Schizophrenia and Hepatitis C positive.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198379 Seq: 1 Gender: M

Reported: 22/06/2004 Weight: 0.00 Hospitalisation: Age: 69Y

Onset Date: 15/03/2004 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism		Parkinsonism.	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 01/12/2003 Stopped: Contin

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Epilim, Cipramil, Verapamil, Somac, Amiloride, Astrex.

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Case Number: 198546

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 28/06/2004			Weigh	t: 0.00		
Hospitalisation:		Age : 99U				
Onset Date:			DO	B:		
Outcome: Death			Causalit	y: Causality possible		
Reaction Details:		r				
Preferred Term	Severity		escription	Treatment		
Drug level above therapeutic		Drug toxicity and dea				
Sudden death		Drug toxicity and dea	th.			
Medicine Details:						
ZYPREXA (Suspected)		Reason:	Schizophrenia			
			Oral			
Batch:	Started:		Stopped:			
Laboratory Investigation	ons:					
Date Type	Range Date Test	ed Result	De	etails		
Additional Information	:	, , ,				
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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198566 Seq: 1 Gender: F

Reported: 28/06/2004 Weight: 82.00 Hospitalisation: Age: 43

Onset Date: 26/09/2002 **DOB**: 08/11/1958

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus	Required Visit to Doctor	Onset of diabetes and hyperglycaemia.	Patient now on Metformin.
Hyperglycaemia	Required Visit to Doctor		

Medicine Details:

OLANZAPINE (Suspected) Reason: Schizophrenia

10.0 Milligram Daily

Batch: Started: 01/08/2001 Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ſ	28/06/2004	Other data				

Additional Information:

Hyperglycaemia diagnosed 12 months after starting Olanzapaine. (tests 6 months after were normal).

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198676 Seq: 1 Gender: F

Reported: 02/07/2004 Weight: 0.00 Hospitalisation: Age: 79

Onset Date: 15/12/2003 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism	Caused or prolonged inpatient hospitalisation	Parkinsonism.	

Medicine Details:

ZYPREXA (Suspected)	Reason:	
Tablet	5.0 Milligram Dai	ly Oral

Batch: Started: Stopped: Contin

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was commenced on 10mg daily, dose was reduced to 5mg and patient experienced symptoms.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 198693 Seq: 1 Gender: F

Reported: 05/07/2004 Weight: 75.00 Hospitalisation: Age: 35

Onset Date: 10/06/2004 **DOB**: 05/02/1969

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion botanoi			
Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus non-insulin-depe	Required Visit to Doctor	Developed diabetes type II.	Diet control.

Medicine Details:

Medicine Details.					
THYROXINE SODIUM (Other drug)			Reason:		
Tablet	100.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
ZYPREXA (Suspected)			Reason:		
	5.0	Milligram	Daily		
Batch:	Started:	L	TERM	Stopped:	14/06/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198736 Seq: 1 Gender: F

Reported: 05/07/2004 Weight: 0.00 Hospitalisation: Age: 30

Onset Date: DOB: 15/08/1973

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Required Visit to Doctor		Patient had a catheter inserted.
	Required Visit to Doctor		Patient had a catheter inserted.

Medicine Details:

TEMAZE (Suspected)		Reason:				
	10.0 Milligram	As necessary	Oral			
Batch:	Started: 29/06/2004	Stopped	1 :			
ZYPREXA (Suspected)		Reason:				
	10.0 Milligram	Daily	Oral			
Batch:	Started: 30/06/2004	Started: 30/06/2004 Stopped				
EPILIM (Suspected)		Reason:				
	1000.0 Milligram	Daily	Oral			
Batch:	Started: 29/06/2004	Stopped	1 :			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198737 Seq: 1 Gender: F
Reported: 05/07/2004 Weight: 55.00
Hospitalisation: Age: 44

pitalisation: Age: 44
Onset Date: DOB: 17/09/1959

Outcome: Recovered without treatment Causality: Causality probable

Reaction Details:

teaction betails.		•	
Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Required Visit to Doctor	Swelling of ankles and feet with itching and discomfort. Area not hot to touch	
Discomfort	Required Visit to Doctor	Swelling of ankles and feet with itching and discomfort. Not hot to touch	
Joint swelling	Required Visit to Doctor	Swelling of ankles and feet with itching and discomfort. Not hot to touch	
Pruritus	Required Visit to Doctor	Swelling of ankles and feet with itching and discomfort. Not hot to touch	

Medicine Details:

PAXAM (Other drug)		Reason:				
	0.5 Milligram	Daily	Oral			
Batch:	Started: 15/06/2004	Stopp	ed:			
EPILIM (Other drug)		Reason:				
	1500.0 Milligram	Daily	Oral			
Batch:	Started: 21/05/2004	Stopp	ed:			
ZYPREXA (Suspected)		Reason:				
	20.0 Milligram	1 time	Oral			
Batch:	Started: 24/05/2004	Stopp	ed:	one dose only		

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198774 Seq: 1 Gender: F

Reported: 07/07/2004 Weight: 52.50 Hospitalisation: Age: 57

Onset Date: 15/04/2004 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touction bottom			
Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Patient experienced deranged liver function tests.	

Medicine Details:

<u>Medicine Details.</u>				
OLANZAPINE (Suspected)		Reason:	Schizophrenia	
	15.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/2000		Stopped:	
LIPITOR (Suspected)		Reason:	Othr&unspec metabolic diseases	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/2004		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
07/07/2004	AST = SGOT		01/01/1999	46	
07/07/2004	AST = SGOT		15/04/2004	73	
07/07/2004	AST = SGOT		01/07/2004	91	
07/07/2004	GGT = SGGT =		01/01/1999	546	
07/07/2004	GGT = SGGT =		15/04/2004	1049	
07/07/2004	GGT = SGGT =		01/07/2004	1185	
07/07/2004	Other data				

Additional Information:

Other drugs taken: Paracetamol, Thyroxine, Frusemide, Atrovent and Ramipril.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198774 Seq: 1 Gender: F

Reported: 07/07/2004 Weight: 52.50 Hospitalisation: Age: 57

Onset Date: 15/04/2004 DOB:
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.				
OLANZAPINE (Suspected)		Reason:	Schizophrenia	
	15.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/2000		Stopped:	
LIPITOR (Suspected)		Reason:	Othr&unspec metabolic diseases	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/2004		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
07/07/2004	SAP = ALP		01/01/1999	344	
07/07/2004	SAP = ALP		15/04/2004	1146	
07/07/2004	SAP = ALP		01/07/2004	1187	

Additional Information:

Other drugs taken: Paracetamol, Thyroxine, Frusemide, Atrovent and Ramipril.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198860 Seq: 1 Gender: F

Reported: 12/07/2004 **Weight:** 50.00

 Hospitalisation:
 Age: 85

 Onset Date: 30/06/2004
 DOB: 07/10/1918

Outcome: Recovered 05/07/2004 Causality: Causality possible

Reaction Details:

reaction Details.								
Preferred Term	Severity	Report Description	Treatment					
	prolonged	and the second lasting over 12+ hours, ??TIA.	Panamax and Polytears.					

Medicine Details:

ZYPREXA (Suspected) Reason:

Wafer 5.0 Milligram Daily Oral

Batch: Started: 03/06/2004 Stopped: 03/07/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Astrix, Fosamax, Kalma, Karvezide and Noten.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 198879
 Seq: 1
 Gender:
 M

 Reported:
 12/07/2004
 Weight:
 0.00

 Hospitalisation:
 Age: 53

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Details.	caction betails.								
Preferred Term	Severity	Report Description	Treatment						
Drug interaction		Drug interaction, serotonin syndrome, depression and suicidal ideation.							
Amnesia									
Confusional state									
Depression									
Disorientation									
Disturbance in attention									
Hyperhidrosis									
Myoclonus									
Serotonin syndrome									
Suicidal ideation									

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Ir	Reason:	Depression				
Capsule	80.0	Milligram	Daily	(Oral	
Batch:	Started:			Stopped:	Continuing	
OLANZAPINE (Interaction)			Reason:	Depression		
Tablet	5.0	Milligram	Daily	(Oral	
Batch:	Started:			Stopped:	Continuing	
DIAZEPAM (Other drug)			Reason:	Otr spec symp p	osychopathol nec	
	15.0	Milligram	Daily			
Batch:	Started:			Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History included recurrent major depressive disorder, generalised anxiety disorder and alcohol dependence in remission. Chopra P, Ng C, Schweitzer I. Serotonin syndrome associated with fluoxetine and Olanzapine. World Journal of Biological Psychiatry. 2004; 5: 114-115.

Fluexetine was stopped, but he was maintained on Olanzapine and Diazepam due to his agitation. Over a week the disorientation, poor concentration, short-term memory and neurological symptoms resolved. After another week he was recommenced on Fluoxetine 20mg in addition to his other medications. There was no observed recurrence of serotonergic or depressive symptoms

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198879 Seq: 1 Gender: M

Reported: 12/07/2004 Weight: 0.00
Hospitalisation: Age: 53
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

FLUOXETINE HYDROCHLORIDE (In	nteraction)	Reason:	Depression	
Capsule	80.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	Continuing
OLANZAPINE (Interaction)		Reason:	Depression	
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	Continuing
DIAZEPAM (Other drug)		Reason:	Otr spec symp psyc	hopathol nec
	15.0 Milligram	Daily		
Batch:	Started:		Stopped:	

Laboratory Investigations:

Additional Information:

History included recurrent major depressive disorder, generalised anxiety disorder and alcohol dependence in remission. Chopra P, Ng C, Schweitzer I. Serotonin syndrome associated with fluoxetine and Olanzapine. World Journal of Biological Psychiatry. 2004; 5: 114-115.

Fluexetine was stopped, but he was maintained on Olanzapine and Diazepam due to his agitation. Over a week the disorientation, poor concentration, short-term memory and neurological symptoms resolved. After another week he was recommenced on Fluoxetine 20mg in addition to his other medications. There was no observed recurrence of serotonergic or depressive symptoms

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 198959
 Seq: 1
 Gender:
 F

 Reported:
 15/07/2004
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 20

Onset Date: 20/06/2004 **DOB**: 27/12/1983

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	Tachycardia, pharyngitis, sweating increased, hypotension.	Clopine ceased.
Hyperhidrosis			
Hypotension	Caused or prolonged inpatient hospitalisation		
Pharyngitis			

Medicine Details:

Modifile Botalie			
CLOPINE (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily Oral	
Batch:	Started: 02/06/2004	Stopped: 22/07/2004	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started: 07/05/2004	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
15/07/2004	Echocardiogram				Echocardiogram on 26 May and 16 July 2004 showed sinus rhythm, normal cardiac chamber and valves
15/07/2004	Electrocardiograph				ECG noted a sinus tachycardia of 130
15/07/2004	Other data				

Additional Information:

Other drug therapy: valproate, clonazepam.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199033 Seq: 1 Gender: M

Reported: 16/07/2004 Weight: 0.00 Hospitalisation: Age: 94

Onset Date: 19/08/2001 DOB:

Outcome: Recovered 19/08/2004 Causality: Causality possible

Reaction Details:

touction potanoi			
Preferred Term	Severity	Report Description	Treatment
Respiratory arrest	Life threatening	Patient developed respiratory arrest and altered conscious state (pupils non - reactive).	Nitrazepam, Haopreidol, Tramadol and Panadeine Forte ceased. Naloxone 4mg IV given.
Altered state of consciousness	Life threatening		

Medicine Details:

PANADEINE FORTE (Suspected) Reason: Pain 1.0 Dose Unspecified As necessary **Tablet** Oral Batch: Started: 18/08/2001 Stopped: 18/08/2001 **MORPHINE SULPHATE (Suspected)** Reason: Pain Injection 2.5 Milligram As necessary Intravenous Batch: Started: 17/08/2001 18/08/2001 Stopped: **HALOPERIDOL** (Suspected) Reason: Otr spec symp psychopathol nec 2.0 Milligram Daily Oral Started: 17/08/2001 18/08/2001 Batch: Stopped: NITRAZEPAM (Suspected) Reason: Otr spec symp psychopathol nec Tablet 5.0 Milligram Daily Oral Batch: Started: 17/08/2001 Stopped: 18/08/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Other drugs taken: Captopril, Thyroxine, Allopurinol and Trimethoprim.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 199033 Seq: 1 Gender: M

Reported: 16/07/2004 Weight: 0.00 Hospitalisation: Age: 94

Onset Date: 19/08/2001 DOB:

Outcome: Recovered 19/08/2004 Causality: Causality possible

Reaction Details:

Medicine Details:

Modifile Botalies				
TRAMADOL HYDROCHLORIDE (Sus	spected)	Reason: Pain		
	200.0 Milligram	Daily	Oral	
Batch:	Started: 18/08/2001	Sto	opped: 19/08/2001	
OLANZAPINE (Suspected)		Reason: Otr spe	ec symp psychopathol nec	
Tablet	50.0 Milligram	Daily	Oral	
Batch:	Started: 18/08/2001	Sto	opped: 20/08/2001	

Laboratory Investigations:

Additional Information:

Other drugs taken: Captopril, Thyroxine, Allopurinol and Trimethoprim.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199292 Seq: 1 Gender: M

Reported: 22/07/2004 Weight: 85.00 Hospitalisation: Age: 24

Onset Date: DOB: 06/12/1979

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Patient developed orofacial dyskinesia including mouth and tongue movements.	Reduction to 20mg Zyprexa.

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 80.0 Milligram Daily Oral

Batch: Started: 01/05/2003 **Stopped:** 01/06/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is dose related.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199418 Seq: 1 Gender: F

Reported: 26/07/2004 Weight: 0.00 Hospitalisation: Age: 85

Onset Date: 30/06/2004 DOB:

Outcome: Recovered 05/07/2004 Causality: Causality possible

Reaction Details:

caction Details.			
Preferred Term	Severity	Report Description	Treatment
		Semi-coma lasting 8 hours and a transient ischaemic attack.	Olanzapine discontinued
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected) Reason:

5.0 Milligram Daily Oral

Batch: Started: 03/06/2004 Stopped: 03/07/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History included: Vascular dymentia. Olanzapine was withheld and then recommenced and the patient had another episode of semi coma this time lasting 12 hours and the patient was hospitalised. Other drug therapy: astrix, fosamax, noten, panamax.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199430 Seq: 1 Gender: F

Reported: 27/07/2004 Weight: 58.00 Hospitalisation: Age: 71

Onset Date: 15/07/2004 **DOB**: 06/11/1932

Outcome: Recovered 15/07/2004 Causality: Causality probable

Reaction Details:

Caction Details.			
Preferred Term	Severity	Report Description	Treatment
Hallucination		Hallucinations, agitation and aggression.	Zyprexa ceased.
Aggression			
Agitation			

Medicine Details:

ZYPREXA (Suspected)

Reason:

2.5 Milligram Daily

Batch: Started: S TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Aurorix, Caltrate, Neo-cytamen, Panamax, Reminyl, Renitec and Thyroxine.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 199503	Seq: 1		Gende	er: F
Reported: 30/07/200	4		Weigh	it: 0.00
spitalisation:			Ag	e : 24
Onset Date:			DO	
Outcome: Recovered	d		Causalit	y: Causality possible
action Details:	<u> </u>	1		
Preferred Term	Severity		ort Description	Treatment
omicidal ideation		Wanted to kill pe and destroyed s	eople, went into a frenzy hed and wall.	
Indiaina Dataila.				
ledicine Details: EFEXOR (Suspected)		Rea	son:	
Batch:	Started:		Stopped:	0
ZYPREXA (Suspected)	- Ctartour	Rea	son:	
,				
Batch:	Started:		Stopped:	0
<u>aboratory Investigat</u>	ions: Range Date Test	ed Result	De	etails
1,700	rango Bato root	- Roodit		, cano
	-	-		
Additional Information	n:			

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	er: 199506	Seq: 1		Gende	er: F
	ed: 30/07/200)4		Weigh	t : 0.00
ospitalisati	on:				e: 45
Onset Da	ate:			DO	
Outcor	ne: Unknown			Causalit	y: Causality certain
eaction De	etails:				
Pre	ferred Term	Severity	Repo	ort Description	Treatment
Mania			Became manic a	and suicidal.	
Suicidal idea	tion				
Medicine I					
ZYPREXA (Su	ispected)		Rea	son: Oral	
Batcl	·	Started:		Stopped:	0
ahorator	v Investigat	ions:			
_aborator	y Investigat ^{Type}	ions: Range Date Te	ested Result	De	ıtails
			ested Result	De	ıtails

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

		Seq:			•	ender:		
Reported:	30/07/2004				v	/eight:		
spitalisation:						Age:		
Onset Date:						DOB:	20/08/1973	
Outcome:	Unknown				Cau	ısality:	Causality possible	
action Detai								
	ed Term	Se	verity	Report	Description		Treatment	
tentional self-ir	njury		Inte	entional self har	m, cut himself			
ledicine Det ZYPREXA (Suspec				Reaso	n:			
Batch:		St	arted:		Stopped:		0	
EFEXOR (Suspect	ted)			Reaso	n:			
Batch:		St	Started: Stopped:			0		
.aboratory In	nvestigatio		Date Tested	Result		Detai	İs	

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reportalisat Onset E Outco	Oate: me: Death, ma				DOB	: 0.00 : 99U
eaction D	Details: eferred Term	Severity	T Re	port Descriptior	<u> </u>	Treatment
Drug toxicity		Ocventy	Drug toxicity	port Description		rreatment
Medicine ZYPREXA (S			R	eason:		
Tabl		40.0	Milligram	Daily	Oral	
Bate	ch:	Started:		Stop	ped:	contin
Laborato Date	ry Investigati Type	ONS: Range Date Te	sted Result		Deta	sile
Date	Туре	Range Date Les	sted Result	+	Deta	alis
Additiona	al Informatior):	- 1			
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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199585 Seq: 1 Gender: F

 Reported:
 02/08/2004
 Weight:
 0.00

 Hospitalisation:
 Age:
 78

 Onset Date:
 16/09/2003
 DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Haemorrhagic stroke			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: 11/04/2003 **Stopped:** 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Medical history included: hypertension and smoking.

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DOB: 19/03/1968

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 199827
 Seq: 1
 Gender:
 M

 Reported:
 10/08/2004
 Weight:
 78.00

Hospitalisation: Age: 35

Outcome: Recovered 18/01/2004 Causality: Causality possible

Reaction Details:

Onset Date: 15/01/2004

caction betails.					
Preferred Term	Severity	Report Description	Treatment		
Serotonin syndrome		Serotonin syndrome, Agitation, loss of concentration and restlessness.			
Agitation					
Disturbance in attention					
Restlessness					

Medicine Details:

TRAMAL (Interaction)		Reason:	Other disturbance of sensa	tion
	500.0 Milligram	Daily	1	
Batch:	Started:		Stopped:	0
ZYPREXA (Interaction)		Reason:		
Tablet	5.0 Milligram	Daily	<i>o</i> Oral	
Batch:	Started:		Stopped:	
AVANZA (Other drug)		Reason:		
Tablet	60.0 Milligram	Daily	<i>o</i> Oral	
Batch:	Started:		Stopped:	
STEMETIL (Other drug)		Reason:		
	10.0 Milligram	Daily	1	
Batch:	Started:		Stopped:	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reduction of Tramadol dose to 400mg/day symptoms settled.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:					
Case Number: 199827	Seq: 1			Gender:	M
Reported: 10/08/2004	-			Weight:	78.00
Hospitalisation:				Age:	35
Onset Date: 15/01/2004				DOB:	19/03/1968
Outcome: Recovered		18/01/2004		Causality:	Causality possible
Reaction Details:					
Medicine Details:					
VALIUM (Other drug)		Rea	son:		
Tablet	5.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
ZOTON (Other drug)		Rea	son:		
Capsule	2.0	Dose Unspecified	Daily	Oral	
Batch:	Started:			Stopped:	
Laboratory Investigations:					
Additional Information:					
Reduction of Tramadol dose to 400mg	/day symptoms	settled.			

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Onset Date: Outcome: Not action Details:	nitted to hospita	al		DOB	99u : : Causality possible	
Preferred Te	erm	Severity	Re	port Description	Treatment	
yponatraemia	p ir	caused or rolonged apatient ospitalisation	·	enced hyponatraemia.		
edicine Details:			Re	eason:		
Tablet	<i>.</i> ,	5.0	Milligram	Oral		
Batch:		Started:	_	Stopped:		
MULTIVITAMINS (Other	drug)		Re	ason:		
				Oral		
Batch:		Started:		Stopped:		
EMAZEPAM (Other dru	ıg)		Re	eason:		
				Oral		
Batch:		Started:		Stopped:		
Daton.	j)		Re	eason:		
				Oral		
			Stopped:			
OXAZEPAM (Other drug		Started:		Stopped:		
DXAZEPAM (Other drug Tablet Batch:	tigations:	Started:		Stopped:		
Tablet Batch:			ed Result	Stopped:	ills	
Tablet Batch: aboratory Inves			ed Result			

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	199855	Seq: 1			Gender:	F
Reported:	10/08/2004				Weight:	0.00
	Admitted to hospi	tal			Age:	99u
Onset Date:					DOB:	
	Not yet recovered				Causality:	Causality possible
Reaction Detai	ls:					
Medicine Deta						
SLOW-K (Other dr				Reason:		
Tablet		•			Oral	
Batch:	.4a.d\	Started:		Decem	Stopped:	
ZYPREXA (Suspec	itea)	10.0	Milligram	Reason: Daily	Oral	
Batch: A	.059086	Started:	wiiiigiaiii	Dally	Stopped:	Continuing
Laboratory In	vestigations:					
Additional Inf	ormation:					

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199893 Seq: 1 Gender: F

Reported: 11/08/2004 Weight: 0.00 Hospitalisation: Age: 36

Onset Date: 06/08/2004 **DOB**: 16/05/1968

Outcome: Recovered 09/08/2004 Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Formication		Formication after starting Zyprexa.	

Medicine Details:

Medicine Details.			
ZOLOFT (Other drug)		Reason:	
Tablet	200.0 Milligram	Daily	
Batch:	Started:	Stopped: 26/07/2004	
ZYPREXA (Suspected)	ı	Reason:	
Wafer	5.0 Milligram	Daily Oral	
Batch:	Started: 05/08/2004	Stopped:	0

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient history: Recalls when took 1 dose of Zyprexa once before, they had formication.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199921 Seq: 1 Gender: F

Reported: 12/08/2004 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 35

Onset Date: 28/07/2004 **DOB**: 24/09/1968

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Ebstein's anomaly	La a a	Ebstein's anomaly - birth defect second pregnancy.	

Medicine Details:

Medicine Details.				
LITHICARB (Suspected)	Reason:			
	2.0 Gram	Daily		
Batch:	Started: 15/05/1997	Stopped:		
ZYPREXA (Suspected)		Reason:		
	5.0 Milligram	Daily		
Batch:	Started: 15/04/2003	Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

First pregnancy was taking Lithium - normal infant.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199929 Seq: 1 Gender: M

Reported: 12/08/2004 **Weight:** 55.00

Hospitalisation: Age: 99u
Onset Date: 02/08/2004
DOB:

Outcome: Recovered 05/08/2004 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness	Required Visit to Doctor	Patient experienced generalised muscle stiffness affecting gait and movement. Spastic appearance rigid with head pulled back.	Cogentin.
Dystonia	Required Visit to Doctor		
Gait disturbance	Required Visit to Doctor		
Muscle rigidity	Required Visit to Doctor		

Medicine Details:

CITALOPRAM HYDROBROMIDE (S	uspected)	Reason:	Depression	
Tablet				Oral
Batch:	Started:		Stopped:	29/07/2004
OLANZAPINE (Suspected)		Reason:	Unspecified n	eurosis
	10.0 Milligram	Daily		
Batch:	Started: 22/07/2004		Stopped:	29/07/2004
VENLAFAXINE HYDROCHLORIDE ((Suspected)	Reason:	Depression	
	38.0 Milligram	Daily		
Batch:	Started: 30/07/2004		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

R	er	n	rt	D	eta	il	S	•

Case Number: 200414 Seq: 1 Gender: F

Reported: 30/08/2004 Weight: 114.00 Hospitalisation: Age: 62

Onset Date: 03/07/2004 **DOB**: 03/04/1942

Outcome: Death, maybe drug 03/07/2004 Causality: Causality possible

Reaction Details:

100.00.00.00.00.00.00.00.00.00.00.00.00.			
Preferred Term	Severity	Report Description	Treatment
Arrhythmia		Probable fatal cardiac arrythmia.	

Medicine Details:

ilculcine Details.			
TEMAZEPAM (Other drug)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecifid affective psychosis	
Batch:	Started:	Stopped : 30/06/2004	
SOLIAN (Suspected)		Reason: Unspecifid affective psychosis	
	400.0 Milligram	Daily	
Batch:	Started: 03/02/2004	Stopped: 03/07/2004	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:200534Seq: 1Gender:MReported:03/09/2004Weight:0.00Hospitalisation:Admitted to hospitalAge: 34

Onset Date: 27/08/2004 **DOB**: 10/04/1970

Outcome: Recovered 30/08/2004 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		BSL was 39.7, 1 day history of thirst and blurry vision.	Stopped Olanzapine, changed to Risperidone.
Thirst	Caused or prolonged inpatient hospitalisation		
Vision blurred	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.			
FLUPENTHIXOL DECANOATE (Other drug)		Reason:	
Injection	1.0 Dose l	Unspecified Fortnightly	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Schizophreni	a
	8.0 Milligra	am Daily	
Batch:	Started: 15/04/2004	4 Stopped:	15/08/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 200772 Seq: 1 Gender: M

Reported: 13/09/2004 Weight: 75.00 Hospitalisation: Age: 15

Onset Date: 16/07/2004 **DOB**: 31/07/1988

Outcome: Recovered 18/07/2004 Causality: Causality possible

Reaction Details:

Neaction Details.	detion betails.								
Preferred Term	Severity	Report Description	Treatment						
Rash maculo-papular	Required Visit to Doctor	Red, maculo-papular rash on face, neck and chest.	Phenergan 30mg daily given.						
Rash erythematous	Required Visit to Doctor								

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 14/07/2004 Stopped: 16/07/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 200850 Seq: 1 Gender: F

Reported: 14/09/2004 **Weight:** 70.00

Hospitalisation: Age: 41

Onset Date: 04/08/2004 **DOB**: 29/03/1963

Outcome: Recovered 01/09/2004 Causality: Causality probable

Reaction Details:

toaction Botano.			
Preferred Term	Severity	Report Description	Treatment
Oedema	Required Visit to Doctor	Oedema of face, hands, legs and difficulty sleeping.	Ceased Olanzapine.
Insomnia	Required Visit to Doctor		

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason:		
	300.0 Milligram	Daily		
Batch:	Started: 12/09/2002		Stopped:	
OLANZAPINE (Suspected)		Reason: O	tr spec symp psychopathol nec	
	5.0 Milligram	Daily	Oral	

Batch: **Started**: 28/07/2004 **Stopped**: 25/08/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient Hep B positive; 16 weeks pregnant. Abuse Anphetamines in previous month.

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Case Number: 200941

Reported: 20/09/2004

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

			Α	ge: 57		
		DOB:				
recovered		Causality: Causality possible				
Se	everity	Report D	escription	Treatment		
Speci	ialist fu	nction, weight gain	ced changes in liver and she developed			
Speci	ialist					
Speci	ialist					
		Reason:	Oral			
s	tarted:		Stopped:			
	Reason: Unspecified schizophrenia					
	10.0 Mi	lligram Dail	y Oral			
s	tarted:		Stopped:			
ations:		I Down		N.AY.		
	Date Tested	Result		Details		
	Requ Spec Cons nal Requ Spec Cons Requ Spec Cons	Severity Required TI Specialist Consultation di Required Specialist Consultation Required Specialist Consultation Required Specialist Consultation Started:	Required Specialist Consultation Required Specialist Consultation Required Specialist Consultation Required Specialist Consultation Required Specialist Consultation Reason: Started: Reason:	Severity Report Description Required Specialist Consultation Reason: Oral		

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 201079
 Seq: 1
 Gender:
 F

 Reported:
 23/09/2004
 Weight:
 0.00

Hospitalisation: Age: 50

Onset Date: 24/04/2004 DOB: 22/06/1953
Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

•	<u> </u>			1
	Preferred Term	Severity	Report Description	Treatment
	Hepatic steatosis		Fatty liver and drug toxicity	
	Drug toxicity			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	Unspecified schizop	hrenia
Injection			Intra	muscular
Batch:	Started: 24/02/2004	S TERM	Stopped: 16/0	4/2004 0
MIRTAZAPINE (Suspected)		Reason:		
Tablet			Oral	
Batch:	Started:		Stopped:	0
Zolpidem Sandoz (Suspected)		Reason:		
Tablet			Oral	
Batch:	Started:		Stopped:	0
ZYPREXA (Suspected)		Reason:	Unspecified schizop	hrenia
Tablet	10.0 Milligran	n Daily	Oral	
Batch:	Started: 18/03/2004		Stopped: 02/0	4/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
23/09/2004	Autopsy report				Severe fatty change in liver and chronic liver disease. Severe diffuse microvesicular fatty changes throughout the liver. Lungs, heart, kidney and brain.

Additional Information:

Chronic liver disease.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 201344
 Seq: 1
 Gender:
 F

 Reported:
 29/09/2004
 Weight:
 0.00

Hospitalisation: Admitted to hospital
Onset Date: 15/08/2004
Age: 90
DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
,	Caused or prolonged inpatient hospitalisation	Dystonia.	

Medicine Details:

ZYPREXA (Suspected) Reason: Anxiety neurosis

10.0 Milligram Daily

Batch: Started: 12/08/2004 Stopped: contin

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The cause of death was due to drug induced dystonia. The patient's medical history included: delusional state with aggressive behaviour and hypertension.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 201534 Seq: 1 Gender: F

Reported: 07/10/2004 Weight: 0.00 Hospitalisation: Age: 42

Onset Date: 18/09/2004 **DOB**: 07/11/1961

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
			Patient developed an itchy maculo-papular rash, mainly on lower limbs and trunk.	Olanzapine ceased, topical soothing agent.
		Required Visit to Doctor		

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason: Unspecifid affective psychosis
Tablet	900.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
CLONAZEPAM (Other drug)		Reason: Unspecifid affective psychosis
	3.0 Milligram	Daily
Batch:	Started: 10/09/2004	Stopped:
NITRAZEPAM (Other drug)		Reason: Unspecifid affective psychosis
Tablet	5.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
OLANZAPINE (Suspected)		Reason: Unspecifid affective psychosis
	10.0 Milligram	Daily
Batch:	Started: 10/09/2004	Stopped: 18/09/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 201542 Gender: F Seq: 1 Weight: 0.00 Reported: 08/10/2004

Hospitalisation: **Age:** 57

Onset Date: 21/09/2004 **DOB**: 16/10/1946

Outcome: Death, maybe drug 21/09/2004 Causality: Causality possible

Reaction Details:

todotion botano.							
Preferred Term	Severity	Report Description	Treatment				
Drug ineffective		The drug was ineffective - the patient committed suicide by jumping.					
Completed suicide							

Medicine Details:

ALPRAZOLAM (Other drug)

	2.0	Gram
Batch:	Started:	Stopped:
STILNOX (Other drug)		Reason:
	10.0	Milligram
Batch:	Started:	Stopped:

Reason:

Batch:

AVANZA (Other drug) Reason:

60.0 Milligram

Batch: Started: Stopped:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason:

1.0 Dose Unspecified 1 time

Batch: Started: 20/09/2004 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

She was taking ongoing Avanza, Zanax and Stilnox. Report 201541 is the first sequence to this report.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation: Onset Date:	08/10/2004 21/09/2004 Death, maybe dru	Seq: 1	21/09/2004			0.00	
Medicine Deta	ails:						
ZYPREXA (Suspec			Reaso	n:			
		15.0 Mi		Daily			
Batch:		Started: 20/09/	2004	Stoppe	ed:	0	
Laboratory In	vestigations:						
Additional Inf She was taking on Report 201541 is to	Formation: going Avanza, Zana he first sequence to	x and Stilnox. this report.					

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Case Number: 201612

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

spitalisa		5 1							
•	Reported: 11/10/2004 Iospitalisation:				Weight: 0.00 Age: 42				
Onset Date: 02/08/2004 Outcome: Not yet recovered						D	OB : 24/05/1962		
						Causa	lity: Causality possible		
action [Details: referred Term	1 2	'ovority	D.c	ort Doorint	<u> </u>	Trockmant		
		- S	Severity		ort Descripti		Treatment		
hrombocy	юрепіа		a	Patient had a ro and it was disco platelet levels.	vered he had	d evaluation decreased			
ledicine	Details:								
	INE MESYLATE (O	ther drug)		Rea	son: Unspe	cified psychosi	s		
Bat	ch:	:	Started:		Sto	opped:	0		
FLUPHENA	ZINE DECANOATE	(Other drug)		Rea	son: Unspe	cified psychosi	S		
Batch: Started:						opped:	0		
	MAATINE LIVEDOO	HLORIDE (Oth	er drug)	Rea	ison: Unspe	cified psychosi	S		
CHLORPRO	MAZINE HYDROC								
CHLORPRO Bat		;	Started:		Sto	opped:	0		
Bat			Started:	Rea	Ston:	opped:	0		
Bat	ch: pine NOS (Other d	rug)	Started: Started:	Rea	ison:	opped:	0		
Bat Benzodiaze Bat	ch: pine NOS (Other d ch:	rug)		Rea	ison:		0		
Bat Benzodiaze Bat	ch: pine NOS (Other d	rug)			ison:	opped:	0 Details		

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reaction Detail	11/10/2004 02/08/2004 Not yet recovered	Seq: 1			0.00
Medicine Deta			Decem	I loom a sifie al calaiman la mania	
ZYPREXA (Suspec	tea)	F.O. Milliarom	Reason:	Unspecified schizophrenia	
Batch:		5.0 Milligram Started: 30/07/2004	Daily	Oral Stopped:	
24,0				оторрош.	
Laboratory In	vestigations:				
Additional Inf	ormation:				

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 201692 Seq: 1 Gender: U

Reported: 13/10/2004 Weight: 80.00 Hospitalisation: Age: 32

Onset Date: 02/10/2004 **DOB**: 17/01/1972

Outcome: Recovered Causality: Causality possible

Reaction Details:

٠,	daction Botano.			
	Preferred Term	Severity	Report Description	Treatment
				Given Cogentin IM 2mg, then oral Cogentin 2mg bd.
	,	Required Visit to Doctor		
		Required Visit to Doctor		

Medicine Details:

 OLANZAPINE (Suspected)
 Reason:
 Unspecified psychosis

 20.0
 Milligram
 Daily
 Oral

Batch: **Started**: 15/09/2004 **Stopped**: 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Hospitalisation:

Case Number: 202017

Reported: 26/10/2004

Onset Date: 10/09/2004

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

DOB:

Age: 17

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Outcome: Unknown		Causality: Causality possible				
action Details:						
Preferred Term	Severity	Report Description	Treatment			
olydactyly		On 10 September 2004 the mother vaginally delivered a full term infant at approximately 40 weeks gestation. The infant was born with an extra digit. The is no corrective treatment planned and infant is otherwise healthy. The mother healthy and had no delivery complication	re the is			
edicine Details:						
YPREXA (Suspected)		Reason: Unspecified schiz				
Batch:	Started:	Stopped:	al			
ANNABIS PREPARATION (Su						
·						
Batch:	Started:	Stopped:				
MISULPRIDE (Suspected)		Reason:				
		Oral				
Batch:	Started:	Stopped:				
aboratory Investigati	ions: Range Date Tes	sted Result	Details			
dditional Informatior	1:					
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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Detail	ls:
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Case Number: 202020 Seq: 1 Gender: M

Reported: 26/10/2004 Weight: 132.00

 Hospitalisation:
 Age: 14

 Onset Date: 21/02/2004
 DOB: 25/04/1989

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Increased appetite	to Doctor	The patient developed an increase in appetite and rapid weight gain of 20-25 kg over a 6 week period leading to severe disfiguring stretch marks over chest, upper back, abdomen and upper arms with skin breakdown in axillary region. The weight gain ceased with cessation of Olanzapine.	Vitamin E cream
Weight increased	Required Visit to Doctor		

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other	drug)	Reason:		
Tablet	20.0 Milligram			Oral
Batch:	Started: 01/11/2002	Stopped:		
SODIUM VALPROATE (Other drug)		Reason:		
Tablet	700.0 Milligram			Oral
Batch:	Started: 25/05/2003	Stopped:		
OLANZAPINE (Suspected)		Reason:		
Tablet	5.0 Milligram	Daily		Oral
Batch:	Started: 21/02/2004	Stopped:		19/05/2004

Laboratory Investigations:

Laboratory investigations.						
Date	Туре	Range	Date Tested	Result	Details	

Additional Information:

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Case Number: 202217

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 01/11/2004		We	eight: 0.00
lospitalisation:			Age: 35
Onset Date:			DOB:
Outcome: Unknown		Caus	sality: Causality possible
Reaction Details:			
Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic horm	one	Patient experienced syndrome of inappropriate antidiuretic hormone secretion and bone marrow suppression	n.
Bone marrow failure			
Medicine Details:			
ZYPREXA (Suspected)		Reason:	-1
Batch:	Started:	Ora Stopped:	ai
Laboratory Investigation		and Decorate I	D. G.
Date Type	Range Date Test	ed Result	Details
Additional Information:			
eport Run: 04/06/2007 05:14PM [Database: pusime02	ADRS004	Page 202 of 530



Case Number: 202221

Reported: 01/11/2004

Onset Date: 15/10/2004

Hospitalisation: Admitted to hospital

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

DOB:

Weight: 0.00

Age: 65

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Outcome: Not yet recovaction Details:	vered		Causali	ity: Causality possible
Preferred Term	Severity	Report I	Description	Treatment
oordination abnormal		Patient experienced		
edicine Details: BENZTROPINE MESYLATE (Other	r drug)	Reason		
SENZIROPINE MESTLATE (Other	arugj	Reason	•	
Batch:	Started:		Stopped:	
YPREXA (Suspected)		Reason		enia
Batch:	Started:		Oral Stopped:	
aboratory Investigation Date Type	ns: Range Date Testo	ed Result		Petails
Date Type	Range Date rest	eu Resuit	D	retalis
dditional Information:				
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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202256 Seq: 1 Gender: M

Reported: 03/11/2004 Weight: 0.00 Hospitalisation: Age: 61

Onset Date: 07/09/2004 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness		Patient complained of dizziness (postural?) in rehabilitation gym with physiotherapy.	Ciprofloxacin and Olanzapine ceased. Patient monitored.
Orthostatic hypotension			

Medicine Details:

CIPROFLOXACIN (Interaction)		Reason:	Otr&nos infect	¶sit disease	es
	1.0 Gram	Daily		Oral	
Batch:	Started: 12/08/2004		Stopped:	07/09/2004	0
OLANZAPINE (Interaction)		Reason:	Behavior disor	ders of childhoo	t
Tablet	10.0 Milligram	Daily		Oral	
Batch:	Started: 06/07/2004		Stopped:	07/09/2004	0
CEPHALEXIN (Other drug)		Reason:			
	2.0 Gram			Oral	
Batch:	Started: 06/07/2004		Stopped:	07/09/2004	
SPIRONOLACTONE (Other drug)		Reason:			
Tablet	50.0 Milligram			Oral	
Batch:	Started: 06/07/2004		Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History: CVA whilst undergoing CABG. Significant anxiety attacks whilst on 6B - olanzapine started by psych team. Previously heavy smoker.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202256 Seq: 1 Gender: M

Reported: 03/11/2004 Weight: 0.00 Hospitalisation: Age: 61

Onset Date: 07/09/2004 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

FRUSEMIDE (Other drug)		Reason:		
	20.0 Milligram			Oral
Batch:	Started: 06/07/2004		Stopped:	
CITALOPRAM HYDROBROMIDE (Other	er drug)	Reason:		
Tablet	20.0 Milligram			Oral
Batch:	Started: 06/07/2004		Stopped:	
OXYCODONE HYDROCHLORIDE (Oth	er drug)	Reason:		
	15.0 Milligram			Oral
Batch:	Started: 07/08/2004		Stopped:	
PARACETAMOL (Other drug)		Reason:		
	4.0 Gram			Oral
Batch:	Started: 06/07/2004		Stopped:	

Laboratory Investigations:

Additional Information:

History: CVA whilst undergoing CABG. Significant anxiety attacks whilst on 6B - olanzapine started by psych team. Previously heavy smoker.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202256 Seq: 1 Gender: M

Reported: 03/11/2004 Weight: 0.00 Hospitalisation: Age: 61

Onset Date: 07/09/2004 **DOB**:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

SALBUTAMOL (Other drug)		Reason:
Inhalation	5.0 Milligram	Inhalation
Batch:	Started:	Stopped:
IPRATROPIUM BROMIDE (Other drug)		Reason:
Inhalation	250.0 Milligram	Inhalation
Batch:	Started: 06/07/2004	Stopped:
HEPARIN SALINE (Other drug)		Reason:
	300.0 Milligram	Oral
Batch:	Started: 06/07/2004	Stopped:
DIAZEPAM (Other drug)		Reason: Anxiety neurosis
	2.0 Milligram	As necessary
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

History: CVA whilst undergoing CABG. Significant anxiety attacks whilst on 6B - olanzapine started by psych team. Previously heavy smoker.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Detail	s:				
Case Number:	202256	Seq: 1		Gender:	М
	03/11/2004			Weight:	
Hospitalisation:	00/11/2004			Age:	
Onset Date:	07/00/2004			DOB:	
Outcome:				Causality:	Causality possible
eaction Deta	ils:				
Medicine Det	aile				
RAMIPRIL (Other			Reason:		
10 11111 1112 (0 11101	u. u.g,	2.0 Milligram	Daily	Oral	
D-4-b-			Daily		0
Batch:		Started: 06/07/2004		Stopped:	0
Laboratory Ir	vestigations:				
•	· ·				
Additional In					
History: CVA while		Cignificant anxiety attack	o whilet on CD		unayah taam Praviayah
haavu amakar	it undergoing CADO.	Significant anxiety attack	s whiist on ob -	· olanzapine started b	y psychiteani. Previously
heavy smoker.	andergoing OADO.	Significant anxiety attack	S Whiist on 6B -	· olanzapine started by	y psychiteani. Previously
neavy smoker.	t undergoing OADO.	Significant anxiety attack	S WHIISLOH 66 -	olanzapine started by	y psychiteani. Freviously

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 202384
 Seq: 1
 Gender:
 F

 Reported:
 09/11/2004
 Weight:
 0.00

 Hospitalisation:
 Age:
 99U

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gamma-glutamyltransferase increa		Patient experienced gamma-glutamyltransferase increased, blood alkaline phosphates increased, alanine aminotransferase increased, severe nausea and vomiting lasting three weeks, drug toxicity, weight increased and drug concentration increased.	
Alanine aminotransferase increase	Severe		
Blood alkaline phosphatase increas	Severe		
Drug toxicity	Severe		
Nausea	Severe		
Vomiting	Severe		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	30.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Laborato	i y iii vootiga				
Date	Туре	Range	Date Tested	Result	Details
09/11/2004	Serum drug level				Olanzapine 144 - above normal range. Olanzapine 123 - above normal range.

Additional Information:

Patient history: Schizophrenia, heaptitis B positive, hepatitis C positive, opiate abuse and alcohol abuse.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202384 Seq: 1 Gender: F

Reported: 09/11/2004 Weight: 0.00
Hospitalisation: Age: 99U
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment					
Weight increased	Severe							

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 30.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Additional Information:

Patient history: Schizophrenia, heaptitis B positive, hepatitis C positive, opiate abuse and alcohol abuse.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 202412
 Seq: 1
 Gender:
 M

 Reported:
 09/11/2004
 Weight:
 100.00

Hospitalisation: Age: 56
Onset Date: 25/10/2004 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
	to Doctor	When patient lies down to sleep at night even though he is on a C PAP machine he wakes up unable to breath. Is also suffering severe constipation.	
	Required Visit to Doctor		

Medicine Details:

40.0 Milligram	Daily	Oral	
Started: 01/04/2004	oped:		
	Reason:		
200.0 Milligram	Daily	Oral	
Started: 30/09/2004	Sto	oped:	
	40.0 Milligram Started: 01/04/2004 200.0 Milligram	Started: 01/04/2004 Stop Reason: 200.0 Milligram Daily	40.0 Milligram Daily Oral Started: 01/04/2004 Stopped: Reason: 200.0 Milligram Daily Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Case Number: 202660

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

ospitalisatio	d: 18/11/2004				Wei	ght: 0.00		
Hospitalisation:				Age: 99U				
Onset Dat	te:			DOB:				
Outcom	e: Unknown				Causa	ality: Causality possible		
eaction Det						T		
	erred Term	Se	everity		ort Description	Treatment		
Suicidal ideation	on			Patient had suic violent.	idal ideation and was	Discharged on Venlafaxine 225mg.		
ggression								
ledicine D	otaile:							
EFEXOR (Susp				Rea	son:			
` .	,				Oral			
Batch:		s	started:		Stopped:			
OLANZAPINE (Suspected)			Rea	son:			
Batch:		S	tarted:		Stopped:			
aboratory Date	Investigation	Ons:	Date Tested	d Result		Details		

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

D t -				Gende	
Reporte	ed: 18/11/2004			Weigh	t: 0.00
spitalisatio	n:			_	e: 63
Onset Dat	te:			DO	B : 19/08/1941
Outcom	e: Unknown			Causalit	y: Causality possible
action De	tails:				
Prefe	erred Term	Severity	Repo	ort Description	Treatment
uicidal ideati	on		Suicidal ideation		
edicine D			Reas	son:	
LANZAPINE (Suspecteu)		Reas	son.	
Batch:		Started:		Stopped:	
	HYDROCHLORIDE (Reas		
Batch:		Started:		Stopped:	
		Started:	Reas		
	spected)	Started:	Reas		
ALCOHOL (Sus	spected) quid	Started:	Reas	son:	
ALCOHOL (Sus Oral Liq Batch:	spected) quid Investigațions	Started:		on: Oral Stopped:	tails

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Case Number: 202666

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

	ted: 18/11/2004	t .				weign	t: 0.00
Hospitalisation:				Age: 99u			
Onset Da	ate:		DOB:				
Outcor	ne: Unknown					Causalit	y: Causality possible
eaction D							
	eferred Term	Se	verity		t Description		Treatment
Suicidal idea	tion			ient had suicid ent.	al ideation and	d was	
Aggression							
Madiaina	Dotoilo						
Medicine I				Reas	on:		
0 	(Сиороской)						
Batcl	h:	St	arted:		Stopp	ed:	
LOVAN (Susp	pected)			Reas	on:		
			40.0 Milli	gram	Daily	Oral	
Batcl	h:	St	arted:		Stopp	ed:	
.aborator	v Investigatio	ons:					
_aborator	y Investigati o	ons: Range	Date Tested	Result		De	tails

Rep



Case Number: 202685

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 18/11/2004			We	i ght: 0.00
pitalisation:				Age : 66
Onset Date:				DOB : 24/12/1937
Outcome: Unknown			Caus	ality: Causality possible
action Details: Preferred Term	Severity	Reno	ort Description	Treatment
uicidal ideation		icidal ideation		Hodinon
ledicine Details:		Reas		
	275.0 Milli	igram	Oral	
Batch:	Started:		Stopped:	
DLANZAPINE (Suspected)		Reas	son:	
Batch:	Started:		Stopped:	
ITHIUM CARBONATE (Suspected)		Reas		
Tablet			Oral	
Batch:	Started:		Stopped:	
aboratory Investigation Date Type I	S: Range Date Tested	Result		Details
		Result		Details
		Result		Details
		Result		Details
Date Type I		Result		Details
Date Type I		Result		Details

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Case Number: 202690

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 18/11/2004			Wei	ght: 0.00
ospitalisation:			,	Age: 34
Onset Date:				OOB: 28/07/1970
Outcome: Unknown			Causa	ality: Causality possible
eaction Details:				
Preferred Term	Severity	R	eport Description	Treatment
uicidal ideation		Suicidal idea	tion and suicide attempt.	
uicide attempt				
ledicine Details: OLANZAPINE (Suspected)			Reason:	
OLANZAI INE (Guspeoteu)	15.	0 Milligram	Daily	
Batch:	Started:	g	Stopped:	
/ENLAFAXINE HYDROCHLORIDE	E (Suspected)	-	Reason:	
		0 Milligram	Daily	
Batch:	Started:	-	Stopped:	
_aboratory Investigatio Date Type	ns: Range Date To	ested Result		Details
Additional Information:				
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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Numb	ber: 202694	Seq: 1				Gender:	U
Report	ted: 18/11/200)4				Weight:	0.00
Hospitalisati	ion:					Age:	99U
Onset D						DOB:	
Outcor	me: Unknown					Causality:	Causality possible
Reaction D	etails:						
Pre	eferred Term	Seve	rity	Repo	ort Description		Treatment
Suicide atter	mpt		Su	iicide attempt.			
Medicine	Details:						
BRUFEN (Sus				Rea	son:		
						Oral	
Batc		Start	ed:		Stoppe	d:	
	E (Suspected)			Rea			
Batc	h:	Start	ed:		Stoppe	d:	
Laborator Date	y Investigat		ate Tested	Result		Detail	a a
Date	туре	Range Da	ale resieu	Nesuit		Detail	3
Additiona	l Informatio	n:					

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: ospitalisation: Onset Date: Outcome:	18/11/2004		: 1					Gender:	U	
Onset Date:								Weight:	0.00	
								Age:	99U	
Outcome:								DOB:	:	
	Unknown						C	ausality:	Causality poss	ible
action Details										
Preferre	d Term	Se	everity	<u> </u>		ort Desc	ription		Treatmer	nt
uicidal ideation				Suicida	al ideatior	١.				
edicine Deta					Rea	ison:				
Tablet			150.0	Milligran	n	Daily		Oral		
Batch:		S	tarted:				Stopped:			
LANZAPINE (Susp	pected)					ison:				
			10.0	Milligran	n	Daily				
Batch:		S	tarted:				Stopped:			
aboratory Inv	/estigatio	ONS: Range	Date Test	ted	Result			Detai	ils	



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Detail	ls:					
Case Number:	202730	Seq: 1			Gende	r: U
Reported:	18/11/2004				Weigh	t: 0.00
lospitalisation:					Age	e: 99U
Onset Date:					DO	3:
Outcome:	Unknown				Causalit	y: Causality possible
<u>eaction Deta</u>		ı				
	ed Term	Severity		ort Descriptio	n	Treatment
Suicidal ideation			Suicidal ideation	l		
Medicine Det	raile:					
	Lalis. DL ACETATE (Suspec	eted)	Rea	son:		
Injection	ACTAIL (GUSPOG		Milligram	Daily		
Batch:		Started:	g. 2	-	pped:	
ZOLOFT (Suspect	ted)		Rea	son:	•	
Tablet		100.0	Milligram	Daily	Oral	
Batch:		Started:		Stop	pped:	
ZYPREXA (Suspe	cted)		Rea	son:		
		9.0	Milligram	Daily		
Batch:		Started:		Stor	pped:	
					•	
Laboratory Ir	1vestigations: Type Rar		ted Result			tails
			ted Result			tails

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Case Number: 202735

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Preferred Term Severity Report Description Treatment dicidal ideation Suicidal ideation, suicide attempt and violence. Suicidal ideation, suicide attempt and violence.				ht: 0.00
Outcome: Unknown action Details: Preferred Term Severity Report Description Treatme preferred Term Severity Report Desc	•			_
Action Details: Preferred Term Severity Report Description Treatme uicidal ideation Suicidal ideation, suicide attempt and violence. Idedicine Details: CIPRAMIL (Suspected) Reason: Tablet Oral Batch: Started: Stopped: DLANZAPINE (Suspected) Reason: DLANZAPINE (Suspected) Reason: DLANZAPINE (Suspected) Reason: Batch: Started: Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Injection Batch: Started: Stopped:				
Preferred Term Severity Report Description Treatme uicidal ideation ggression uicide attempt Suicidal ideation, suicide attempt and violence.			Causa	ity: Causality possible
Suicidal ideation, suicide attempt and violence. Suicidal ideation, suicide attempt and violence.		0	December Description	Taratarant
Aggression Nuicide attempt Medicine Details: CIPRAMIL (Suspected) Tablet Batch: Started: Oral Batch: Stopped: OLANZAPINE (Suspected) Reason: Batch: Started: Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) Injection Batch: Started: Stopped: Agency Reason: Injection Batch: Started: Stopped:		1		Treatment
Iedicine Details: CIPRAMIL (Suspected) Reason: Tablet Oral Batch: Started: Stopped: Otal COLANZAPINE (Suspected) Reason: Otal Batch: Started: Stopped: Otal COLANZAPINE (Suspected) Reason: Otal COLANZAPINE (Suspected) Otal	uicidal ideation		Suicidal ideation, suicide attempt and violence.	
Tablet Oral Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Batch: Started: Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Injection Batch: Started: Stopped:	ggression			
Tablet Oral Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Batch: Started: Stopped: Stopped: Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Injection Batch: Started: Stopped: Stopped: Aboratory Investigations:	uicide attempt			
CIPRAMIL (Suspected) Tablet Oral Batch: Started: CIANZAPINE (Suspected) Batch: Started: Started: Stopped: Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) Injection Batch: Started: Started: Stopped: Reason: Stopped: Stopped: Aboratory Investigations:				
Tablet Oral Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Batch: Started: Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Injection Batch: Started: Stopped:				
Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Batch: Started: Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Injection Batch: Started: Stopped:				
Batch: Started: Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) Injection Batch: Started: Stopped: Stopped: Aboratory Investigations:		Startod		
Batch: Started: Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Injection Batch: Started: Stopped:		Started:		
ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Injection Batch: Started: Stopped: aboratory Investigations:	DLANZAPINE (Suspected)		Reason.	
Injection Batch: Started: Stopped: aboratory Investigations:	Batch:	Started:	Stopped:	
Batch: Started: Stopped: aboratory Investigations:	ZUCLOPENTHIXOL ACETATE (Sus	spected)	Reason:	
aboratory Investigations:	Injection			
		Started:	Stopped:	
	Batch:			
	aboratory Investigation		ed Result	Details
	aboratory Investigation		ed Result	Details
Additional Information:	aboratory Investigation Date Type		ed Result	Details
Additional Information:	aboratory Investigation Date Type		ed Result	Details

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisati	ed: 18/11/200 on:	Seq: 04	1			Gender: Weight: Age:	0.00 29
Onset Da							09/08/1975
	ne: Unknown					Causality:	Causality possible
Reaction De		1 00	a wido .	Done	at December	1	Tractment
Aggression	ferred Term	Se	verity	ntient became	ort Description		Treatment
Aggression		l l	l c	allerit became	violent.	<u> </u>	
Medicine I	Details:						
OLANZAPINE				Rea	son:		
					_		
Batch			arted:	D	Stoppe	d:	
Injecti	IIXOL ACETATE	(Suspected)		Rea	son:		
Batch		St	arted:		Stoppe	4.	
Dato	<u>. </u>				Сторро	<u> </u>	
Laborator Date	/ Investiga t Type	tions: Range	Date Tested	Result		Detail	ls
Additional	Informatio	n:					

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

er: 202741	Seq:	1			Gender:	U
ed: 18/11/200	_				Weight:	0.00
					_	
					_	20/12/1991
						Causality possible
						, , , , , , , , , , , , , , , , , , ,
	Se	verity	Repo	ort Description		Treatment
			Rea	son:		
		arted:			ed:	
	(Suspected)		Rea	son:		
:	St	arted:		Stopp	ed:	
		Data Tactada	Pasult		Deta	ile.
туре	Range	Date Testeu	Result		Deta	15
Informatio	n:					
	Details: (Suspected) : IXOL ACETATE on : Type	Details: (Suspected) : St IXOL ACETATE (Suspected) : St IXOL PROPERTY Se IXOL ACETATE (Suspected) Type Range	ed: 18/11/2004 on: ite: ne: Unknown etails: ferred Term	ed: 18/11/2004 on: tte: ne: Unknown etails: ferred Term Severity Report Patient prone to Patient prone to Started: IXOL ACETATE (Suspected) Started: Type Range Date Tested Result	ed: 18/11/2004 on: Ite: Ine: Unknown Patails: Ferred Term Severity Report Description Patient prone to violence. Details: (Suspected) Reason: IXOL ACETATE (Suspected) Reason: IXOL ACETATE (Suspected) Started: Stopp IXOL ACETATE (Suspected) Started: Stopp	ed: 18/11/2004 Weight: Doi: Age: tet: DOB: Causality: Stails: Ferred Term Severity Report Description Patient prone to violence. Details: (Suspected) Reason: IXOL ACETATE (Suspected) Reason: Doi: Started: Stopped: Tinvestigations: Type Range Date Tested Result Details: Type Range Date Tested Result Details Type Range Date Tested Result Details

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Case Number: 202744

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

anitaliaatian.	14		we	eight: 0.00
spitalisation:				Age : 24
Onset Date:				DOB : 20/09/1980
Outcome: Unknown			Caus	ality: Causality possible
action Details: Preferred Term	Sovority	Popor	Description	Treatment
verdose	Severity	Patient overdosed	Description	
veruose		Patient overdosed	•	Zyprexa 5mg nocte and Cipramil 40mg. Both restarted.
ledicine Details:				
CIPRAMIL (Suspected)		Reaso		
Tablet	Otanta da		Ora	ıl
Batch:	Started:		Stopped:	
ZYPREXA (Suspected)		Reaso	n:	
Batch:	Started:		Stopped:	
aboratory Investigat	ions:			
aboratory Investigat Date Type	ions: Range Date Te	sted Result		Details

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Case Number: 202746

Reported: 18/11/2004

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: U

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

lospitalisation:						Age : 43		
Onset Date:					0	DOB: 05		: - -
Outcome: Unknown					Cal	isality: Ca	ausality poss	ible
eaction Details: Preferred Term	96	verity		Report Desc	rintion		Treatmer	nt
Anxiety	36	venty	i			ad	Healinei	IL
AllAlety			and had suic	idal ideation	was depresse า.	, u		
Depression								
Suicidal ideation								
Medicine Details: OLANZAPINE (Suspected)				Reason:				
Tablet		5.0	Milligram	rtouson.	C	ral		
Batch:	S [,]	tarted:	J. J. J. J. J. J. J. J. J. J. J. J. J. J		Stopped:			
EFEXOR (Suspected)				Reason:	• • • • • • • • • • • • • • • • • • • •			
		150.0	Milligram	Daily	C	ral		
Batch:	Si	tarted:			Stopped:			
Laboratory Investigati	ons:							
Date Type	Range	Date Test	ed Result			Details		
Additional Information	1:							
eport Run: 04/06/2007 05:15PM	Database: pu	usime02		ADRS004			Page 223	of 530



Hospitalisation:

Case Number: 202749

Reported: 18/11/2004

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Weight: 0.00

Age: 99u

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Onset Da	ate:						DOB:		
Outcor	ne: Unknown					Cau	sality: Ca	ausality poss	ible
eaction De	etails:								
Pre	eferred Term	Se	everity	Repo	ort Desc	ription		Treatmer	nt
Mania			F ic o	atient became leation, was vic utbursts and ak	manic, h lent, hac athisia.	ad suicidal I angry violent	Discha 200m or 5m	arged on Fluvo g and Olanzap g nocte.	oxamoine oine 200mg
Aggression									
Akathisia									
Suicidal idea	tion								
Medicine I	Details:								
OLANZAPINE	(Suspected)			Rea	son:				
Batch	h:	s	tarted:			Stopped:			
LUVOX (Susp	pected)			Rea	son:				
Table	t					Or	al		
Batch	h:	s	tarted:			Stopped:			
Laborator	y Investigati	ons:							
Date	Туре	Range	Date Tested	l Result			Details		
\dditional	I Information	n:							
oort Run: 04/0	06/2007 05:15PM	Database: pı	usime02	Д	DRS004			Page 224	of 530



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Preferred Term Severity Report Description Treatmet Suicide attempt Medicine Details: XANAX (Suspected) Tablet Batch: Started: Stopped: EFEXOR (Suspected) Reason: Coral Batch: Started: Stopped: EFEXOR (Suspected) Reason: Oral Batch: Started: Stopped: Benzodiazepine NOS (Suspected) Reason: Batch: Started: Stopped: Batch: Started: Stopped: Batch: Started: Stopped:	Age: 62 Onset Date: 04/08/2003 Outcome: Unknown Causality: Causality possible Couton Edils: Preferred Term Severity Report Description Treatment icide attempt Coulous attempt Coulous atte	Donort	er: 202761	Seq:	. !		Ge	ender: U
Onset Date: 04/08/2003 Outcome: Unknown Causality: Causality causality possessed preferred Term Suicide attempt Medicine Details: XANAX (Suspected) Batch: Started: Started: Stopped: EFEXOR (Suspected) Batch: Started: Started: Stopped: Batch: Started: Stopped: Stopped: Reason: Oral Stopped: Oral Stopped: Oral Stopped: Feason: Oral Batch: Started: Stopped: Feason: Oral Batch: Started: Stopped: Feason: Oral Batch: Stopped: Stopped: Feason: Oral Batch: Stopped: Stopped: Feason: Oral Batch: Stopped: Stopped: Feason: Feason: Oral Batch: Stopped: Feason: Feason: Feason: Oral Batch: Stopped: Feason: Feason: Feason: Feason: Feason: Feason: Oral Batch: Stopped: Feason: Feason: Feason: Oral Stopped: Feason: Oral Stopped: Feason: Age: 62 Onset Date: 04/08/2003 Outcome: Unknown Causality: Causality possible Council	Keport		•			We	eight: 0.00	
Outcome: Unknown Peaction Details: Preferred Term Severity Report Description Treatment Suicide attempt Medicine Details: XANAX (Suspected) Reason: Tablet Started: Stopped: Batch: Started: Stopped: EFEXOR (Suspected) Reason: FEXOR (Suspected) Reason: Batch: Started: Stopped:	Outcome: Unknown Interview of the preferred Term Severity Report Description Treatment Preferred Term Severity Report Description Treatment Icide attempt Suicide attempt. Preferred Term Severity Report Description Treatment Suicide attempt. Preferred Term Severity Report Description Treatment Suicide attempt. Preferred Term Severity Report Description Treatment Suicide attempt. Preferred Term Severity Reason: Treatment Treatm	ospitalisati	on:					Age: 62
Preferred Term Severity Report Description Treatment Suicide attempt Medicine Details: XANAX (Suspected) Reason: Tablet Oral Batch: Started: Stopped: EFEXOR (Suspected) Reason: Coral Batch: Started: Stopped: EFEXOR (Suspected) Reason: Batch: Started: Stopped:	Preferred Term Severity Report Description Treatment icide attempt Suicide attempt Suicide attempt. Reason: Tablet Season: Stapped: Oral Batch: Started: Stopped: FEXOR (Suspected) Reason: Oral Batch: Started: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped:	Onset Da	ate: 04/08/2003					DOB : 16/08/1940
Preferred Term Severity Report Description Treatmet Buicide attempt Suicide attempt. Medicine Details: XANAX (Suspected) Tablet Oral Batch: Started: Stopped: EFEXOR (Suspected) Reason: Batch: Started: Stopped: EFEXOR (Suspected) Reason: Oral Batch: Started: Stopped: EFEXOR (Suspected) Reason: Oral Batch: Started: Stopped: Benzodiazepine NOS (Suspected) Reason: Batch: Started: Stopped: Benzodiazepine NOS (Suspected) Reason: Batch: Started: Stopped: Benzodiazepine NOS (Suspected) Reason: Batch: Started: Stopped:	Preferred Term Severity Report Description Treatment Suicide attempt	Outcor	ne: Unknown				Caus	sality: Causality possible
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XANAX (Suspected) Tablet Batch: Started: Stopped: Oral ZYPREXA (Suspected) Reason: Batch: Started: Stopped: FEFEXOR (Suspected) Reason: Oral Batch: Started: Stopped: Benzodiazepine NOS (Suspected) Reason: Oral Batch: Started: Stopped: Aboratory Investigations:	ANAX (Suspected) Tablet Oral Batch: Started: Stopped: Oral PREXA (Suspected) Reason: Stopped: FEXOR (Suspected) Reason: Oral Batch: Started: Stopped: Oral Batch: Stopped: Oral Batch: Stopped: Enzodiazepine NOS (Suspected) Reason: Stopped: Enzodiazepine NOS (Suspected) Reason:	Suicide atten	npt		Sui	cide attempt.		
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Batch: Started: Stopped: EFEXOR (Suspected) Reason: Oral Batch: Started: Stopped: Benzodiazepine NOS (Suspected) Reason: Batch: Started: Stopped:	Batch: Started: Stopped: FEXOR (Suspected) Reason: Oral Batch: Started: Stopped: enzodiazepine NOS (Suspected) Reason: Batch: Started: Stopped:	Batch	n:	S	started:		Stopped:	0
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Benzodiazepine NOS (Suspected) Batch: Started: Stopped: Benzodiazepine NOS (Suspected) Batch: Started: Stopped: Batch: Stopped:	Reason: Oral Batch: Started: Stopped: enzodiazepine NOS (Suspected) Batch: Started: Stopped: Stopped: Doratory Investigations:							
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Benzodiazepine NOS (Suspected) Batch: Started: Stopped: aboratory Investigations:	Batch: Started: Stopped:					Rea	son:	
Batch: Started: Stopped:	Batch: Started: Stopped:					Rea		le
aboratory Investigations:	boratory Investigations:	EFEXOR (Sus	spected)	s	started:	Rea	Ora	al
aboratory Investigations:	boratory Investigations:	EFEXOR (Sus	spected) n:		started:		Ora Stopped :	al
		EFEXOR (Sus Batch Benzodiazepi	spected) n: ne NOS (Suspected	1)			Ora Stopped: son:	al
		EFEXOR (Sus Batch Benzodiazepi	spected) n: ne NOS (Suspected	1)			Ora Stopped: son:	al
Date Type Range Date Tested Result Details		EFEXOR (Sus Batch Benzodiazepi Batch	spected) n: ne NOS (Suspected	s			Ora Stopped: son:	al
		EFEXOR (Sus Batch Benzodiazepi Batch	epected) n: ne NOS (Suspected n: y Investigatio	s ons:	itarted:	Rea	Ora Stopped: son:	
		EFEXOR (Sus Batch Benzodiazepi Batch	epected) n: ne NOS (Suspected n: y Investigatio	s ons:	itarted:	Rea	Ora Stopped: son:	
		EFEXOR (Sus Batch Benzodiazepi Batch	epected) n: ne NOS (Suspected n: y Investigatio	s ons:	itarted:	Rea	Ora Stopped: son:	
		EFEXOR (Sus Batch Benzodiazepi Batch	epected) n: ne NOS (Suspected n: y Investigatio	s ons:	itarted:	Rea	Ora Stopped: son:	
		EFEXOR (Sus Batch Benzodiazepi Batch	epected) n: ne NOS (Suspected n: y Investigatio	s ons:	itarted:	Rea	Ora Stopped: son:	
Additional Information:	lditional Information:	Batch Benzodiazepi Batch Batch Date	n: ne NOS (Suspected n: y Investigatio Type	ons: Range	itarted:	Rea	Ora Stopped: son:	
Additional Information:	lditional Information:	Batch Benzodiazepi Batch Batch Date	n: ne NOS (Suspected n: y Investigatio Type	ons: Range	itarted:	Rea	Ora Stopped: son:	
Additional Information:	Iditional Information:	Batch Benzodiazepi Batch Batch Date	n: ne NOS (Suspected n: y Investigatio Type	ons: Range	itarted:	Rea	Ora Stopped: son:	
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Report Run: 04/06/2007 05:15PM Database: pusime02 ADRS004 Page 225 of 530



Case Number: 202764

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 18/11/20	004				Weigh	it: 0.00	
ospitalisation:						e : 24	
Onset Date:					DO	B : 22/10/1980	
Outcome: Unknow	n				Causali	y: Causality poss	ible
eaction Details:							
Preferred Term	Sev	erity	Re	port Description	on	Treatmer	nt
Akathisia			Patient experi	enced akathisia			
Medicine Details:							
OLANZAPINE (Suspected)			R	eason:			
		10.0	Milligram	Daily			
Batch:		rted:		Sto	pped:		
VENLAFAXINE HYDROCHLO	RIDE (Suspected)			eason:			
			Milligram	Daily			
Batch:	Sta	rted:		Sto	pped:		
Laboratory Investiga Date Type		Date Teste	ed Result	1	Do	etails	
Additional Informati	on:						
eport Run: 04/06/2007 05:15l	PM Database: pusi	ime02		ADRS004		Page 226	of 530



Case Number: 202768

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Repor	ted: 18/11/200)4			Weigl	nt: 0.00
Iospitalisati						je : 48
Onset D						DB : 04/08/1956
Outco	me: Unknown				Causali	ty: Causality possible
eaction D	etails:					
Pre	eferred Term	Se	verity	Rep	ort Description	Treatment
Suicide atter	npt		Pa atte	tient stabbed empt.	self in stomach - suicide	
Medicine	Details:					
	(Suspected)			Rea	son:	
		_				
Batc	h:	S	tarted:		Stopped:	
	<u>y Investigat</u>			ı		
Date	Туре	Range	Date Tested	Result	D	etails
Additiona	l Informatio	n:				
port Run · 04/0	06/2007 05·15PN	/ Database: ni	ısime02	1	DRS004	Page 227 of 530

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Case Number: 202773

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Report	ted: 18/11/2004	ļ			We	eight: 0	.00	
lospitalisati						Age: 6	5	
Onset Da	ate:					DOB : 2	3/06/1939	
Outcor	ne: Unknown				Caus	sality: C	Causality poss	ible
eaction D	etails:							
Pre	eferred Term	Se	verity	Rep	ort Description		Treatmer	nt
Suicidal idea	tion		Pat wis	tient had mild h.	I hypomania and a deat	h		
Medicine l ZYPREXA (Su				Ros	ason:			
ZII KEXA (OC	ispected)			Not				
Batcl	h:	St	tarted:		Stopped:			
MIRTAZAPINI	E (Suspected)			Rea	ison:			
Table	t				Ora	al		
Batcl	h:	St	tarted:		Stopped:			
AROPAX (Sus	spected)			Rea	ison:			
					Ora	al		
Batcl	h:	St	tarted:		Stopped:			
Laborator Date	y Investigati Type	ons: Range	Date Tested	Result		Details		
Additional	l Information	:						
eport Run: 04/0	06/2007 05:15PM	Database: pເ	ısime02		ADRS004		Page 228	of 530

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	er: 202780	Seq: 1		9611	der: U
Report	ted: 18/11/2004			Wei	ght: 0.00
ospitalisati					Age: 24
Onset Da					OB: 08/10/1980
Outcor	ne: Unknown			Causa	lity: Causality possible
eaction De					1
	eferred Term	Severity		t Description	Treatment
Aggression			Patient became al	ousive.	
Medicine I SERTRALINE	Details:	(Suspected)	Reaso	on:	
Table	t			Oral	
Batch	h:	Started:		Stopped:	
OLANZAPINE Batch		Started:	Reaso	on: Stopped:	
ZUCLOPENTI	HIXOL ACETATE (S	uspected)	Reaso		
	ion				
Injecti				Stopped:	
Injecti Batci	h:	Started:		Stopped.	
Batch	y Investigatio	ons:	sted Result	Эторрец.	Details
Batch		ons:	sted Result	Эторрец.	Details

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Numbe	r: 202781	Seq:	1			Gender:	U
Reporte	d: 18/11/200)4			,	Weight:	0.00
Hospitalisation	1:					Age:	99U
Onset Dat	e:					DOB:	
Outcome	: Unknown				Ca	ausality:	Causality possible
Reaction Det	ails:						
Prefe	rred Term	Se	everity	Repo	ort Description		Treatment
Aggression			P	atient became	violent.		
Medicine Do				Rea	son:		
Batch:			tarted:		Stopped:		
VENLAFAXINE	HYDROCHLOR			Rea	son:		
Batch: ZUCLOPENTHIX	OL ACETATE		tarted:	Poo	Stopped:		
Injection		(Suspecteu)		Nea	son.		
Batch:		Si	tarted:		Stopped:		
Laboratory Date	Investigat	ions:	Date Tested	d Result		Detai	le.
Date	туре	Range	Date Testet	Result		Detai	15
Additional I	nformatio	n:					

Report Run: 04/06/2007 05:15PM Database: pusime02 ADRS004 Page 230 of 530



Case Number: 202782

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

aanitaliaatian.	004				Weight	: 0.00
ospitalisation:					_	e: 41
Onset Date:						3 : 20/08/1963
Outcome: Unknow	'n				Causality	: Causality possible
action Details:						
Preferred Term	Sev	verity		ort Descr		Treatment
uicidal ideation uicide attempt		Su	icidal ideation	and suici	de attempt.	
ledicine Details:						
MIRTAZAPINE (Suspected)			Rea	son:		
Tablet					Oral	
Batch:	Sta	arted:			Stopped:	
YPREXA (Suspected)			Rea	son:		
Batch:	Sta	arted:			Stopped:	
FEXOR (Suspected)			Rea	son:		
		300.0 Mill	ligram	Daily	Oral	
Batch:	Sta	arted:			Stopped:	
		Date Tested	Result			aile
aboratory Investiga Date Type	Range	Date Testeu	resuit		Dei	ans
	Range	Date Tested	result		Dei	ans
	Range	Date resteu	result		De	ano
aboratory Investiga Date Type ditional Information		Date resteu	resun		Det	

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Report Run: 04/06/2007 05:15PM Database: pusime02

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Numbe	r: 202802	Seq:	1		Ger	nder:	U
Reported	d: 18/11/200)4			Wei	ight:	0.00
Hospitalisation	1 :					Age:	99U
Onset Date	e:					DOB:	
Outcome	: Unknown				Caus	ality:	Causality possible
Reaction Det	ails:					-	
	rred Term	Se	everity	Repo	ort Description		Treatment
Drug withdrawa	al syndrome		Su	iicidal ideation	after Zyprexa ceased.		
Suicidal ideation	n						
Medicine De	ataile:						
ZYPREXA (Susp				Rea	son:		
	·						
Batch:		S	tarted:		Stopped:		
<u>Laboratory</u>	Investigat	tions:					
Date	Type	Range	Date Tested	Result		Details	s
Additional I	nformatio	n:					

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Numb	er: 202806	Seq: 1		Gender	U
	ed: 18/11/200			Weight:	
Hospitalisati				Age:	
Onset D					: 25/06/1984
Outcor	ne: Unknown			Causality:	Causality possible
Reaction De	etails:				
	ferred Term	Severity	Repo	ort Description	Treatment
Intentional se	elf-injury		Deliberate self h	arm.	
Medicine I					
ZYPREXA (Su	ispected)		Rea	son:	
D. t.		Ot and and		Otania di	
Batcl	า:	Started:		Stopped:	
I also vato v	. In 4 in 4	•			
Date	y Investigat Type	Range Date Tes	ted Result	Deta	ile
Date	, ypc	Tange Date 165	1 Count	Deta	
Additiona	Informatio	n:	•		

Report Run: 04/06/2007 05:15PM Database: pusime02 ADRS004 Page 233 of 530



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reporte	r: 202809	Seq: 1		Gende	r: U
	d: 18/11/2004	-		Weight	: 0.00
lospitalisatio	n:			Age	: 99U
Onset Dat	e:			DOE	3:
Outcome	: Unknown			Causality	: Causality possible
eaction Det	ails:				
Prefe	erred Term	Severity	Repo	t Description	Treatment
Akathisia			Patient developed suicide attempt.	d akathisia and had a	
Suicide attemp	ot				
Medicine D	otaile:				
	COL ACETATE (S	uspected)	Reas	on:	
Injection					
Batch:		Started:		Stopped:	
OLANZAPINE (Suspected)		Reas	on:	
Batch:		Started:		Stopped:	
Batch:	cted)	Started:	Reas		
	cted)	Started:	Reas		
LUVOX (Suspec	eted)	Started:	Reas	on:	
Tablet Batch:	Investigation	Started:		on: Oral	ails

Report Run: 04/06/2007 05:15PM Database: pusime02 ADRS004 Page 234 of 530



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Donort	er: 202834	Seq: 1		Gender	. 0
Report	ted: 19/11/2004			Weight:	0.00
ospitalisatio				_	99U
Onset Da				DOB	
	ne: Unknown			Causality	Causality possible
action De		<u> </u>			
	ferred Term	Severity		ort Description	Treatment
Suicide atten	npt		Suicidal ideation	and suicide attempt.	
MIRTAZAPINE	Details: E (Suspected)		Rea	son:	
Tablet				Oral	
Batch	n:	Started:		Stopped:	
EFEXOR (Sus	spected)		Rea	son:	
				Oral	
Batch	ո։	Started:		Stopped:	
		Started:	Rea	Stopped:	
ZYPREXA (Su	ispected)		Rea	son:	
	ispected)	Started:	Rea		
ZYPREXA (Su Batch	ispected)	Started:		son:	ils

Report Run: 04/06/2007 05:15PM Database: pusime02 ADRS004 Page 235 of 530



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Onset Date: Outcome: Unknown Causality: Causality possible action Details: Preferred Term Severity Report Description Treatment agression Violent and suicide attempt. Pedicine Details: PARAN SR (Suspected) Reason: Tablet Oral Batch: Started: Stopped: PYPREXA (Suspected) Reason: Started: Stopped:	spitalisation: Onset Date: Outcome: Unknown Causality: Causality possible action Details: Preferred Term Severity Report Description Treatment gression aicide attempt Proferred Term Severity Report Description Treatment gression aicide attempt Proferred Term Severity Report Description Treatment Preferred Term Severity Report Description Preferred Term Se	Reported: 19/11/2004			
Onset Date: Outcome: Unknown Causality: Causality possible action Details: Preferred Term Severity Report Description Treatment aggression Unicide attempt Violent and suicide attempt	Onset Date: Outcome: Unknown action Details: Preferred Term Severity Report Description Treatment ggression Usicide attempt Violent and suicide attempt. Violent and suicide attempt.		1		Weight: 0.00
Outcome: Unknown action Details: Preferred Term Severity Report Description Treatment agression violent and suicide attempt. Pedicine Details: PARAN SR (Suspected) Reason: Tablet Oral Batch: Started: Stopped: PYPREXA (Suspected) Reason: Stopped: PYPREXA (Suspected) Reason: Stopped:	Outcome: Unknown action Details: Preferred Term Severity Report Description Treatment gression uicide attempt Pedicine Details: PyBAN SR (Suspected) Reason: Tablet Oral Batch: Started: Stopped: PYPREXA (Suspected) Reason: Started: Stopped:	spitalisation:			Age : 99U
Action Details: Preferred Term Severity Report Description Treatment ggression uicide attempt Violent and suicide attempt.	Preferred Term Severity Report Description Treatment ggression vicide attempt. Violent and suicide attempt. Violent and suicide attempt.	Onset Date:			DOB:
ggression uicide attempt Violent and suicide attempt.	Preferred Term Severity Report Description Treatment ggression uicide attempt Violent and suicide attempt.	Outcome: Unknown		C	Causality: Causality possible
Preferred Term Severity Report Description Treatment ggression uicide attempt Violent and suicide attempt.	Preferred Term Severity Report Description Treatment ggression uicide attempt Violent and suicide attempt.	action Details:			
Medicine Details: ZYBAN SR (Suspected) Tablet Batch: Started: Stopped: ZYPREXA (Suspected) Reason: Stopped: Stopped: Stopped:	Medicine Details: ZYBAN SR (Suspected) Tablet Batch: Started: Stopped: ZYPREXA (Suspected) Reason: Stopped: Stopped: Stopped:		Severity	Report Description	Treatment
Medicine Details: ZYBAN SR (Suspected) Tablet Batch: Started: ZYPREXA (Suspected) Reason: Batch: Started: Stopped: Stopped:	Medicine Details: ZYBAN SR (Suspected) Tablet Batch: Started: ZYPREXA (Suspected) Reason: Batch: Started: Stopped: Stopped:	aggression	V	iolent and suicide attempt.	
Tablet Oral Batch: Started: Stopped: ZYPREXA (Suspected) Reason: Batch: Started: Stopped:	Tablet Oral Batch: Started: Stopped: Batch: Started: Stopped: Stopped: St	Suicide attempt			
ZYBAN SR (Suspected) Tablet Oral Batch: Started: Stopped: ZYPREXA (Suspected) Batch: Started: Stopped: Stopped: Aboratory Investigations:	Tablet Oral Batch: Started: Stopped: Batch: Started: Stopped: Stopped: St				
Batch: Started: Stopped: ZYPREXA (Suspected) Reason: Batch: Started: Stopped:	Batch: Started: Stopped: ZYPREXA (Suspected) Reason: Batch: Started: Stopped:	ZYBAN SR (Suspected)		Reason:	
Batch: Started: Stopped: _aboratory Investigations:	Batch: Started: Stopped: _aboratory Investigations:				
Batch: Started: Stopped:	Batch: Started: Stopped:		Started:		
aboratory Investigations:	aboratory Investigations:	ZYPREXA (Suspected)		Reason:	
aboratory Investigations:	aboratory Investigations:				
		Batch:	Started:	Stopped:	
	Date Type Range Date Tested Result Details	Batch:	Started:	Stopped:	
Date Type Range Date Tested Result Details			ons:		

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Case Number: 202838

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported:	19/11/2004						We	ight:	0.00	
ospitalisation:								Age:	99U	
Onset Date:							I	DOB:		
Outcome:	Unknown						Caus	ality:	Causality possi	ble
<u>eaction Detai</u>				7				•		
	ed Term	Se	everity			ort Desc			Treatmen	t
Suicide attempt				Suic	idal ideatior	and suid	cide attempt.			
Medicine Deta					Rea	son:				
Tablet	LEATE (Ousp	colouj			Noc	3011.	Ora	I		
Batch:		S	tarted:				Stopped:			
ZYPREXA (Suspec	ted)				Rea	son:				
			15.0	Millig	ram	Daily				
Batch:		S	tarted:				Stopped:			
ZUCLOPENTHIXO	ACETATE (S	uspected)			Rea	son:				
Injection			200.0	Millig	ram	Daily				
Batch:		S	tarted:				Stopped:			
Laboratory In	vestigatio	ONS: Range	Date Test	ted	Result			Detai	ls	
Additional Inf	ormation	:								
eport Run: 04/06/200	7 05:15PM	Database: pu	usime02		,	ADRS004			Page 237	of 530



Onset Date:

Case Number: 202839

Reported: 19/11/2004

Hospitalisation: Admitted to hospital

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: U

DOB:

Weight: 0.00

Age: 99U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Preferred Term Severity Report Description Treatment Caused or prolonged inpatient hospitalisation Gaused or prolonged inpatient hospitalisation Rathisia Caused or prolonged inpatient hospitalisation Reason: Caused or prolonged inpatient hospitalisation Reason: Caused or prolonged inpatient hospitalisation Reason: Cral Batch: Started: Stopped: ZYPREXA (Suspected) Reason: Batch: Started: Stopped: Stopped: Aboratory Investigations: Date Type Range Date Tested Result Details Additional Information:	Outcome: Unknown		Causality	: Causality possible
Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient inposition in the control of the cont		· · · · · · · · · · · · · · · · · · ·		
ggression Caused or prolonged inpatient hospitalisation Edicine Details: Betch: Started: Stopped: PYPREXA (Suspected) Reason: Cral Batch: Started: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped:			'	Treatment
prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Edicine Details: FEEXOR (Suspected) Reason: Oral Batch: Started: Stopped: PYPREXA (Suspected) Reason: Stopped: Stopped: Stopped: Batch: Started: Stopped:	omicidal ideation	prolonged inpatient	Homicidal and suicidal ideation, violent and akathisia.	
Prolonged Inpatient Prolonged Inpatient Prospitalisation Prolonged Inpatient Prospitalisation Prospitalisation Prolonged Inpatient Prospitalisation	ggression	prolonged inpatient		
Batch: Started: Stopped: PREADOR: Batch: Started: Stopped: Batch: Started: Stopped: Batch: Started: Stopped: Batch: Started: Details	kathisia	prolonged inpatient		
Batch: Started: Stopped: PREADOR: Batch: Started: Stopped: Batch: Started: Stopped: Batch: Started: Stopped: Batch: Started: Details	ledicine Details:			
Batch: Started: Stopped: Present (Suspected) Reason: Batch: Started: Stopped: Stopped: Stopped: Stopped: Date Type Range Date Tested Result Details			Reason:	
Batch: Started: Stopped: Batch: Started: Stopped: Stopped: Date Type Range Date Tested Result Details				
Batch: Started: Stopped: aboratory Investigations: Date Type Range Date Tested Result Details		Started:		
aboratory Investigations: Date Type Range Date Tested Result Details	YPREXA (Suspected)		Reason:	
aboratory Investigations: Date Type Range Date Tested Result Details Details	Batch:	Started:	Stopped:	
	aboratory Investigatio	ons:		
dditional Information:			ed Result Deta	ails
	additional Information	:		
oort Run: 04/06/2007 05:15PM Database: pusime02 ADRS004 Page 238 of 5	oort Dun - 04/06/2007 - 05:45DM	Database: pusimen2	ADDS004	Page 238 of 530



Case Number: 202839

Reported: 19/11/2004

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

ospitalisation: Admitted to I	nospital		ge: 99U
Onset Date:			OB:
Outcome: Unknown		Causal	lity: Causality possible
action Details:			
Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation		
ledicine Details:			
EFEXOR (Suspected)		Reason:	
		Oral	
Batch:	Started:	Stopped:	
YPREXA (Suspected)		Reason:	
5	2		
Batch:	Started:	Stopped:	
-h			
aboratory Investigatio	ns:		
alaliti a mal lunfa uun ati a m			
dditional Information:			
ort Run · 04/06/2007 05·15PM	Database: pusime02	ADRS004	Page 239 of 530

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

202841	Seq:	1		Gen	der: U
: 19/11/200)4			Weig	ght: 0.00
! !				À	.ge: 99U
					OB:
Unknown				Causa	lity: Causality possible
ils:					•
	Se	verity	Repo	ort Description	Treatment
on			omicidal ideation	on and akathisia.	
ected)			Rea	son:	
	04	toutod.		Ctonnod.	
'uanastad\	31	tarted:	Poo		
ouspecteu)			Rea	SOII.	
	St	tarted:		Stopped:	
		Data Tastada	Doguit		Dotaila
Туре	Range	Date Tested	Result		Details
ıformatio	n:				
	: : : : : : Unknown ails: red Term ion tails: ected) suspected) nvestigat Type	: 19/11/2004 : : Unknown ails: red Term Serion tails: ected) suspected) suspected)	tails: ected) Started: Suspected) Started: Type Range Date Tested	: 19/11/2004 : : : : Unknown ails: red Term	: 19/11/2004 : AR : DR : Unknown Causa ails: red Term Severity Report Description ion Homicidal ideation and akathisia. tails: sected) Reason: Started: Stopped: Suspected) Reason: Started: Stopped:

Report Run: 04/06/2007 05:15PM Database: pusime02 ADRS004 Page 240 of 530



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Weight: 0.00 Age: 99U DOB: Causality: Causality possible Report Description Treatment Cidal ideation and violent.
DOB: Causality: Causality possib Report Description Treatment
DOB: Causality: Causality possib Report Description Treatment
Causality: Causality possib
Report Description Treatment
Reason:
Oral
Stopped:
Reason:
Stopped:
оторреи.
Result Details

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

r: 202845	Seq: 1		Gender	. 0
d: 19/11/2004	1		Weight	0.00
				99U
			Causality	: Causality possible
	Severity			Treatment
n		Suicidal ideation		
	pected)	Rea		
			Oral	
	Started:		Stopped:	0
	Started:		Stopped:	
Investigati Type	ons:	ested Result	Stopped:	nils
Investigati Type	ons:	ested Result		tils
	n: e: e: Unknown rails: erred Term on	e: e: Unknown ails: erred Term Severity on etails: MALEATE (Suspected)	e: e: e: e: Unknown tails: erred Term Severity Reported ideation on Suicidal ideation etails: MALEATE (Suspected) Reaction	n: Age: e: DOB e: Unknown causality rails: erred Term Severity Report Description on Suicidal ideation. etails: MALEATE (Suspected) Reason: Oral Started: Stopped:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

ase Nulliber. 202047	Seq. I		Genae	;i. U
Reported: 19/11/2004			Weigh	t: 0.00
ospitalisation:			Ag	e: 99U
Onset Date:			DO	
Outcome: Unknown				y: Causality possible
eaction Details:				- ·
Preferred Term	Severity	Report D	escription	Treatment
Aggression	Vi	iolent and suicidal i	deation.	
Suicidal ideation				
Medicine Details: ZYBAN SR (Interaction)		Reason:		
Tablet			Oral	
Batch:	Started:		Stopped:	
ZYPREXA (Interaction)		D		
211 (anto-action)		Reason:		
	Started:	Reason:	Stopped:	
Batch:	Started:	Reason:	Stopped:	
Batch: _aboratory Investigation:				etails
Batch: Laboratory Investigation:	s:			etails

Report Run: 04/06/2007 05:15PM Database: pusime02 ADRS004 Page 243 of 530



Case Number: 202856

Reported: 19/11/2004

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

lospitalisation: Onset Date:	Age: 99U DOB:				
Outcome: Unknown			_	: Causality possible	
eaction Details:			Guasant	. Caddanty possible	
Preferred Term	Severity	Report Desc	cription	Treatment	
Homicidal ideation		Homicidal and suicidal id and overdose.			
Akathisia					
Overdose					
Suicidal ideation					
Medicine Details:					
AROPAX (Suspected)		Reason:			
			Oral		
Batch:	Started:		Stopped:		
ZYPREXA (Suspected)		Reason:			
Batch:	Started:		Stopped:		
Laboratory Investigatio	ns:				
Date Type	Range Date Test	ed Result	Det	ails	
Additional Information: Patient also taking amphetamine:	S.				
eport Run: 04/06/2007 05:15PM	Database: pusime02	ADRS004		Page 2	

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Numb	oer: 202860	Seq:	1		G	ender:	U
Report	ted: 19/11/200)4			W	/eight:	0.00
Hospitalisati	on:					Age:	99U
Onset Da						DOB:	
Outcor	me: Unknown				Cau	ısality:	Causality possible
Reaction De	etails:						
Pre	eferred Term	Sev	erity	Repo	ort Description		Treatment
Suicide atten	npt		Su	uicide attempt.			
Medicine I	Details:						
AROPAX (Sus				Rea	son:		
					C	ral	
Batcl		Sta	rted:		Stopped:		
ZYPREXA (Su	uspected)			Rea	son:		
Batcl	h:	Sta	rted:		Stopped:		
Laborator Date	y Investigat Type		Date Tested	Result		Detail	s
Date	Туре	Range	Date Testeu	Result		Detail	5
Additional	I Informatio	n:					

Report Run: 04/06/2007 05:15PM Database: pusime02 ADRS004 Page 245 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:203274Seq: 1Gender: MReported:06/12/2004Weight:0.00Hospitalisation:Admitted to hospitalAge: 99u

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano			
Preferred Term	Severity	Report Description	Treatment
		obessive compulsive disorder.	Electro convulsive therapy given. Lithium ceased.

Medicine Details:

Wieulcine Delans.					
LITHIUM CARBONATE (Other drug)			Reason:		
Tablet				Oral	
Batch:	Started:			Stopped:	
ZYPREXA (Suspected)			Reason:		
Tablet	5.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Medical history of Bipolar disorder.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Num	ber: 203294	Seq: 1		Gende	er: M
	rted: 06/12/200	-			nt: 0.00
ospitalisat		•			e: 99u
Onset I				DO	
	ome: Death, ma	lybe drug			ty: Causality possible
eaction E		, 0			, , ,
	referred Term	Severity	y Re	eport Description	Treatment
Orug level i	ncreased			vel in blood increased.	
Overdose			Patient died, o	drug toxicity.	
Drug ineffe	ctive				
Medicine ZYPREXA (S			R	eason:	
			R I0.0 Milligram	deason: Daily	
	Suspected)	1 Started	10.0 Milligram		0
ZYPREXA (S	Guspected) ch:	Started	10.0 Milligram	Daily	0
ZYPREXA (S Bat	ch:	Started	IO.0 Milligram	Daily Stopped:	
Bat Laborato Date	Guspected) ch:	Started	10.0 Milligram	Daily Stopped:	etails

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:	
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Case Number:203375Seq: 1Gender:MReported:08/12/2004Weight:0.00Hospitalisation:Admitted to hospitalAge: 36

Onset Date: 08/11/2004 **DOB:** 16/11/1967

Outcome: Recovered 10/11/2004 Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Stevens-Johnson syndrome		of hands and feet.	Ibuprofen and Paracetamol.
Oedema peripheral	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VENTOLIN (Other drug)		Reason:	
Inhalation		Inhalation	
Batch:	Started:	Stopped:	
FLIXOTIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 08/11/2004	Stopped: 09/11/2004	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 05:15PM Database: pusime02 ADRS004 Page 248 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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$\mathbf{\nu}$	Δn	\sim 1	**	ם ו	taı	ls:
1	CN	vi	L	UG	Lai	13.

Case Number: 203630 Seq: 1 Gender: F

Reported: 17/12/2004 Weight: 60.00 Hospitalisation: Age: 48

Onset Date: 23/11/2004 **DOB**: 28/01/1956

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Somnolence		Excessive somnolence post general anaesthetic.	

Medicine Details:

PROPOFOL (Suspected)		Reason:		
Injection		1 time		
Batch:	Started:		Stopped:	
MORPHINE SULPHATE (Suspected)				
		1 time		
Batch:	Started:		Stopped:	
SEVOFLURANE (Suspected)		Reason:		
Inhalation		1 time		
Batch:	Started:		Stopped:	
VECURONIUM BROMIDE (Suspected)		Reason:		
Injection, powder for	6.0 Milligram	1 time		
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient had 2 previous GAs with similar technique exept no propofol (seroflurane inductions) - normal recovery with dose GAs, but took 5 hours to regain concioussness this time.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
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Case Number: 203630 Seq: 1 Gender: F

Reported: 17/12/2004 Weight: 60.00 Hospitalisation: Age: 48

Onset Date: 23/11/2004 **DOB**: 28/01/1956

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

DEXAMETHASONE (Suspected)			Reason:		
	8.0	Milligram	1 time		
Batch:	Started:			Stopped:	
NITROUS OXIDE (Suspected)			Reason:		
Inhalation		Litre	Per minu	te	
Batch:	Started:			Stopped:	
OLANZAPINE (Suspected)			Reason:		
	5.0	Milligram	Daily		
Batch:	Started:			Stopped:	22/11/2004

Laboratory Investigations:

Additional Information:

Patient had 2 previous GAs with similar technique exept no propofol (seroflurane inductions) - normal recovery with dose GAs, but took 5 hours to regain concioussness this time.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 203860
 Seq: 1
 Gender:
 F

 Reported:
 04/01/2005
 Weight:
 0.00

 Hospitalisation:
 Admitted to hospital
 Age: 42Y

Onset Date: 02/07/2003 DOB:
Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose	prolonged	influenza like illness, sedation, found to be not breathing whilst travelling on a bus.	Zyprexia was decreased to 10mg daily.
Drug toxicity	Caused or prolonged inpatient hospitalisation		
Sedation	Caused or prolonged inpatient hospitalisation		

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ı۱	ЛΩ	ИI	CI	ne	1)0	таі	IG.

mearenie Betaner			
VALIUM (Other drug)		Reason:	
	5.0 Milligram		Oral
Batch:	Started:	;	Stopped:
BENZTROPINE MESYLATE (Other drug)		Reason:	
Batch:	Started:	;	Stopped:
SERTRALINE HYDROCHLORIDE (Other dr	ug)	Reason:	
Batch:	Started:	;	Stopped:
ZYPREXA (Suspected)		Reason:	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started:	;	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
04/01/2005	Other data				Cause of death was positional asphyxiation. Coroners report stated that there were toxic levels of Olanzapine in the patient's blood. Direct cause: Disease or condition directly leading to death: a) Olanzapine toxicity. Toxicology: Olanzapain (1.2mg/l), Diazepam (0.3mg/L), nordiazepam (0.8mg/L), benztropine (0.1mg/L) and sertraline (0.2mg/L) in blood. Quantitative procedures on blood showed diazepam

Additional Information:

The patient's medical history included behavioural disorder, intellectual disabilities, mild physicial disability and non-communicative.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Deta	ils:						
ospitalisation Onset Date	i : 04/01/200	to hospital)3	1		V	ender: /eight: Age: DOB:	0.00 42Y
action Det		aybe drug			Cat	isaiity.	Causanty possible
ledicine De				Res	ason:		
VALION (Other)	arug)		5.0 Mill			ral	
Batch:		s	tarted:		Stopped:		
BENZTROPINE	MESYLATE (O	ther drug)		Rea	ason:		
Batch:		S	tarted:		Stopped:		
SERTRALINE H	YDROCHLORI	DE (Other drug)		Rea	ason:		
Batch:		s	tarted:		Stopped:		
ZYPREXA (Susp	ected)			Rea	ason:		
Tablet			30.0 Mill	igram	Daily	ral	
Batch:		S	tarted:		Stopped:		
.aboratory			1		1		
Date	Туре	Range	Date Tested	Result	(0.2mm/l. the 0.05.2.0	Detai	
					0.08-0.125. txr fr -0-7).	3-14,fr -), sertraline ng/L). No	b, fr>5), nordiazepam benziropine (0.1mg/L, thr e (0.2mg/L, thr 0.1-0.3, txr - , fr e alcohol was detected in the
			ı		•		
dditional l	nformatio	n.					

Additional information:

The patient's medical history included behavioural disorder, intellectual disabilities, mild physicial disability and non-communicative.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 204233 Seq: 1 Gender: M

Reported: 14/01/2005 Weight: 0.00 Hospitalisation: Age: 27

Onset Date: 30/11/2004 **DOB**: 08/08/1977

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Neutropenia	Life threatening	Neutropenia.	Olanzapine discontinued.

Medicine Details:

CHLORPROMAZINE HYDROCHLO	RIDE (Other drug)	Reason:	
	300.0 Milligram		
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	5.0 Milligram	Daily Oral	
Batch:	Started: 30/09/2004	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
	10.0 Milligram	Daily	
Batch:	Started: 16/11/2004	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
14/01/2005	Neutrophils				1.67 and 1.45

Additional Information:

further information received and stated that the patient's condition has stabilized Report 218010 is the second sequence to this report.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:204253Seq: 1Gender: MReported:14/01/2005Weight: 80.00Hospitalisation:Admitted to hospitalAge: 29

Onset Date: DOB: 11/09/1975

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	erity Report Description Treatment		
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	The patient experienced cardiomyopathy requiring heart transplant urgently. Ejection fraction about 20%	ICU admission, Solian ceased. Antibiotics and possible heart transplant. Perindopril and carvedilol on discharge	
	Caused or prolonged inpatient hospitalisation			
Cardiac failure	Caused or prolonged inpatient hospitalisation			

Medicine Details:

EFEXOR-XR (Other drug)			Reason:	Depression		
Capsule	300.0	Milligram		Oral		
Batch:	Started:		L TERM	Stopped:		
SOLIAN (Suspected)			Reason:	Unspecified schizop	hrenia	
	400.0	Milligram	Daily	Oral		
Batch:	Started:		STERM	Stopped:	0	
OLANZAPINE (Suspected)			Reason:			
	20.0	Milligram	Daily			
Batch:	Started:		L TERM	Stopped:	0	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
14/01/2005	Creatine				peaked at 343
14/01/2005	Other data	cardiac			dilated left ventricle of 78mm (normal 56mm)with severely depressed systolic function, estimated ejection fraction of <20% and mild mitral regurgitation.
14/01/2005	White blood cells				23.3 on day 3

Additional Information:

Olanzapine withdrawn on week before admission. No previous exposure to amisulpride. PH of anxiety, panic disorder and alcohol abuse. Literautre Report: Brakoulias V, banna E, Cohen P, geary G. Amisulpride and cardiomyopathy. Australian And New Zealand Journal pf Psychiatry. August 2005;39(8) 738

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:204253Seq: 1Gender: MReported:14/01/2005Weight:80.00Hospitalisation:Admitted to hospitalAge: 29

Onset Date: DOB: 11/09/1975

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Palpitations	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EFEXOR-XR (Other drug)			Reason:	Depression		
Capsule	300.0	Milligram		0	ral	
Batch:	Started:		L TERM	Stopped:		
SOLIAN (Suspected)			Reason:	Unspecified schiz	zophrenia	
	400.0	Milligram	Daily	0	ral	
Batch:	Started:		S TERM	Stopped:	0	
OLANZAPINE (Suspected)			Reason:			
	20.0	Milligram	Daily			
Batch:	Started:		L TERM	Stopped:	0	

Laboratory Investigations:

Additional Information:

Olanzapine withdrawn on week before admission. No previous exposure to amisulpride. PH of anxiety, panic disorder and alcohol abuse. Literautre Report: Brakoulias V, banna E, Cohen P, geary G. Amisulpride and cardiomyopathy. Australian And New Zealand Journal pf Psychiatry. August 2005;39(8) 738

Report Run: 04/06/2007 05:15PM Database: pusime02 ADRS004 Page 255 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 204253 Gender: M Seq: 1 Reported: 14/01/2005 Weight: 80.00

Hospitalisation: Admitted to hospital Age: 29

DOB: 11/09/1975 Outcome: Recovered Causality: Causality possible

Reaction Details:

Onset Date:

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EFEXOR-XR (Other drug)			Reason:	Depression		
Capsule	300.0	Milligram			Oral	
Batch:	Started:		L TERM	Stopped:		
SOLIAN (Suspected)			Reason:	Unspecified sch	nizophrenia	
	400.0	Milligram	Daily	1	Oral	
Batch:	Started:		STERM	Stopped:	()
OLANZAPINE (Suspected)			Reason:			
	20.0	Milligram	Daily			
Batch:	Started:		L TERM	Stopped:	()

Laboratory Investigations:

Additional Information:

Olanzapine withdrawn on week before admission. No previous exposure to amisulpride. PH of anxiety, panic disorder and alcohol abuse. Literautre Report: Brakoulias V, banna E, Cohen P, geary G. Amisulpride and cardiomyopathy. Australian And New Zealand Journal pf Psychiatry. August 2005;39(8) 738

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:204256Seq: 1Gender:UReported:14/01/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 69

Onset Date: 03/12/2004 **DOB:** 25/10/1935

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	prolonged	The patient experienced myocarditis, increased troponin and ejection fraction decreased.	Olanzapine ceased, ACE inhibitors, supportive.
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	Unspecified so	chizophrenia
	10.0 Milligram	Daily		
Batch:	Started: 22/11/2004		Stopped:	03/12/2004
MIRTAZAPINE (Suspected)		Reason:	Depression	
Tablet	60.0 Milligram	Daily		Oral
Batch:	Started: 15/01/2004		Stopped:	03/12/2004
KEFLEX (Suspected)		Reason:	Othr diseases	of urinary tract
	2.0 Milligram	Daily		Oral
Batch:	Started: 24/11/2004		Stopped:	07/12/2004
HALOPERIDOL (Suspected)		Reason:	Otr spec symp	psychopathol nec
	2.0 Milligram	Daily		
Batch:	Started: 22/11/2004		Stopped:	07/12/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
14/01/2005	Other data				LV impariment EF 30%
14/01/2005	Troponin				troponin rised 4.4

Additional Information:

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Case Number: 204455

Reported: 22/01/2005

Onset Date: 15/10/2004

Hospitalisation: Admitted to hospital

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

DOB:

Weight: 0.00

Age: 22

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Outcome: Recovered			Cau	sality: Causality possible	
eaction Details:					
Preferred Term	Severity	Re	port Description	Treatment	
Oystonia	Caused or prolonged inpatient hospitalisatio	which he expl like and anxie	enced a dystonic reactior ained to the doctor that it ty attack.	Antihistamine. SPECT ordered to scan for possible seizure. Zyprexa discontinued.	
Anxiety	Caused or prolonged inpatient hospitalisatio	n			
Medicine Details:	_				
ZOLOFT (Other drug)		R	eason:		
Tablet			Oı		
Batch:	Started:		Stopped:	0	
VITAMIN NOS (Other drug)		R	eason:		
Batch:	Started:		Stopped:		
ZYPREXA (Suspected)		R	eason: Depression		
Tablet	5.0) Milligram	Daily Oral		
Batch:	Started:		Stopped:		
_aboratory Investigation	Ons: Range Date Te	ested Result		Details	
Additional Information					
Auditional information	•				
port Run: 04/06/2007 05:15PM	Database: pusime02		ADRS004	Page 258 of 530	



Hospitalisation:

Onset Date:

Case Number: 204537

Reported: 24/01/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 61.70

Age: 26

DOB: 15/10/1978

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

FOLIC ACID (Other drug) 5.0 Milligram Batch: Started: Stopped: ZYPREXA (Suspected) Reason: Unspecified schizophrenia 5.0 Milligram Daily Batch: Started: L TERM Stopped: Aboratory Investigations:	Outcome: Not yet reco	overed		Causality:	Causality possible
Extrapyramidal reaction with right tremor right lower limb and increased tone with rigidity. Started: Started: Stopped:		1	1		
right lower limb and increased tone with rigidity. Pedicine Details: Pedicine Det		Severity			Treatment
ledicine Details: FOLIC ACID (Other drug) Batch: Started: Stopped: ZYPREXA (Suspected) Batch: Started: L TERM Stopped: Stopped: Started: L TERM Stopped:	xtrapyramidal disorder		Extrapyramidal right lower limb a rigidity.	reaction with right tremor and increased tone with	
Tedicine Details: FoLic Acid (Other drug) Reason:	ypertonia				
Reason: Stopped:					
FOLIC ACID (Other drug) 5.0 Milligram Batch: Started: Stopped: ZYPREXA (Suspected) Reason: Unspecified schizophrenia 5.0 Milligram Daily Batch: Started: L TERM Stopped: Aboratory Investigations:	remor				
Batch: Started: Stopped: ZYPREXA (Suspected) Reason: Unspecified schizophrenia 5.0 Milligram Daily Batch: Started: L TERM Stopped: Aboratory Investigations:					
Batch: Started: Stopped: ZYPREXA (Suspected) Reason: Unspecified schizophrenia 5.0 Milligram Daily Batch: Started: L TERM Stopped: Aboratory Investigations:					_
Batch: Started: Stopped: ZYPREXA (Suspected) Reason: Unspecified schizophrenia 5.0 Milligram Daily Batch: Started: L TERM Stopped: aboratory Investigations:	FOLIC ACID (Other drug)	_		son:	
ZYPREXA (Suspected) 5.0 Milligram Daily Batch: Started: L TERM Stopped: .aboratory Investigations:	Ratch:		0 Milligram	Stannad	
5.0 Milligram Daily Batch: Started: L TERM Stopped: aboratory Investigations:		Starteu.	Rea		
Batch: Started: L TERM Stopped: aboratory Investigations:	ETT NEXA (Ouspected)	5			
aboratory Investigations:	Batch:			•	
	_aboratorv Investigatio	ons:			
Date Type Range Date Tested Result Details	Date Type		ested Result	Detai	s
	Additional Information	:			
Additional Information:	oort Run: 04/06/2007 05:15PM	Database: pusime02	P	ADRS004	Page 259 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 204628 Seq: 1 Gender: M

Reported: 25/01/2005 Weight: 67.40 Hospitalisation: Age: 30

Onset Date: 18/10/2004 **DOB**: 27/11/1973

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis		The patient experienced leucocytosis.	Ceased Lithium.

Medicine Details:

FLUPENTHIXOL DECANOATE (Other drug)		Reason:	Unspecified psycho	sis
Injection	40.0 Milligram	Yearl	y	
Batch:	Started: 20/08/2004	STERM	Stopped:	
LORAZEPAM (Other drug)		Reason:	Otr spec symp psyc	hopathol nec
Tablet	4.0 Milligram	Daily	Oral	
Batch:	Started: 08/04/2004	STERM	Stopped:	
OLANZAPINE (Suspected)		Reason:	Unspecified psycho	sis
	20.0 Milligram	Daily	Oral	
Batch:	Started: 10/04/2004	S TERM	Stopped: 28/1	2/2004
LITHIUM CARBONATE (Suspected)		Reason:		
LITHIUM CARBONATE (Suspected) Tablet	750.0 Milligram		Oral	

Laboratory Investigations:

Dat	te	Туре	Range	Date Tested	Result	Details
25/01/2	2005	Other data				13/12/2004 - Neutrophils, lymphocytes and basophils elevated.
25/01/2	2005	White blood cells		18/10/2004	12.7 x 10 9	
25/01/2	2005	White blood cells		13/12/2004	13.5 x 10 9	
25/01/2	2005	White blood cells		03/01/2005	11.6 x 10 9	

Additional Information:

Patient has been exposed previously.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 204803
 Seq: 1
 Gender:
 M

 Reported:
 01/02/2005
 Weight:
 0.00

 Hospitalisation:
 Age: 75

Onset Date: 04/08/2004 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Dotano.			
Preferred Term	Severity	Report Description	Treatment
Loss of consciousness		being discharged from hospital on Monday 02/08/04. Patient bradycardia, arrived in	
Bradycardia Confusional state			

Medicine Details:

TEMAZEPAM (Other drug)			Reason:	Specific disord	ers of sleep	
Tablet	20.0	Milligram			Oral	
Batch:	Started:			Stopped:		
COLOXYL WITH SENNA (Other drug)			Reason:	Constipation		
Tablet	3.0	Dose Unspec	ified		Oral	
Batch:	Started:			Stopped:		
ARICEPT (Suspected)			Reason:	Unspecified ps	sychosis	
Tablet	5.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:	04/08/2004	less than 1 wk
OLANZAPINE (Suspected)			Reason:	Hallucinations		
Tablet	10.0	Milligram	Daily		Oral	
Batch:	Started:	ST	ERM	Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has diffuse Lewy body disease.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	204803	Seq: 1			Ge	ender:	M	
Reported:	01/02/2005				W	eight:	0.00	
Hospitalisation:						Age:	75	
Onset Date:	04/08/2004					DOB:		
Outcome:	Not yet recovered	I			Cau	sality:	Causality possible	
Reaction Detai	ls:							
Madiaina Date	oilo							
Medicine Deta				Reason:	Paralysis agitans			
Tablet	cteuj	250.0	Milligram	Daily	Or	al		
Batch:		Started:	wiiiigram	Daily	Stopped:	aı		
Datcii.		Starteu.			Stopped.			
	41 41							
Laboratory In	vestigations:							
Additional Inf								
Patient has diffuse	Lewy body disease							

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:204818Seq: 1Gender:MReported:02/02/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 53

Onset Date: 12/08/2004 **DOB:** 18/11/1950

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
		arrest.	Cessation of suspected offending agents.
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TEMAZE (Other drug)		Reason:	
	10.0 Milligram		
Batch:	Started: 29/07/2004	Stopped:	
DIAZEPAM (Other drug)		Reason:	
		Oral	
Batch:	Started: 29/07/2004	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started: 28/07/2004	Stopped: 11/08/2004	
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily Oral	
Batch:	Started: L T	TERM Stopped: 20/08/2004	

Laboratory Investigations:

<u> </u>								
Date	Туре	Range	Date Tested	Result	Details			

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 205125
 Seq: 1
 Gender: M

 Reported:
 09/02/2005
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 84
Onset Date: 25/11/2004 DOB:

Outcome: Recovered 06/01/2005 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	l
Neuroleptic malignant syndrome			Haloperidol and Olanzapine ceased.	

Medicine Details:

HALOPERIDOL (Interaction)		Reason:	Otr spec symp	psychopathol nec
Tablet	2.0 Milligram	Daily		Oral
Batch:	Started: 20/11/2004		Stopped:	21/11/2004
OLANZAPINE (Interaction)		Reason:	Otr spec symp	psychopathol nec
Tablet	2.0 Milligram	Daily		Oral
Batch:	Started: 22/11/2004		Stopped:	25/11/2004
AMPICILLIN (Other drug)		Reason:		
Injection	1.0 Gram			Intravenous
Batch:	Started: 19/11/2004		Stopped:	20/11/2004
OXAZEPAM (Other drug)		Reason:		
Tablet	8.0 Milligram			Oral
Batch:	Started: 20/11/2004		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
09/02/2005	Creatine		25/11/2004	2973	CKMB=27

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE, ZYPREXA, Zyprexa IM, Zyprexa Zydis

Re	por	t De	tai	s:
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Gender: F Case Number: 205334 Seq: 1

Reported: 16/02/2005 Weight: 42.00 Hospitalisation: Age: 60

Onset Date: 20/03/2004 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Blood pressure 70/40 on the 22/03/04.	Required medical attention.

Medicine Details:

Batch:

THYROXINE SODIUM (Other drug) Reason: Myxedema

175.0 Microgram

Batch: Started: Stopped:

MYADEC (Other drug) Reason:

1.0 Dose Unspecified

Stopped:

Started: MOVICOL (Other drug) Reason: Constipation

1.0 Dose Unspecified Daily

Batch: Started: Stopped:

DOXYCYCLINE HYDROCHLORIDE (Suspected) Reason: Pneumonia, unspecified

Tablet 100.0 Milligram Daily Oral

Batch: Started: 20/03/2004 Stopped: 22/03/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Case Number: 205334

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Ospitalisation: Onset Date: 20 Outcome: Repart of the control of t	//03/2004				****	ght:	
Outcome: Re	/03/2004					Age:	
					[OOB:	
action Details:	ecovered				Causa	ality:	Causality possible
ledicine Detail	<u>s:</u>			Reason:			
EPILIM (Suspected) Oral Liquid, Sy	min.	2.0	Gram	Daily	Oral		
Batch:	ταρ	Started:	Giaili	Dally	Stopped:		
CLOZARIL (Suspected	d)	Starteu.		Reason:	Unspecified schizop	hronia	
Tablet	4)	800 O	Milligram	Daily	Oral		
Batch:		Started:	wiiiigram	Dally	Stopped:		
DLANZAPINE (Suspe	ctod)	Starteu.		Reason:	Unspecified schizop	hronia	
Tablet	steuj	5.0	Milligram	Daily	Oral		
Batch:		Started:	Willingram	Daily	Stopped: 22/0		
Dalcii.		Starteu.			Stopped. 22/0	3/2004	

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:205643Seq: 1Gender:MReported:01/03/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 53

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	prolonged inpatient hospitalisation	Patient experienced serotonin syndrome, confusional state, memory impairment, speech disorder, tremor, hypertidrosis, myoclonus, anxiety disorder, somatic hallucination and disorientation.	Fluoxetine ceased. Recommenced Fluoxetine 20mg/daily.
Anxiety	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

wedicine Details:				
FLUOXETINE HYDROCHLORIDE (II	nteraction)	Reason: Depress	ion	
Capsule	80.0 Milligram	Daily	Oral	
Batch:	Started:	Stop	ped:	
OLANZAPINE (Interaction)		Reason: Depress	ion	
Tablet	2.0 Milligram	Daily	Oral	
Batch:	Started:	Stop	ped:	
DIAZEPAM (Other drug)		Reason:		
Batch:	Started:	Stop	ped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Literature report: World J Biol Psychiatry (2004) 5, 114-115: Serotonin Syndrome Associated with Fluoxetine and Olanzapine, Prem Chopra, Chee Ng, Isaac Schweltzer. Patient received a high dose of Fluoxetine previously with no adverse effects, the patient only developed serotonin syndrome after the addition of Olanzapine for three weeks.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:205643Seq: 1Gender:MReported:01/03/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 53

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Disorientation	Caused or prolonged inpatient hospitalisation		
Hallucination	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (In	nteraction)	Reason: Depression	
Capsule	80.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
OLANZAPINE (Interaction)		Reason: Depression	
Tablet	2.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Literature report: World J Biol Psychiatry (2004) 5, 114-115: Serotonin Syndrome Associated with Fluoxetine and Olanzapine, Prem Chopra, Chee Ng, Isaac Schweltzer. Patient received a high dose of Fluoxetine previously with no adverse effects, the patient only developed serotonin syndrome after the addition of Olanzapine for three weeks.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:	Re	port	Detai	ls:
------------------------	----	------	-------	-----

Case Number:205643Seq: 1Gender:MReported:01/03/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 53

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Memory impairment	Caused or prolonged inpatient hospitalisation		
Myoclonus	Caused or prolonged inpatient hospitalisation		
Speech disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (In	teraction)	Reason: Depression	
Capsule	80.0 Milligra	m Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Interaction)		Reason: Depression	
Tablet	2.0 Milligra	m Daily	Oral
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Literature report: World J Biol Psychiatry (2004) 5, 114-115: Serotonin Syndrome Associated with Fluoxetine and Olanzapine, Prem Chopra, Chee Ng, Isaac Schweltzer. Patient received a high dose of Fluoxetine previously with no adverse effects, the patient only developed serotonin syndrome after the addition of Olanzapine for three weeks.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number:205643Seq: 1Gender: MReported:01/03/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 53

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (In	teraction)	Reason: Depression	
Capsule	80.0 Milligra	m Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Interaction)		Reason: Depression	
Tablet	2.0 Milligra	m Daily	Oral
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Literature report: World J Biol Psychiatry (2004) 5, 114-115: Serotonin Syndrome Associated with Fluoxetine and Olanzapine, Prem Chopra, Chee Ng, Isaac Schweltzer. Patient received a high dose of Fluoxetine previously with no adverse effects, the patient only developed serotonin syndrome after the addition of Olanzapine for three weeks.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Hospitalisati	er: 205906 ed: 10/03/200 on: ate: 17/02/200		1		Ą	er: M nt: 0.00 je: 29 DB: 06/12/1975
	ne: Recovere			18/02/2005		ty: Causality possible
Reaction D	etails:					
	ferred Term	Sev	verity	Repo	ort Description	Treatment
Chest pain			Th wa	e patient expense inversion \	erienced chest pain and T /1-6.	
Electrocardio	gram T wave	inversio				
Medicine I	Details:					
	E MESYLATE (O	ther drug)		Rea	son:	
Batcl		Sta	arted:		Stopped:	
ASPIRIN (Oth	er drug)			Rea	son:	
Batcl			arted:		Stopped:	
ESOMEPRAZ	OLE MAGNESIUI	M TRIHYDRATE (Other drug)	Rea	son:	
Batcl	1:	Sta	arted:		Stopped:	
Bisoprolol Fu	marate (Other dr	ug)		Rea	son:	
Batcl	1:	Sta	arted:		Stopped:	
Loborotor	, Investigat	longi				
Date	/ Investigat		Date Tested	Result	D	etails
	chocardiogram	. tuilige	24.0 . 00.04		Post recovery echocardiogram	
	roponin				Normal.	
	Informatio nistory of cardio	n: myopathy to Clo	ozapine.			

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
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Case Number: 205906 Seq: 1 Gender: M

Reported: 10/03/2005 Weight: 0.00 Hospitalisation: Age: 29

Onset Date: 17/02/2005 **DOB:** 06/12/1975

Outcome: Recovered 18/02/2005 Causality: Causality possible

Reaction Details:

Medicine Details:

PERINDOPRIL (Other drug)		Reason:		
Batch:	Started:		Stopped:	
CLOZAPINE (Suspected)		Reason:		
Tablet	125.0 Milligram	Daily		Oral
Batch:	Started:		Stopped:	17/02/2005
OLANZAPINE (Suspected)		Reason:		
	30.0 Milligram	Daily		
Batch:	Started:		Stopped:	

Laboratory Investigations:

Additional Information:

Patient has a history of cardiomyopathy to Clozapine.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:206118Seq: 1Gender:UReported:16/03/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 82Y

Onset Date: 16/02/2005 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia	Caused or prolonged inpatient hospitalisation	Patient admitted bradycardic with atrial fibrillation, hypothermic, pin-point pupils and unresponsive with brief respiratory arrest.	
Atrial fibrillation	Caused or prolonged inpatient hospitalisation		
Hypothermia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMARYL (Other drug)		Reason:		
	4.0 Milligra	am		
Batch:	Started:		Stopped:	
ASPIRIN (Other drug)		Reason:		
	100.0 Milligra	am		
Batch:	Started:		Stopped:	
LIPITOR (Other drug)		Reason:		
Batch:	Started:		Stopped:	
CHLORVESCENT (Other drug)		Reason:		
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Recent change in dose. Zyprexa 2.5mg n 12/01/05. Admitted on 10mg d 16/02/05. History - NIDDM, AF, MI (15 years ago) HT and dementia.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:					
Case Number: 206118	Seq: 1	Gene	der: ∪		
Reported: 16/03/2005		Weight: 0.00			
ospitalisation: Admitted to h	ospital		.ge: 82Y		
Onset Date: 16/02/2005		D	OB:		
Outcome: Not yet recov	ered	Causa	lity: Causality possible		
action Details:			1		
Preferred Term	Severity	Report Description	Treatment		
liosis	Caused or prolonged inpatient hospitalisation				
Respiratory arrest	Caused or prolonged inpatient hospitalisation				
Jnresponsive to stimuli	Caused or prolonged inpatient hospitalisation				
Medicine Details:					
FRUSEMIDE (Other drug)		Reason:			
Batch:	Started:	Stopped:			
PANAMAX (Other drug)		Reason:			
Batch:	Started:	Stopped:			
KEFLEX (Other drug)		Reason:			
Batch:	Started:	Stopped:			
FLUCLOXACILLIN SODIUM (Other	drug)	Reason:			
Batch:	Started:	Stopped:			
aboratory Investigation	es:				

Additional Information:

Recent change in dose. Zyprexa 2.5mg n 12/01/05. Admitted on 10mg d 16/02/05. History - NIDDM, AF, MI (15 years ago) HT and dementia.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 206118
 Seq: 1
 Gender: U

 Reported:
 16/03/2005
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 82Y
Onset Date: 16/02/2005
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

PROTAPHANE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
DILATREND (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
LANOXIN PG (Suspected)		Reason:	
Tablet	62.0 Microgram	Daily Oral	
Batch:	Started:	Stopped:	
NEULACTIL (Suspected)		Reason:	
Tablet	12.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Recent change in dose. Zyprexa 2.5mg n 12/01/05. Admitted on 10mg d 16/02/05. History - NIDDM, AF, MI (15 years ago) HT and dementia.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation: Onset Date:	16/03/2005 Admitted to hospi				c	Gender: Weight: Age: DOB: ausality:	0.00 82Y	ssible
Reaction Detai						uuounty.	caacamy poo	
Medicine Deta				Reason:				
Wafer		10.0	Milligram	Daily		Oral		
Batch:		Started:			Stopped:	07/02/2005	5	
Laboratory In	vestigations:							
	Additional Information: Recent change in dose. Zyprexa 2.5mg n 12/01/05. Admitted on 10mg d 16/02/05. History - NIDDM, AF, MI (15 years ago) HT and dementia.							

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 206159
 Seq: 1
 Gender:
 F

 Reported:
 17/03/2005
 Weight:
 0.00

Hospitalisation: Age: 24

Onset Date: DOB: 05/09/1980

Outcome: Recovered Causality: Causality possible

Reaction Details:

1	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Blood prolactin increased		The patient's prolactin levels increased.	Treated with Cabergoline. All medications ceased except Methadone.	

Medicine Details:

METHADONE HYDROCHLORIDE (Other	Reason:				
Batch:	Started:		Stopped:		
ZYPREXA (Suspected)		Reason:	Change in voi	ce	
				Oral	
Batch:	Started: 01/11/2004		Stopped:	17/12/2005	0
SODIUM VALPROATE (Suspected)		Reason:			
				Oral	
Batch:	Started:		Stopped:		0
AVANZA (Suspected)		Reason:			
Tablet				Oral	
Batch:	Started:		Stopped:		0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
17/03/2005	Prolactin		17/11/2004	8034	
17/03/2005	Prolactin		20/12/2004	112	

Additional Information:

It is unknown how long the patient was receiving Olanzapine before she experienced elevated prolactin levels. All medications were ceased except Methadone and the prolactine levels returned to normal.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:		Seq: 1			Gender: Weight:		
Hospitalisation:	17/03/2005				Age:		
Onset Date:					_	05/09/1980	
	Recovered			C		Causality possible	ے
Reaction Detai				J	ausanty.	Odusanty possibil	
Neaction Detai	113.						
Medicine Det							
DIAZEPAM (Suspe	ected)		Reason:				
Batch:		Started:		Stopped:		0	
TEMAZEPAM (Sus	spected)		Reason:				
					Oral		
Batch:	4 10	Started:	_	Stopped:		0	
CAMPRAL (Suspe	ected)		Reason:		01		
Tablet		Otentedi		04	Oral	0	
Batch:		Started:		Stopped:		0	
Laboratory In	vestigations:						
•	Ü						
Additional Inf	formation						
		s receiving Olanzapine befor he prolactine levels returned	a sha avnariar	nced elevat	ed prolacti	in levels All medica	itions

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DOB: 21/06/1989

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report I	Details:
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 Case Number:
 206280
 Seq: 1
 Gender:
 F

 Reported:
 28/03/2005
 Weight:
 54.00

Hospitalisation: Age: 15

Outcome: Recovered with sequelae Causality: Causality possible

Reaction Details:

Onset Date: 09/01/2005

,	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Suicide attempt	threatening	Attempt to hang herself with television cord from curtain rail in hospital bedroom. Nurse said she found her at the last moment.	
	Drug ineffective	Life threatening		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
PROZAC (Suspected)		Reason:	
Tablet	Milligram	Daily Oral	
Batch:	Started: 16/12/2004	Stopped:	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

One patient with ADRs 206280, 206281, 206282 206283

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report D	Details:
----------	----------

 Case Number:
 206282
 Seq: 1
 Gender:
 F

 Reported:
 28/03/2005
 Weight:
 54.00

 Hospitalisation:
 Age: 15

Onset Date: 20/12/2004 **DOB**: 21/06/1989

Outcome: Recovered with sequelae Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life threatening	Suicide attempt. Ingested 40 Panadol tablets. Also frequent self harming	Charcoal and drip of drug to break down the paracetamol.
Drug ineffective	Life threatening		
Self injurious behaviour	Life threatening		

Medicine Details:

PANADOL (Suspected)		Reason:
Batch:	Started:	Stopped:
OLANZAPINE (Suspected)		Reason:
Batch:	Started:	Stopped:
PANADEINE (Suspected)		Reason:
Batch:	Started:	Stopped: 0
PROZAC (Suspected)		Reason:
Tablet	20.0 Milligram	Daily Oral
Batch:	Started: 16/12/2004	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

One patient with ADRs 206280, 206281, 206282 206283

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report De	etails:									
Case Num		6283	Seq	: 1				Gend	er: F	
		/03/2005	004		Weight: 54.00					
lospitalisati								_	je : 15	
Onset D	ate: 23	/03/2005			DOB : 21/06/1989					
Outco	me: No	t yet recover	ed				С	ausali	ty: Causality possible	
eaction D	etails:									
Pre	eferred	Term	Se	everity	Report Description				Treatment	
Suicide atter	mpt		Life threa	itening F	Attempted suic Panadol, 20 P Zyprexa.)	ide by ingest anadeine, 7 (tion of 80 Dlanzapii) ne	Charcoal, drips of various antidotes including one for breaking down paracetamol, ventilator, all monitors, intensive care for 20 hours. She is now having constant convulsions. These started or 26 March 2005 and are continuing. On 26 march they were of long duration and with only breaks of 10 or 20 minutes. On 27 March they were of various duration and sometimes an hour or	
Medicine ZYPREXA (S					Ro	eason:				
Bato	:h:		S	Started:		S	Stopped:			
PANADOL (S	Suspected	1)			Re	eason:				
Batc	h:		S	Started:		8	Stopped:			
PANADEINE	(Suspect	ed)			Re	eason:				
Bato	:h:		9	Started:		9	Stopped:			
PROZAC (Su					Re	eason:				
Table				N	/lilligram	Daily		Oral		
Bato	h:		S	Started: 16/12	2/2004		Stopped:			
	_									
		stigations		Data Tasta	d Daguit	1			ataila	
Date	Тур	DE Ka	inge	Date Tester	d Result			D	etails	
Date	, y	No.	90	Date Tester	i Nesuit				Cuno	

Additional Information:

One patient with ADRs 206280, 206281, 206282 206283. She takes Olanzapine to help her sleep. She is not psychotic (per reporter).

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:						
Case Number: 206283	Seq: 1	Gender: F				
Reported: 28/03/2005		Weight: 54.00				
Hospitalisation:				Age: 15		
Onset Date: 23/03/2005		DOB : 21/06/1989				
Outcome: Not yet recover	red	Causality: Causality possible				
Reaction Details:						
Preferred Term	Severity	Report Descri	iption	Treatment		
				two apart. Today she has already had some fits today. The hospital cannot work out the cause.		
Convulsion	Life threatening					
Drug ineffective	Life threatening					
Medicine Details:						
ZYPREXA (Suspected)		Reason:				
Batch:	Started:		Stopped:			
PANADOL (Suspected)		Reason:				
Batch:	Started:		Stopped:			
PANADEINE (Suspected)		Reason:				
Batch:	Started:		Stopped:			
PROZAC (Suspected)		Reason:				
Tablet	Milligram	n Daily	C	Dral		
Batch:	Started: 16/12/2004		Stopped:			

Laboratory Investigations:

Additional Information:

One patient with ADRs 206280, 206281, 206282 206283. She takes Olanzapine to help her sleep. She is not psychotic (per reporter).

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 206455 Seq: 1 Gender: F

Reported: 01/04/2005 Weight: 75.00
Hospitalisation: Admitted to hospital Age: 56

Onset Date: 08/03/2005 **DOB**: 01/02/1949

Outcome: Recovered 15/03/2005 Causality: Causality possible

Reaction Details:

D (17	0 ''	B (B) (T ((
Preferred Term	Severity	Report Description	Treatment
Rash macular	prolonged inpatient	Patient developed macular rashes, generalised eruptive rashes over body/limbs/groin/lower abdomen area/chest/armpit/arm/thighs.	Phenergan 20mg tds.

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Tablet	5.0 Milligram		Oral
Batch:	Started: 03/03/2005	Stopped:	06/03/2005
SODIUM VALPROATE (Suspected)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 01/03/2005	Stopped:	08/03/2005
OLANZAPINE (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 07/03/2005	Stopped:	08/03/2005

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisatio	ed: 01/04/2005	Seq: 1		W ei	nder: F ight: 104.00 Age: 46Y DOB:	
	ne: Recovered		07/03/2005		ality: Causality certain	
Reaction De	etails:					
	ferred Term	Severity	Repo	ort Description	Treatment	
Arthralgia			Patient experiencravings and blu	ced joints pains, food rred vision.	Zyprexa ceased.	
Food craving Vision blurred	l .					
Medicine [Details:					
TOFRANIL (O			Reas	son: Depression		
Batch	:	Started:		Stopped:		
METFORMIN H	TYDROCHLORIDE (Ot	her drug)	Reas			
Batch	:	Started:	Stopped:			
Symbicort Tur	buhaler (Other drug)		Reas	son:		
Batch	:	Started:		Stopped:		
CALTRATE (O	ther drug)	-	Reas	son:		
Batch	:	Started:		Stopped:		
Laboratory	/ Investigation	s:				
Date		Range Date Tes	sted Result		Details	

Additional Information:

Patient had had same reactions while previously on Zyprexa June 2004-> Dec 30th 2004. was symptom free until re-started it late Feb. Lowered dose then ceased Zyprexa 5/03/05.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

eport Details:						
Case Number: 206466	Seq: 1				Gender:	F
Reported: 01/04/2005					Weight:	104.00
ospitalisation:					Age:	46Y
Onset Date: 26/02/2005					DOB:	
Outcome: Recovered		07/03/200)5	С	ausality:	Causality certain
eaction Details:						
Medicine Details:						
ZYPREXA (Suspected)		R	eason:			
Tablet	5.0	Milligram	Daily		Oral	
Batch:	Started: 24/	02/2005		Stopped:	05/03/2005	5 0
aboratory Invostigations:						
.aboratory Investigations:						
.aboratory Investigations:						
_aboratory Investigations:						
.aboratory Investigations:						

Additional Information:

Patient had had same reactions while previously on Zyprexa June 2004-> Dec 30th 2004. was symptom free until re-started it late Feb.

Lowered dose then ceased Zyprexa 5/03/05.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Gender: F Case Number: 206678 Seq: 1 Weight: 0.00 Reported: 05/04/2005 Hospitalisation:

Age: 53 Onset Date: 03/03/2005 **DOB**: 08/01/1952

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		During the first two weeks of the patient receiving Olanzapine she experienced elevated liver function tests and jaundice.	Olanzapine ceased.
Alanine aminotransferase increase Aspartate aminotransferase increa Blood bilirubin increased Blood lactate dehydrogenase incre Fatigue Gamma-glutamyltransferase increa Influenza like illness Jaundice			

Medicine Details:

Micalcinic Details.			
LUVOX (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Depression	
	5.0 Milligram	Daily Ora	ıl
Batch:	Started: 22/02/2005	Stopped: 08/0	03/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/04/2005	ALT = SGPT				514 on 03/03/2005
05/04/2005	AST = SGOT				253 on 03/03/2005
05/04/2005	Bilirubin				27 on 03/03/2005
	GGT = SGGT =				414 on 03/03/2005
05/04/2005	LDH				477 on 03/03/2005

Additional Information:

Alanine aminotranserase value of approximately 500u/l. No normal values provided, but the psychiatrist commented that it was greater than ten times the expected value.

Patients medical history included depression, diabetes and a ball baldder problem.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Details:
--------	----------

 Case Number:
 206888
 Seq: 1
 Gender:
 F

 Reported:
 11/04/2005
 Weight:
 0.00

Hospitalisation: Age: 70

Onset Date: DOB: 10/04/1935
Outcome: Unknown Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term Severity		Report Description	Treatment
Tardive dyskinesia	ability	After commencing Olanzapine the patient experienced abnormal movement of the torso and orobuccal region, described by her family as stiff and robotic. She was diagnosed with tardive dyskinesia.	Olanzapine ceased.

Medicine Details:

CELEBREX (Other drug)		Reason:	
Capsule	200.0 Milligram	Oral	
Batch:	Started:	Stopped:	
KLIOGEST (Other drug)		Reason:	
Tablet	2.0 Milligram	Oral	
Batch:	Started:	Stopped:	
TEMAZEPAM (Other drug)		Reason:	
	10.0 Milligram	Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Depression	
	10.0 Milligram	Daily Oral	
Batch:	Started:	Stopped: 08/02/2005	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Numbe	r: 207039	Seq:	1		Gend	ler: M
	d: 14/04/200	-			Weig	ht: 0.00
Hospitalisatio					_	ge: 58
-	e: 06/02/200	15				DB : 11/04/1946
Outcom	e: Not yet re	covered			Causal	ity: Causality possible
Reaction De	=					3
	erred Term	Se	everity	Repo	ort Description	Treatment
Rash			Th the an	e patient deve	eloped a rash starting on reading down the arms very red, blotchy and	Amiodarone ceased.
Pruritus						
Medicine D				D		
RAMIPRIL (Oth	er arug)			Rea	son:	
Batch:		S	tarted:		Stopped:	
SPIRONOLACT	ONE (Other dru	ıg)		Rea	son:	
Batch:		e	tarted:		Stannadi	
FRUSEMIDE (O	thor drug)		iarieu.	Rea	Stopped:	
PROSEWIDE (O	tilei ulug)			Nea	son.	
Batch:		S	tarted:		Stopped:	
CARVEDILOL H	IYDROCHLORII	DE (Other drug)		Rea	son:	
Batch:		S	tarted:		Stopped:	
Laboratory	Investigat	ions:				
Date	Туре	Range	Date Tested	Result	С	Petails
Additional Report 207033			eport.			

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:				
Case Number: 207039 Reported: 14/04/2005 ospitalisation: Onset Date: 06/02/2005 Outcome: Not yet recovered	Seq: 1			0.00
action Details:				
ledicine Details:				
PRAVACHOL (Other drug)		Reason:		
Batch:	Started:		Stopped:	
DIGOXIN (Other drug)		Reason:		
Batch:	Started:		Stopped:	
NARFARIN SODIUM (Other drug)		Reason:		
Batch:	Started:		Stopped:	
AMIODARONE HYDROCHLORIDE (Sus		Reason:		
Tablet Batch:	200.0 Milligram Started: 21/01/2005	Daily	Oral Stopped: 07/02/2005	•
	Started: 21/01/2003		310ppeu. 07/02/2003	
aboratory Investigations:				
dditional Information:				
eport 207033 is the first sequence to	this report.			

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation: Onset Date: Outcome: Reaction Detai	14/04/2005 06/02/2005 Not yet recovered Is:	Seq: 1			0.00
Medicine Deta			D		
OLANZAPINE (Sus	spectea)	5.0 Milligram	Reason: Daily		
Batch:		Started: 06/02/2005	Dally	Stopped:	
Laboratory In	vestigations:				
Additional Inf Report 207033 is the	f ormation: ne first sequence to	this report.			

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 207223 Seq: 1 Gender: F

Reported: 19/04/2005 Weight: 75.00 Hospitalisation: Age: 53

Onset Date: 27/02/2005 **DOB**: 08/01/1952

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touction bottom			
Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Patient developed acute hepatic symptoms, flu-like illness, elevated LFT.	

Medicine Details:

Medicine Details.			
FLUVOXAMINE MALEATE (Other drug)		Reason: Depression	
Tablet	50.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily Oral	
Batch:	Started: 23/02/2005	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 207619
 Seq: 1
 Gender:
 U

 Reported:
 05/05/2005
 Weight:
 0.00

 Hospitalisation:
 Age:
 99u

Onset Date: 22/11/2004 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion botains.			
Preferred Term	Severity	Report Description	Treatment
Pyrexia		Patient developed fever, tiredness, lethargy, joint pain, headche, anorexia and muscle aches.	Fluid resus and Bromocriptine given.
Anorexia			
Arthralgia			
Fatigue			
Headache			
Myalgia			

Medicine Details:

CLOZAPINE (Suspected)	Reason:				
Tablet					Oral
Batch:	Started: 17	11/2004		Stopped:	
OLANZAPINE (Suspected)			Reason:		
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started:		L TERM	Stopped:	
ATORVASTATIN (Suspected)			Reason:		
Tablet	40.0	Milligram	Daily		Oral
Batch:	Started:		L TERM	Stopped:	23/11/2004
FLUOXETINE HYDROCHLORIDE (Suspected	d)		Reason:		
	20.0	Milligram	Daily		Oral
Batch:	Started:		L TERM	Stopped:	23/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Nil muscle rigidity.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 20761 Reported: 05/05 Hospitalisation: Onset Date: 22/11 Outcome: Unknot Reaction Details: Medicine Details:	/2005 /2004		Gender: Weight: Age: DOB: Causality:	0.00 99u
CELEBREX (Suspected)		Reason:		
Capsule	20.0 Milligrar		Oral	
Batch:	Started:	S TERM Stopped		
Laboratory Investi	gations:			
Additional Informa Nil muscle rigidity.	tion:			

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 207760
 Seq: 1
 Gender:
 M

 Reported:
 12/05/2005
 Weight:
 0.00

 Hospitalisation:
 Age: 28

Onset Date: 20/04/2005 **DOB**: 02/01/1977

Outcome: Recovered with sequelae Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Diabetic ketoacidosis	Life threatening		Fluid and electrolyte replacement. Insulin. Zyprexa and Seroquel ceased. Abilify commenced
Polyuria	Life threatening		
Weight decreased	Life threatening		

Medicine Details:

Modifile Botalie:			
ZYPREXA (Suspected)		Reason:	
Tablet	20.0 Milligram	1 time	Oral
Batch:	Started: 01/04/2004	Stopped:	02/05/2005
SEROQUEL (Suspected)		Reason:	
Tablet	400.0 Milligram	1 time	Oral
Batch:	Started: 01/04/2004	Stopped:	02/05/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
12/05/2005	Biochemistry				Hypokalemia, hyperglycaemia

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 207829 Seq: 1 Gender: M

Reported: 13/05/2005 **Weight:** 98.00

Hospitalisation: Age: 49Y
Onset Date: 20/07/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cogwheel rigidity	Caused or prolonged inpatient hospitalisation	The patient experienced cogwheeling, stiffness and extrapyramidal syndrome.	Given Benztropine.
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.		
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia
	8.0 Milligram	Daily Oral
Batch:	Started:	Stopped : 23/07/1998
OLANZAPINE (Suspected)		Reason:
	8.0 Milligram	Daily
Batch:	Started:	Stopped: 20/07/1998

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Clinical trial RODOS WAVE I:RODOS.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 207913 Seq: 1 Gender: F

Reported: 17/05/2005 Weight: 39.00 Hospitalisation: Age: 62

Onset Date: 04/04/2005 DOB: 07/05/1942

Outcome: Recovered 12/04/2005 Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Agranulocytosis		The patient developed agranulocytosis - her neutrophil count dropped to zero.	Neupogen given.

Medicine Details:

SERETIDE ACCUHALER NOS (Other dru	ng)	Reason:	Asthma	
Batch:	Started:		Stopped:	
ASPIRIN (Other drug)		Reason:	Acute,ill-def ce	erebrovascular disease w/o hyperte
	100.0 Milligram	Daily		Oral
Batch:	Started:		Stopped:	
MIRTAZAPINE (Suspected)		Reason:	Depression	
Tablet	30.0 Milligram	Daily		Oral
Batch:	Started: 30/01/2005		Stopped:	04/04/2005
EFEXOR-XR (Suspected)		Reason:	Depression	
Capsule	150.0 Milligram	Daily		Oral
Batch:	Started: 16/02/2005		Stopped:	04/04/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
17/05/2005	Bone marrow				Consistent with drug effect.

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	207913	Seq: 1				Gender:	F	
Reported:	17/05/2005					Weight:	39.00	
Hospitalisation:						Age:	62	
Onset Date:	04/04/2005					DOB:	07/05/1942	
Outcome:	Recovered		12/04	4/2005	С	ausality:	Causality possible	
Reaction Detai	ils:							
Medicine Det	aile:							
OLANZAPINE (Sus				Reason:	Depression			
,	. ,	5.	.0 Milligram	Daily	•			
Batch:			22/02/2005	·	Stopped:	04/04/2005	;	
LOSEC (Suspecte	d)			Reason:				
		20.	.0 Milligram	Daily				
Batch:		Started:		L TERM	Stopped:	04/04/2005	;	
								<u>_</u>
I aboratory In	vestigations:							
	. rootigationor							
Additional Int	la von ati a m .							
Additional Inf	ormation:							

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Do	etails:					
Case Num	nber: 207940	Seq: 1			Gend	ler: M
Repoi	rted: 17/05/200	5			Weig	ht: 0.00
ospitalisat	tion: Admitted to	o hospital			Ag	ge: 78
Onset D	Date: 18/02/2009	5			DO	DB : 19/05/1926
Outco	ome: Not yet red	covered			Causal	ity: Causality possible
eaction D	Details:					
Pr	referred Term	Severit	y	Repor	t Description	Treatment
3radycardia	a	Caused or prolonged inpatient hospitalisa	hypot unres	hermia, pin-	ed bradycardia, severe point pupils and ritical condition.	
Hypothermi	а	Caused or prolonged inpatient hospitalisa				
Miosis		Caused or prolonged inpatient hospitalisa				
Medicine ASPIRIN (Ot				Reaso	on:	
Bato	ch:	Started	l:		Stopped:	
TEMAZEPAN	M (Other drug)			Reaso	on:	
Bato	ch:	Started:			Stopped:	
RIVOTRIL (C	Other drug)			Reas	on:	
Bato	ch:	Started	l:	Stopped:		
DIPROSONE	E (Other drug)			Reaso	on:	
	Batch:		l:	Stopped:		
Bato						
	rv Investigati	ons:				
	ry Investigati		e Tested	Result		Details

Additional Information:

Patient history: Dementia and multiple other medical problems. Another patient admitted on 17.2.05 with same reaction. Common factor could be starting or changed dose Zyprexa.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 207940 Seq: 1 Gender: M

Reported: 17/05/2005 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 78

Onset Date: 18/02/2005 **DOB**: 19/05/1926

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Unresponsive to stimuli	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 2.5 Milligram 2 times Oral

Batch: Started: 16/02/2005 **Stopped:** 18/02/2005

Laboratory Investigations:

Additional Information:

Patient history: Dementia and multiple other medical problems. Another patient admitted on 17.2.05 with same reaction. Common factor could be starting or changed dose Zyprexa.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 207984 Seq: 1 Gender: F

Reported: 19/05/2005 Weight: 62.00 Hospitalisation: Age: 24Y

Onset Date: 25/04/2005 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Face oedema		Patient experienced facial oedema.	Nil

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecifid affective psychosis

5.0 Milligram Daily Oral

Batch: Started: 18/04/2005 **Stopped:** 25/04/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Gender: F Case Number: 208386 Seq: 1

Weight: 64.00 Reported: 01/06/2005 Hospitalisation: Admitted to hospital **Age:** 36

Onset Date: 01/10/2004 **DOB**: 13/11/1967

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis	Caused or prolonged inpatient hospitalisation	Severe drug-related hepatitis	Supportive
Jaundice	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis Tablet 10.0 Milligram 1 time Oral Batch: Started: 01/06/2003

Stopped: 20/10/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
01/06/2005	Biochemistry				Bili: 590; ALP: 182; GGT: 69; AST: 1830; ALT: 1690; LDH: 500 LFT's normal 27/1/05.
01/06/2005	Liver biopsy				Liver biopsy showed zone 3 ballooning degeneration with giant cell transformation apoptotic bodies and portal and acinar infiltrates of lymphocytes and plasma cells.

Additional Information:

Liver Biopsy complicated by major bleeding requiring admission to ICU and laparotomy.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208386 Seq: 1 Gender: F

Reported: 01/06/2005 Weight: 64.00 Hospitalisation: Admitted to hospital Age: 36

Onset Date: 01/10/2004 **DOB:** 13/11/1967

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Tablet 10.0 Milligram 1 time Oral

Batch: Started: 01/06/2003 **Stopped:** 20/10/2004 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
01/06/2005	Other data				PT 27S (control 10s) initially - reveresed with Vit K to 13s. HAV, HBV, HCV, EBV, CMV serology negative. Ultrasound showed no evidence of biliary obstruction.

Additional Information:

Liver Biopsy complicated by major bleeding requiring admission to ICU and laparotomy.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report De	tails:					
Report Iospitalisati Onset Da Outcor	ate: ne: Unknown	Seq	: 1		Aç DC	er: F nt: 0.00 ge: 25 DB: 30/11/1979 ty: Causality possible
eaction D	etalis: eferred Term		everity	Pano	ort Description	Treatment
Suicide atter		3			e a suicide attempt.	rreaunent
Medicine CIPRAMIL (SI				Rea	son:	
Table	t				Oral	
Batcl	h:		Started:		Stopped:	
EFEXOR (Sus		S	Started:	Rea	son: Oral Stopped:	
ZYPREXA (Su				Rea	son:	
Batcl	h:	5	Started:		Stopped:	
Laborator Date	y Investigation	S: Range	Date Tested	Result	D	etails
	I Information: 2 is the second sequ	ence to th	nis report.			

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 208444	Seq: 1		Gend	er: F
Reported: 03/06/2009			Weigl	ht: 0.00
spitalisation:			Αg	je : 32
Onset Date:			DC	DB : 24/08/1972
Outcome: Unknown			Causali	ty: Causality possible
action Details:		,		
Preferred Term	Severity		ort Description	Treatment
ggression		The patient becaphysically threat	ame violently aggressive, ening and abusive.	Zyprexa ceased.
ledicine Details:				
ZYPREXA (Suspected)		Rea	son:	
Batch:	Started:		Stopped:	
abaratary Investigati	ionor			
aboratory Investigati Date Type	Range Date Test	ed Result	D	etails
Additional Information	ղ:			

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Case Number: 208446

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

		**Cigi	nt: 0.00
		Ag	je : 20
			DB : 20/02/1985
		Causali	ty: Causality possible
0	5 (5	a a winting	T(
Severity		•	Treatment
	Zyprexa and made ar self-harm. After it was 'flu-like' illness, which	nother attempt at s stopped she had a could have been	Zyprexa ceased.
	Reason:		
Started:		Stopped:	0
IS: Range Date Test	ed Result	D	etails
Range Date Test	ed Result	D	etails
		The patient continued Zyprexa and made ar self-harm. After it was 'flu-like' illness, which influenza or Zyprexa syndrome.	The patient continued to be suicidal on Zyprexa and made another attempt at self-harm. After it was stopped she had a 'flu-like' illness, which could have been influenza or Zyprexa withdrawal syndrome. Reason:

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Hospitalisation:

Case Number: 208452

Reported: 03/06/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Weight: 0.00

Age: 46

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Onset D	ate:						DC)B : 18/07/19	58	
Outco	me: Recovered	t		Causality: Causality possible						ble
action D	etails:									
Pre	eferred Term	Se	everity	Repo	ort Desc	ription		Tre	atmen	t
uicidal idea	ation		ar	ne patient expend a suicidal acombination of Zoohol.	ct while t	aking a		Zyprexa, Lexa ceased.	apro an	ıd alcohol
uicide atter	mpt									
Medicine				Rea	son:					
ZIFKLAA (SI	uspecieuj			Neas	30II.					
Batc		S	tarted:			Stopped:				
Lexapro (Sus	spected)			Reas	son:		Oral			
Batc	h:	s	tarted:			Stopped:	Olai			
ALCOHOL (S	suspected)			Reas	son:					
Oral L	Liquid						Oral			
Batc	h:	S	tarted:			Stopped:				
.aborator	y Investigati	ions:								
Date	Туре	Range	Date Tested	Result			D	etails		
\ dditiono	Linformation	••								
Additiona	I Information	1:								
ort Run: 04/0	06/2007 05:15PM	Ι Database: ρι	usime02	А	DRS004			Page	e 306	of 530
								, ago		2. 555



Hospitalisation:

Case Number: 208458

Reported: 03/06/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Age: 59

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Onset Date:			DC	DB : 04/09/1945
Outcome: Unknown			Causali	ty: Causality possible
action Details:				
Preferred Term	Severity	· ·	rt Description	Treatment
uicide attempt	Caused or prolonged inpatient hospitalisation	The patient expersuicide attempt a she attempted to	rienced suicidal ideation, nd homicidal ideation - kill her parents.	
omicidal ideation	Caused or prolonged inpatient hospitalisation			
edicine Details:				
DLANZAPINE (Suspected)		Reas	on:	
Batch:	Started:		Stopped:	
FLUOXETINE HYDROCHLORID		Reas		
			Oral	
Batch:	Started:		Stopped:	
aboratory Investigati	ions:			
Date Type	Range Date Teste	ed Result	D	etails
Additional Information	1:			



Case Number: 208460

Reported: 03/06/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

lospitalisation:					Aç	ge: 30			
Onset Date:				DOB : 07/12/1974					
Outcome: Un	known			Causality: Causality possible					
eaction Details:									
Preferred 1	erm	Se	everity	Repo	ort Description	Treatmer	nt		
Akathisia			m fu	nedications and	ntarily ceased all I within days she was in stless, obsessively suicidal				
Aggression Drug withdrawal syn Suicidal ideation	drome								
Medicine Details THIAMINE (Other drug				Roa	son:				
TITIAMINE (Other drug	,			Nea	3011.				
Batch:		St	tarted:		Stopped:				
ZYPREXA (Suspected)				Rea	son:				
Batch:		Si	tarted:		Stopped:				
VALIUM (Suspected)				Rea	son:				
Batch:		Si	tarted:		Stopped:				
_aboratory Inve		Ons: Range	Date Tested	Result	С	Details			
Additional Infor	mation	:							
oort Run: 04/06/2007	05:15PM	Database: pu	usime02	A	ADRS004	Page 308	of 530		



Hospitalisation:

Onset Date:

Case Number: 208466

Reported: 03/06/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Weight: 0.00

Age: 41

DOB: 30/06/1963

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Outcome: Unknown		Causal	ity: Causality possible
action Details:			
Preferred Term	Severity	Report Description	Treatment
kathisia	innationt	The patient became restless, developed akathisia and was suicidal and homicidal. He experienced a suicide attempt - tried to drive into a tree. He was also agitated.	Failed to respond to ECT or tricycles. Given Olanzapine 10mg and Zuclopenthixol 300mg.
gitation	Caused or prolonged inpatient hospitalisation		
uicide attempt	Caused or prolonged inpatient hospitalisation		
ledicine Details:			
AROPAX (Suspected)		Reason:	
		Oral	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
_aboratory Investigatio	one:		
Date Type	Range Date Test	ed Result D	Details
Additional Information	:		
oort Run: 04/06/2007 05:15PM	Database: pusime02	ADRS004	Page 309 of 530



Case Number: 208468

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

t Date: come: Unknown Details: Preferred Term Severity Report Description Treatment The patient experienced a serious suicidal attempt after three months of akathisia made serious, nearly lethal attempts, and developed deep vein thrombosis. Thrombosis Reason: Preferred Term Reason: Preferred Term Reason: Preferred Term Severity Report Description Treatment Withdrawal over prolonged period. Needed Warfarin. Withdrawal over prolonged period. Needed Warfarin. Withdrawal over prolonged period. Needed Warfarin. Weekly started: Started: Stopped: Reason: 15.0 Milligram Daily Stopped: MINE (Suspected) Reason: 200.0 Milligram Daily Oral Stopped: MINE MALEATE (Suspected) Reason: Stopped: MINE MALEATE (Suspected) Started: Started: Stopped:	Onset Date: Outcome: Unknown Preferred Term Preferred Term Suicide attempt The patient experienced a serious suicidal attempt after three months of akathisia - made serious, nearly lethal attempts, and developed deep vein thrombosis Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Batch: Started: Start	Reported: 03/06/2005					Weigl	nt: 0.00
Come: Unknown Details: Preferred Term Severity Report Description Treatment The patient experienced a serious suicidal attempt after three months of akathisia made serious, nearly lethal attempts, and developed deep vein thrombosis The Details: The Details: The patient experienced a serious suicidal attempt after three months of akathisia made serious, nearly lethal attempts, and developed deep vein thrombosis. The Details: THINDLACETATE (Suspected) Jection John Milligram Weekly Jection Started: Started: Started: Started: Started: Started: Stopped: John Milligram Daily Oral John Milligram Daily Oral John Stopped: John Milligram Daily Oral John Stopped: John Milligram Daily John Stopped: Joh	Outcome: Unknown Baction Details: Preferred Term Solicide attempt Akathisia Deep vein thrombosis Medicine Details: Wedicine Details: Wedicine Details: Batch: Started: Started: Started: Started: Started: Started: Started: Started: Starped: Started: Starped: S	lospitalisation:					Αg	je : 70Y
Preferred Term Severity Report Description Treatment Itempt The patient experienced a serious suicidal attempt after three months of akathisia - made serious, nearly lethal attempts, and developed deep vein thrombosis. Pre Details: INTHIXOL ACETATE (Suspected) Reason: Jection 200.0 Milligram Weekly Jatch: Started: Stopped: PINE (Suspected) Reason: Jis.0 Milligram Daily Jatch: Started: Stopped: Jatch: Started: Stopped: Jack Started: Stopped: Jack Started: Stopped: Jack Started: Stopped: Jack Started: Stopped: Jack Started: Stopped: Jack Started: Stopped: Jack Started: Stopped: Jack S	Preferred Term Severity Report Description Treatment Suicide attempt The patient experienced a serious suicidal attempt after three months of akathisia-made serious, nearly lethal attempts, and developed deep vein thrombosis. Withdrawal over prolonged attempt after three months of akathisia-made serious, nearly lethal attempts, and developed deep vein thrombosis. Wedicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Injection 200.0 Milligram Weekly Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: 15.0 Milligram Daily Batch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily Oral Batch: Started: Stopped: Date Type Range Date Tested Result Details	Onset Date:					DC	DB:
Preferred Term Severity Report Description Treatment Itempt The patient experienced a serious suicidal attempt after three months of akathisia - made serious, nearly lethal attempts, and developed deep vein thrombosis. INTHIXOL ACETATE (Suspected) Reason: Political Profession 200.0 Milligram Weekly	Preferred Term Severity Report Description Treatment Suicide attempt The patient experienced a serious suicidal attempt after three months of akathisia made serious, nearly lethal attempts, and developed deep vein thrombosis. Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Reason:	Outcome: Unknown				С	ausali	ty: Causality possible
The patient experienced a serious suicidal attempt after three months of akathisia made serious, nearly lethal attempts, and developed deep vein thrombosis. Interpretation	Akathisia Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Injection Started: Started: Started: Started: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet Started: Started: Started: Started: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet Started: Started: Started: Started: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet Started: Started: Started: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet Started: Started: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet Started: Started: Stopped: Date Type Range Date Tested Result Details Details	eaction Details:						
attempt after three months of aktahisia made serious, nearly lethal attempts, and developed deep vein thrombosis. Thrombosis	Akathisia developed deep vein thrombosis Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Injection Batch: Started: Started: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet Batch: Started: Started: Started: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet T	Preferred Term	Severity	Rep	ort Desci	ription		Treatment
Details: NTHIXOL ACETATE (Suspected) jection 200.0 Milligram Weekly statch: Started: Stopped: PINE (Suspected) 15.0 Milligram Daily statch: Started: Stopped: MINE MALEATE (Suspected) 200.0 Milligram Daily Oral statch: Started: Stopped: Additional Started: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped:	Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Injection Batch: Started: Started: Stopped: OLANZAPINE (Suspected) Batch: Started: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet Started: Started: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Batch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet Daily Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet Reason: Stopped: Stopped: Stopped: Daily Oral Batch: Stopped: Date Type Range Date Tested Result Details	Suicide attempt		attempt after thr made serious, n	ee month early leth	s of akathi al attempts	sia -	Withdrawal over prolonged period. Needed Warfarin.
Details: NTHIXOL ACETATE (Suspected) jection 200.0 Milligram Weekly satch: Started: Stopped: PINE (Suspected) 15.0 Milligram Daily satch: Started: Stopped: MINE MALEATE (Suspected) 200.0 Milligram Daily Oral satch: Started: Stopped: Additional Composition of the Compos	Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Injection 200.0 Milligram Weekly Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: 15.0 Milligram Daily Batch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily Oral Batch: Started: Stopped: Started: Stopped:	Akathisia						
Reason: jection 200.0 Milligram Weekly statch: Started: Stopped: PINE (Suspected) Reason: 15.0 Milligram Daily statch: Started: Stopped: MINE MALEATE (Suspected) Reason: ablet 200.0 Milligram Daily Oral statch: Started: Stopped: Stopped:	Reason:	Deep vein thrombosis						
jection 200.0 Milligram Weekly latch: Started: Stopped: PINE (Suspected) Reason: 15.0 Milligram Daily Stopped: MINE MALEATE (Suspected) Reason: ablet 200.0 Milligram Daily Oral statch: Started: Stopped: Stopped: Cory Investigations:	Injection 200.0 Milligram Weekly Batch: Started: Stopped:			D.				
Started: Stopped: PINE (Suspected) 15.0 Milligram Daily Started: Stopped: MINE MALEATE (Suspected) Started: Pine Stopped: Stopped:	Batch: Started: Stopped: OLANZAPINE (Suspected) Batch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet 200.0 Milligram Daily Oral Batch: Started: Stopped: Stopped: PReason: 200.0 Milligram Daily Oral Stopped: Stopped: Date Type Range Date Tested Result Details							
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15.0 Milligram Daily satch: Started: Stopped: MINE MALEATE (Suspected) Reason: ablet 200.0 Milligram Daily Oral satch: Started: Stopped:	Batch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily Oral Batch: Started: Stopped: Stopped: Stopped: Daily Oral Batch: Started: Stopped:		Started:			Stoppea:		
AMINE MALEATE (Suspected) Reason: Ablet 200.0 Milligram Daily Oral Astach: Started: Stopped:	Batch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily Oral Batch: Started: Stopped: Stopped: Stopped: Date Type Range Date Tested Result Details	OLANZAPINE (Suspected)	15.0					
MINE MALEATE (Suspected) ablet 200.0 Milligram Daily Oral atch: Started: Stopped: Cory Investigations:	Tablet 200.0 Milligram Daily Oral Batch: Started: Stopped: _aboratory Investigations: Date Type Range Date Tested Result Details	Potoh.		Milligram	Dally	Ctonnodi		
ablet 200.0 Milligram Daily Oral satch: Started: Stopped: cory Investigations:	Tablet 200.0 Milligram Daily Oral Batch: Started: Stopped:		Starteu.	Rea	son.	Stopped.		
atch: Started: Stopped:	Batch: Started: Stopped: -aboratory Investigations: Date Type Range Date Tested Result Details		200.0				Oral	
ory Investigations:	_aboratory Investigations: Date Type Range Date Tested Result Details			wiiiigraiii	Daily	Stonned:	Olui	
	Date Type Range Date Tested Result Details	_aboratory Investigations:						
	Additional Information:		Date Tes	sted Result			D	etails
	Additional Information:							
	Additional Information:	Laboratory Investigations: Date Type Range	Date Tes	sted Result			D	etails

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Case Number: 208476

Reported: 03/06/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisati						Age : 75Y				
Onset D				DOB:						
	me: Not yet rec	overea		Causality: Causality possible						
Reaction D	etans: eferred Term	Se	verity	Reno	ort Description	Treatment				
Oedema per		30	Pa		ed peripheral oedema an					
Cardiac failu	re									
Medicine				_						
ZYPREXA (Su			7.F M:		son: Unspecified psycho					
Table Batc		64	7.5 Mil	ligram L TERM	Daily Oral Stopped:					
Laborator Date	y Investigation	O NS: Range	Date Tested	Result		Details				
Buto	1,700	rango	Date Tooled	rtoduit		Dotailo				
Additiona	I Information	:								
leport Run: 04/0	06/2007 05:15PM	Database: pu	sime02	A	ADRS004	Page 311 of 530				



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	oa	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 208607
 Seq: 1
 Gender:
 F

 Reported:
 09/06/2005
 Weight:
 0.00

Hospitalisation: Required a visit to the doctor
Onset Date:

Age: 29Y
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Orgasmic sensation decreased		The patient has been unable to orgasm since commencing Zyprexa.	

Medicine Details:

ZYPREXA (Suspected)

Reason:

10.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Post stress disorder and on many medications.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208666 Seq: 1 Gender: F

Reported: 10/06/2005 Weight: 54.00 Hospitalisation: Age: 15

Onset Date: 08/06/2005 DOB: 21/06/1989

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life threatening		Akathisia -> given extra Olanzapine.
Akathisia	Life threatening		

Medicine Details:

Micalcinic Details.						
OLANZAPINE (Suspected)			Reason:			
	10.0	Milligram	Daily	Oral		
Batch:	Started:		S	Stopped:	0	
FLUOXETINE HYDROCHLORIDE (Suspected)		Reason:			
	20.0	Milligram	Daily	Oral		
Batch:	Started:		5	Stopped:	0	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

One patient with ADRs 206280, 206281, 206282, 206283, 208666. She takes Olanzapine to help her sleep. She is not psychotic (per reporter).

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208666 Seq: 1 Gender: F

Reported: 10/06/2005 Weight: 54.00 Hospitalisation: Age: 15

Onset Date: 08/06/2005 **DOB**: 21/06/1989

Outcome: Recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Drug withdrawal syndrome	Life threatening		

Medicine Details:

ilculcine Details.						
OLANZAPINE (Suspected)		R	eason:			
	10.0 Mi	lligram	Daily	Oral		
Batch:	Started:		Sto	opped:	0	
FLUOXETINE HYDROCHLORIDE (S	uspected)	R	eason:			
	20.0 Mi	lligram	Daily	Oral		
Batch:	Started:		Sto	opped:	0	

Laboratory Investigations:

Additional Information:

One patient with ADRs 206280, 206281, 206282, 206283, 208666. She takes Olanzapine to help her sleep. She is not psychotic (per reporter).

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208671 Seq: 1 Gender: M

Reported: 14/06/2005 Weight: 60.00 Hospitalisation: Age: 15

Onset Date: DOB: 03/08/1989

Outcome: Unknown Causality: Causality possible

Reaction Details:

100.00.00.00			
Preferred Term	Severity	Report Description	Treatment
Blood triglycerides increased	prolonged	whilst on olanzapine - date: 2 weeks post initiation and then 3 weeks post initiation	necessiated change of medication

Medicine Details:

OLANZAPINE (Suspected) Reason:

Tablet 12.5 Milligram 1 time Oral

Batch: Started: 23/05/2005 Stopped: 14/06/2005

Laboratory Investigations:

Laborato	i ji iii vootiga				
Date	Туре	Range	Date Tested	Result	Details
14/06/2005	Biochemistry				20/05/2005 triglyceride 0.8mmol/L; 2/6/2005 triglyceride 1.7mmol/L 9/6/05 triglyceride 3.8mmol/L

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 208713
 Seq: 1
 Gender: M

 Reported:
 16/06/2005
 Weight:
 0.00

 Hospitalisation:
 Age: 29

Onset Date: 21/05/2005 **DOB**: 01/11/1975

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Swollen tongue		difficulty speaking, shakey and trouble with	Treated with Cogentin 2mg oral 02/02/05 and 1mg 02/03/05
Coordination abnormal			
Nervousness			
Speech disorder			

Medicine Details:

OMEPRAZOLE (Other drug)		Reason:	
	20.0 Milligram		
Batch:	Started: 19/05/2005	Stopped:	
CLOPIXOL-ACUPHASE (Suspected)		Reason:	
Injection	100.0 Milligram	Daily	Intramuscular
Batch:	Started: 20/05/2005	Stopped:	
QUETIAPINE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 20/05/2005	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 21/05/2005	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:208837Seq: 1Gender:FReported:21/06/2005Weight:0.00Hospitalisation:Required a visit to the doctorAge: 37Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

٠,	Saction Botano									
	Preferred Term	Severity	Report Description	Treatment						
	Necrobiosis lipoidica diabeticorum		Patient developed Necrobiosis Lipoidica Diabeticorum on legs and fat necrosis.							
	Fat necrosis									

Medicine Details:

VALIUM (Suspected)		Reason:	Convulsions	
		As ne	cessary	
Batch:	Started:		Stopped:	
ZYPREXA (Suspected)		Reason:	Unspecified schizophrenia	
	22.5 Milligram	Daily		
Batch:	Started:	L TERM	Stopped:	0
TEGRETOL (Suspected)		Reason:	Convulsions	
Tablet	800.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	
DIABEX (Suspected)		Reason:	Diabetes mellitus	
Tablet	1.0 Gram	Daily	Oral	
Batch:	Started: 15/05/2005		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Family history: Grandmother developed type 1 diabetes in later years. Has had previous leg ulcer (from a tick bite) her blisters take a long time to heal. Seizures since 10 years of age.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 208869
 Seq: 1
 Gender:
 F

 Reported:
 21/06/2005
 Weight:
 0.00

 Hospitalisation:
 Age: 41Y

Onset Date: 15/02/2004 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

74.01.01. D 01401							
Preferred Term	Severity	Report Description	Treatment				
Gamma-glutamyltransferase increa		Patient experienced increased gamma glutamyl transferase, alanine aminotransferase and alkaline phosphatase levels.					
Alanine aminotransferase increase Blood alkaline phosphatase increase							

Medicine Details:

ZYPREXA (Suspected) Reason: Manic-depression psycho,manic

Tablet 10.0 Milligram Daily Oral

Batch: Started: 15/12/2003 Stopped:

Laboratory Investigations:

<u>Laborato</u>	i y ilittootiga				
Date	Туре	Range	Date Tested	Result	Details
21/06/2005	ALT = SGPT		15/06/2003	88 U/liter	
21/06/2005	ALT = SGPT		15/02/2004	229 U/liter	
21/06/2005	ALT = SGPT		15/01/2005	314 U/liter	
21/06/2005	ALT = SGPT		05/04/2005	273 U/liter	
21/06/2005	Bilirubin				Total 24
21/06/2005	GGT = SGGT =		15/06/2002	54 U/liter	
21/06/2005	GGT = SGGT =		15/06/2003	77 U/liter	

Additional Information:

History: Bipolar disorder.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208869 Seq: 1 Gender: F

 Reported: 21/06/2005
 Weight: 0.00

 Hospitalisation:
 Age: 41Y

 Onset Date: 15/02/2004
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected) Reason: Manic-depression psycho,manic

Tablet 10.0 Milligram Daily Oral

Batch: Started: 15/12/2003 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
21/06/2005	GGT = SGGT =		15/01/2005	350 U/liter	
21/06/2005	GGT = SGGT =		15/02/2004	176 U/liter	
21/06/2005	GGT = SGGT =		05/04/2005	180 U/liter	
21/06/2005	Other data		15/02/2004		Alkaline Phosphatase
21/06/2005	Other data		15/01/2005		Alkaline Phosphatase
21/06/2005	Other data		05/05/2005		Alkaline Phosphatase

Additional Information:

History: Bipolar disorder.

Report Run: 04/06/2007 05:15PM Database: pusime02 ADRS004 Page 319 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208945 Seq: 1 Gender: F

Reported: 22/06/2005 Weight: 0.00 Hospitalisation: Age: 42

Onset Date: 24/05/2005 DOB: 21/08/1962

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aspartate aminotransferase increa	prolonged inpatient hospitalisation	Five days after starting Olanzapine treatment the patient experienced elevated aspartate aminotransferase, alanine aminotransferase and gamma glutamyl transferase levels.	Olanzapine ceased.
	Caused or prolonged inpatient hospitalisation		
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected) Reason: Otr spec symp psychopathol nec

10.0 Milligram Daily Oral

Batch: Started: 19/05/2005 Stopped: 24/05/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
22/06/2005	ALT = SGPT		19/05/2005	20	
22/06/2005	ALT = SGPT		24/05/2005	305	
22/06/2005	AST = SGOT		19/05/2005	17	
22/06/2005	AST = SGOT		24/05/2005	205	
22/06/2005	GGT = SGGT =		19/05/2005	34	
22/06/2005	GGT = SGGT =		24/05/2005	76	
22/06/2005	SAP = ALP		19/05/2005	48	

Additional Information:

Dose was increased from 5mg per day at night to 10mg per day. Thyroid irregularities (thyroid disorder NOS).

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208945 Seq: 1 Gender: F

Reported: 22/06/2005 Weight: 0.00 Hospitalisation: Age: 42

Onset Date: 24/05/2005 **DOB**: 21/08/1962

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected) Reason: Otr spec symp psychopathol nec

10.0 Milligram Daily Oral

Batch: **Started**: 19/05/2005 **Stopped**: 24/05/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
22/06/2005	SAP = ALP		24/05/2005	78	

Additional Information:

Dose was increased from 5mg per day at night to 10mg per day. Thyroid irregularities (thyroid disorder NOS).

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Ren	ort	Deta	ils:
-----	-----	------	------

Case Number: 208978 Seq: 1 Gender: F

Reported: 23/06/2005 Weight: 55.00 Hospitalisation: Age: 75Y

Onset Date: 20/05/2005 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Pain in extremity		The patient experienced aching legs, severe enough for her to refuse to take the drug.	Zyprexa Zydis ceased.

Medicine Details:

Zyprexa Zydis (Suspected) Reason: Unspecified psychosis

Wafer 5.0 Milligram Daily Oral

Batch: Started: 26/04/2005 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208989 Seq: 1 Gender: F

Reported: 23/06/2005 Weight: 0.00 Hospitalisation: Age: 65

Onset Date: 24/03/2005 **DOB**: 18/12/1939

Outcome: Recovered 24/03/2005 Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Convulsion	prolonged	lasted for 25 minutes. There was no history of epilepsy.	IV Diazepam.

Medicine Details:

CELEBREX (Other drug) Reason: Osteoarthritis

Batch: Started: Stopped:

HYDROCHLOROTHIAZIDE (Other drug) Reason: Essential benign hypertension

Batch: Started: Stopped:

CANDESARTAN CILEXETIL (Other drug) Reason: Essential benign hypertension

Batch: Started: Stopped:

Risperdal Consta (Suspected) Reason: Unspecified psychosis

Injection 1.0 Dose Unspecified 1 time Intramuscular Batch: Started: 10/03/2005 Stopped: 10/03/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient history: thiazide - hyponatraemia

Report Run: 04/06/2007 05:16PM Database: pusime02 ADRS004 Page 323 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	port	: Dei	tails:

Case Number: 208989 Seq: 1 Gender: F

Reported: 23/06/2005 Weight: 0.00 Hospitalisation: Age: 65

Onset Date: 24/03/2005 **DOB**: 18/12/1939

Outcome: Recovered 24/03/2005 Causality: Causality possible

Reaction Details:

Medicine Details:

modifie Botalio.		
ZYPREXA (Suspected)		Reason: Unspecified psychosis
	5.0 Milligram	Daily Oral
Batch:	Started: 17/03/2005	Stopped: 24/03/2005
RISPERDAL (Suspected)		Reason: Unspecified psychosis
	1.0 Milligram	Daily Oral
Batch:	Started: 18/02/2005	Stopped: 17/03/2005

Laboratory Investigations:

Additional Information:

Patient history: thiazide - hyponatraemia

Report Run: 04/06/2007 05:16PM Database: pusime02 ADRS004 Page 324 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 209083 Seq: 1 Gender: F

Reported: 24/06/2005 Weight: 60.00 Hospitalisation: Age: 47

Onset Date: 15/02/2005

Outcome: Recovered

DOB: 23/11/1957

Causality: Causality certain

Reaction Details:

todotion botanoi			
Preferred Term	Severity	Report Description	Treatment
Condition aggravated		The patient experienced worsening of rheumatoid arthritis producing frank joint effusion in one knee.	Reducing dose.

Medicine Details:

Medicine Details.					
EFEXOR-XR (Other drug)			Reason:		
	2.5	Gram			
Batch:	Started:		L TERM	Stopped:	
TEMAZEPAM (Other drug)			Reason:		
Capsule	20.0	Milligram	Daily		Oral
Batch:	Started:		L TERM	Stopped:	
SODIUM VALPROATE (Other drug)			Reason:		
	1.0	Gram	Daily		
Batch:	Started:		STERM	Stopped:	
ZYPREXA (Suspected)			Reason:		
	5.0	Milligram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

This seemed to be an Olanzapine affect since it improved with dose reduction and increase with rechallenge at higher dose.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 209302 Seq: 1 Gender: F

Reported: 30/06/2005 Weight: 90.00 Hospitalisation: Required a visit to the doctor Age: 34

Onset Date: 06/04/2005 **DOB**: 26/07/1970

Outcome: Recovered 07/04/2005 Causality: Causality possible

Reaction Details:

Caction Detailer			
Preferred Term	Severity	Report Description	Treatment
Transient ischaemic attack		Patient experienced transient ischaemic attack.	

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
PROTHIADEN (Suspected)		Reason: Depression	
	225.0 Milligram	Daily	

Batch: Started: L TERM Stopped:

Laboratory Investigations:

<u> Luboi atoi</u>	y ilivostiga				
Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Hospitalisation:

Case Number: 209424

Reported: 04/07/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Weight: 0.00

Age: 25Y

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Onset Da	ate:						DOB:		
Outcon	ne: Death					C	Causality:	Causality possi	ble
action De									
Pre	ferred Term		everity		Report D	escription		Treatmen	t
sthma		Death	1	administra agitated si simultaned symptoms the reporti	ation the patate appear ously with a and dyspoing psychia us, with de	of IM Olanzap tient died. His rs to have occu acute asthmati- noea, describe- trist as status ath following sl	urred c d by		
eath		Death	1						
ledicine [Details: AZINE HYDROCH	LORIDE (Othe	r drug)		Reason:		Oral		
Batch	n:	s	tarted:			Stopped:			
ZYPREXA (Su	spected)				Reason:	Unspecified s	chizophrenia		
							Oral		
Batch	n:	S	tarted:			Stopped:		0	
CLONAZEPA	VI (Suspected)				Reason:	Otr spec sym	p psychopatho	ol nec	
				Milligram	1 tiı				
Batch		S	tarted:		Bassani	Stopped:		al non	
Zyprexa IM (S Injectio			10.0	Milligram	Reason: Dai		p psychopatho Intramuscul		
Batch		ç	tarted:	wiiiigram	Dai	Stopped:		0 0	
Date	1.		tarteu.			эторреи.		0	
abaratan	, Invoctianti	one							
Date	y Investigati Type	Range	Date Test	ted Res			Details		



Case Number: 209449

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

•					Weigl	
	ion: Admitted	to hospital			Ąg	je : 30Y
Onset D	oate: 12/09/200)3			DC	DB:
Outco	me: Recovere	d			Causali	ty: Causality possible
eaction D			T			T
	eferred Term		everity Report Description		Treatment	
iver functio	n test abnorma	prolon inpatie	ged tes	ne patient deve st abnormality	eloped mixed liver function	Withdrawal of Cephazolin.
Medicine ASPIRIN (Ot				Rea	son:	
Bato	·h·	St	arted:		Stopped:	
	MOL (Other drug)		ui tou.	Rea	son:	
	(0					
	:h:	St	arted:		Stopped:	
Bato						
	DIUM (Other drug	1)		Rea	son:	
HEPARIN SC				Rea	son:	
HEPARIN SC	:h:		arted:		son: Stopped:	
HEPARIN SC	:h:		arted:		son:	
HEPARIN SC Batc	ch: Other drug)	St			Stopped:	
HEPARIN SC	ch: Other drug)	St	arted: arted:		son: Stopped:	
Bato MAXOLON (6 Bato	ch: Other drug) ch: ry Investigat	St ions:	arted:	Rea	Stopped: Stopped:	
Bato Bato Bato Bato Bato Date	ch: Other drug) ch: ry Investigat	St		Rea Result	Stopped: Stopped: Stopped:	etails
Bato Bato Bato Bato Date 05/07/2005	ch: Other drug) ch: ry Investigat	St ions:	arted:	Rea Result	Stopped: Stopped:	etails

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: 05/07/2005 spitalisation: Admitted to he Onset Date: 12/09/2003 Outcome: Recovered action Details:	ospital		Ag DO	t: 0.00 e: 30Y
edicine Details: CEPHAZOLIN SODIUM (Suspected)		Reason:	Otr&nos infec¶sit of	diseases
Injection	3.0 Gram	Daily	Intraver	
Batch:	Started: 08/09/2003		Stopped: 12/09/2	003
LANZAPINE (Suspected)		Reason:	Unspecified psychosis	
	15.0 Milligram	Daily		
Batch:	Started : 01/01/2002		Stopped:	
aboratory Investigation.	s:			
dditional Information:				
oort Run : 04/06/2007	atahase: nusime02	ADRS00)4	Page 320 of 53

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Case Number: 209543

Reported: 06/07/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Weight: 73.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

	on. Required a	visit to the doctor	•	Ag	je: 74
Onset Da	ate: 23/05/2005	5		DC	DB : 07/03/1931
Outcor	me: Recovered			Causali	ty: Causality probable
eaction De					
Pre	eferred Term	Severity	Repor	t Description	Treatment
Hyperglycae	mia		glucose - hypergly	enced instability in blood caemia immediately cement of Olanzapine.	Olanzapine ceased.
Blood glucos	se fluctuation				
Medicine l	Details:				
ASTRIX 100 (Reaso	on:	
Batcl	h:	Started:		Stopped:	
LITHIUM CAR	RBONATE (Other dr	rug)	Reaso	on:	
Batcl	h:	Started:		Stopped:	
	(04)		Reaso		
DIAFORMIN (Otner arug)		rease		
DIAFORMIN (Started:		Stopped:	
	h:	Started:		Stopped:	
Batci DIAMICRON (h: (Other drug)		Reaso	on:	
Batcl	h: (Other drug)	Started: Started:	Reaso		
Batci DIAMICRON (Batci Laborator	h: (Other drug) h: y Investigatio	Started:	Reaso	on: Stopped:	etails
Batcl DIAMICRON (Batcl	h: (Other drug) h:	Started:	Reaso	on: Stopped:	etails
Batcl DIAMICRON (Batcl Laborator Date	h: (Other drug) h: y Investigatio	Started: Ons: Range Date	Reaso	on: Stopped:	etails

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Detail	s:					
Hospitalisation: Onset Date:	06/07/2005 Required a visit to	Seq: 1				73.00
Reaction Detai					,	, ,
Medicine Det				Person		
OLANZAPINE (Sus	speciea)	2.5	6 Milligram	Reason: Daily		
Batch:		Started:			Stopped:	
Laboratory In	vestigations:					
Additional Inf	formation:					

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

•	etails:				
Case Num	nber: 209550	Seq: 1		C	Gender: M
Repo	rted: 06/07/20	005		V	Veight: 0.00
-lospitalisa	tion:				Age: 33
Onset I	Date: 15/12/20	004			DOB : 29/08/1971
Outco	ome: Unknow	n		Ca	usality: Causality possible
eaction [Details:				
Pi	referred Term	Severity	Rep	oort Description	Treatment
Weight incr	reased		Patient experie	nced weight gain.	On 16 May 2005 he ynwent a left sided subcutaneous mastectomy.
Medicine			D		
OLANZAPIN	NE (Suspected)	40		ason: Unspecified schi	zophrenia
Bat	ech.	10 Started:	0.0 Milligram	Daily	
				Stopped:	
		Started.		Stopped:	
				Stopped:	
	ry Investiga	ations:	Γested Result	Stopped:	Details
Laborato		ations:	Γested Result	Stopped:	Details

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Num	ber: 210213	Seq: 1					Gender:	F	
Repor	ted: 28/07/200	5					Weight:	0.00	
Hospitalisat	ion:						Age:	41	
Onset D	ate: 20/06/200	5					DOB:	04/04/1964	
Outco	me: Unknown					С	ausality:	Causality possi	ble
Reaction D	etails:								
Pro	eferred Term	Severity		Repo	ort Des	scription		Treatmen	t
Tardive dysł	kinesia		The pa	tient deve esia.	loped i	mild tardive			
Medicine				Reas	son:				
Table				r.cu.	JOII.		Oral		
Bato		Started:				Stopped:	0.4.		
EFEXOR (Su				Reas	son:	оторрош.			
	opecies,						Oral		
Bato	h:	Started:				Stopped:	Orai		
SEROQUEL	(Suspected)			Reas	son:	Unspecified ps	sychosis		
Table		600.0) Milligran	n	Daily		Oral		
Bato	h:	Started:	J	S TERM		Stopped:		0	
OLANZAPINI	E (Suspected)			Reas	son:				
		5.0) Milligran	n	Daily		Oral		
Bato	h:	Started: 1	1/09/2004			Stopped:	29/09/2004		
									<u> </u>
Laborator Date	y Investigat		atad	Dogult			Deteil		
Date	Туре	Range Date Te	sieu	Result			Detail	8	
Additiona	l Informatio	n:							

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	/07/2005	Seq: 1			Gende Weigh	er: M nt: 67.00
ospitalisation: Re	quired a visit to	o the doctor			Ag	e: 68
Onset Date: 22/					_	B : 02/03/1937
Outcome: Re			05/07/2005		Causalit	ty: Causality probable
eaction Details: Preferred T		Severity	Repo	ort Descrip	tion	Treatment
		3013,	The patient expe			Olanzapine ceased.
.,,po.,g.,,caca			hyperglycaemia commencing Ola monitoring is usu a rapid increase	two weeks inzapine. ⊦ ially 7 or 8	after lome glucose mmol. He had	
Medicine Details CARBAMAZEPINE (Otl			Rea	son: Unsp	pecifid affective psy	ychosis
Batch:		Started:			Stopped:	
		Started:	Reas	S	stopped: ential benign hyper	tension
Batch: TRITACE (Other drug) Batch:		Started:	Reas	son: Esse	ential benign hyper	tension
TRITACE (Other drug)			Reas Reas	son: Esse		
TRITACE (Other drug) Batch: ASPIRIN (Other drug)		Started:		son: Esse son: Prop	ential benign hyper Stopped: hylactic inoculation	
TRITACE (Other drug) Batch: ASPIRIN (Other drug) Batch:				son: Esse son: Prop	ential benign hyper	
Batch: ASPIRIN (Other drug) Batch: Batch: DIAMICRON (Other drug)		Started: Started:	Reas	son: Esse son: Prop son: Diab	ential benign hyper Stopped: hylactic inoculation Stopped: etes mellitus	
TRITACE (Other drug) Batch: ASPIRIN (Other drug) Batch: DIAMICRON (Other drug)	ng)	Started:	Reas	son: Esse son: Prop son: Diab	ential benign hyper stopped: hylactic inoculation stopped:	
Batch: ASPIRIN (Other drug) Batch: Batch: DIAMICRON (Other drug)	ug) stigations:	Started: Started:	Rea:	son: Esse son: Prop son: Diab	ential benign hyper Stopped: hylactic inoculation Stopped: etes mellitus Stopped:	

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Case Number: 210256

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported:	29/07/2005			Weight:	67.00
ospitalisation:	Required a visit to the	doctor		Age:	
Onset Date:	22/06/2005			DOB:	02/03/1937
Outcome:	Recovered	05/07/2	.005	Causality:	Causality probable
eaction Detai	ils:				
Medicine Det	ails:				
DIABEX (Other dru			Reason:	Diabetes mellitus	
Batch:		Started:		Stopped:	
ZYPREXA (Suspec	cted)		Reason:	Unspecifid affective psych	osis
		10.0 Milligram	Daily		
Batch:		Started: 09/06/2005		Stopped: 30/06/2005	i
	41 41				
Laboratory In	vestigations:				
Additional Inf	formation:				
Additional iiii	omation.				
			ADDSOC		

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:210332Seq: 1Gender: MReported:02/08/2005Weight: 0.00Hospitalisation:Admitted to hospitalAge: 39

Onset Date: 30/06/2005 DOB: 09/05/1966

Outcome: Recovered 04/07/2005 Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Hepatitis			Ceased Mirtazapine, Olanzapine, Valproate, Carbamazepine, Cephalexin. Monitor, ultrasound.
Autoimmune hepatitis			

Medicine Details:

MIRTAZAPINE (Suspected)		Reason:	Depression		
Batch:	Started: 22/06/2005		Stopped:	28/06/2005	0
OLANZAPINE (Suspected)		Reason:	Depression		
Batch:	Started : 22/06/2005		Stopped:	28/06/2005	0
SODIUM VALPROATE (Suspected)		Reason:	Depression		
Batch:	Started: 22/06/2005		Stopped:	28/06/2005	0
CARBAMAZEPINE (Suspected)		Reason:	Depression		
Batch:	Started: 22/06/2005		Stopped:	28/06/2005	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 210 Reported: 02 Hospitalisation: Ad Onset Date: 30 Outcome: Re Reaction Details:	/08/2005 mitted to hospital /06/2005 covered	1 04/07/20	05		0.00	
CEPHALEXIN (Suspec		1	Reason: Other pro	phylactic procedu	ıres	
Batch:	St	carted: 13/06/2005	Stopp	ed: 29/06/2005	5 0	
Laboratory Inve	stigations:					
Additional Infor	mation:					

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 210448
 Seq: 1
 Gender: M

 Reported:
 05/08/2005
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 30

Onset Date: 24/05/2005 **DOB**: 28/06/1974

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation		Olanzapine ceased.

Medicine Details:

viedicine Details:				
PARACETAMOL (Other drug)		Reason:	Pain	
	Antigen un	it		
Batch:	Started:		Stopped:	
LORAZEPAM (Other drug)		Reason:	Otr spec symp psychopatho	ol nec
	1.0 Milligram			
Batch:	Started:		Stopped:	
OLANZAPINE (Suspected)		Reason:	Unspecified schizophrenia	
	10.0 Milligram	Daily	1	
Batch:	Started: 22/05/2005		Stopped:	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
05/08/2005	Other data				ANC - 22/05/05 - 3.97 and 25/05/05 0.96.

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:210508Seq:1Gender:MReported:08/08/2005Weight:0.00Hospitalisation:Admitted to hospitalAge:23

Onset Date: 14/07/2005 **DOB:** 13/08/1981

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation	The patient had a five day history of nausea, vomiting, thirst and polyurea. He was diagnosed with diabetic ketoacidosis.	
Diabetic ketoacidosis	Caused or prolonged inpatient hospitalisation		
Polyuria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Other drug)		Reason: Depression
	50.0 Milligram	Daily
Batch:	Started:	Stopped : 01/07/2005
STELAZINE (Other drug)		Reason: Unspecified schizophrenia
	5.0 Milligram	Daily
Batch:	Started: 15/07/2004	Stopped : 01/07/2005
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia
	20.0 Milligram	Daily Oral
Batch:	Started: 15/07/2004	Stopped: 19/07/2005 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
08/08/2005	Serum glucose				BSL = 18.3, pH = 7.13, Lactate = 1.8, K+ = 3.6

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls	:
----	----	----	----	-----	----	---

Case Number:210508Seq: 1Gender:MReported:08/08/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 23

Onset Date: 14/07/2005 **DOB**: 13/08/1981

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u>teaction betails.</u>			
Preferred Term	Severity	Report Description	Treatment
Thirst	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Other drug)		Reason: Depression
	50.0 Milligram	Daily
Batch:	Started:	Stopped: 01/07/2005
STELAZINE (Other drug)		Reason: Unspecified schizophrenia
	5.0 Milligram	Daily
Batch:	Started: 15/07/2004	Stopped: 01/07/2005
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia
	20.0 Milligram	Daily Oral
Batch:	Started: 15/07/2004	Stopped: 19/07/2005 0

Laboratory Investigations:

Additional Information:

Report Run: 04/06/2007 05:16PM Database: pusime02 ADRS004 Page 340 of 530



Case Number: 210522

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 09/08/200)5		Weigh	t: 0.00			
ospitalisation:		Age : 27Y					
Onset Date: 15/07/200	05		DO	B:			
Outcome: Not yet re	ecovered	Causality: Causality possible					
eaction Details:							
Preferred Term	Severity	Report Descript	ion	Treatment			
Arrhythmia		Patient developed arrhythmi beginning Zyprexa a couple	a after				
		beginning Zyprexa a deaple	or years ago.				
Medicine Details:							
ZYPREXA (Suspected)		Reason:					
	.	_					
Batch:	Started:		topped:				
Laboratory Investigat		ted Result	De	otails			
Date Type	Range Date Test	ed Result	De	etalis			
A alditi a va al lusta vuos ati a							
Additional Informatio	·n:						
port Run: 04/06/2007 05:16PI	M Database: pusime02	ADRS004		Page 341 of 53			

Rep



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

 Report Details:

 Case Number:
 210550
 Seq:
 1
 Gender:
 M

 Reported:
 10/08/2005
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 43

Onset Date: 12/07/2005 DOB: 03/05/1962

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose	Caused or prolonged inpatient hospitalisation	Patient experienced prescribed overdose, cardiac failure and cardiomyopathy.	Olanzapine dose reduced to 10mg daily and Trifluoperazine dose reduced to 5mg daily.
Cardiac failure	Caused or prolonged inpatient hospitalisation		
Cardiomyopathy	Caused or prolonged inpatient hospitalisation		

Medicine Details:

<u>wealcine Details:</u>				
STELAZINE (Other drug)		Reason:	Unspecified psychosis	
	10.0 Milli	gram Daily	Oral	
Batch:	Started:		Stopped:	
HALOPERIDOL (Suspected)		Reason:		
Batch:	Started:		Stopped:	0
ZYPREXA (Suspected)		Reason:	Unspecified psychosis	
	30.0 Milli	gram Daily	,	
Batch:	Started:	L TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	210569	Seq:	1			Ger	nder: M		
Reported:	11/08/200)5				Wei	ght: 0.00		
ospitalisation:	Admitted	to hospital					Age: 37		
Onset Date:	01/04/200)5				Γ	OOB: 19/02	/1968	
Outcome:	Recovere	ed		15/08/2005		Causa	ality: Causa	ality proba	able
action Deta	ils:								
Preferr	ed Term	Sev	verity	Repo	rt Descript	ion	-	Treatmen	ıt
leutrophilia		Cause prolong inpatie hospita	ged	eutrophilia susp	ected.		Zyprexa ce	eased.	
ledicine Det				Reas	on:				
Tablet	,		Mil	igram		Oral			
Batch:		Sta	arted:		St	topped: 17/0			
aboratory Ir	nvestigat	tions:							
Date	Туре	Range	Date Tested	Result			Details		
dditional In	formatio	n:							

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls	:
----	----	----	----	-----	----	---

Case Number: 210695 Seq: 1 Gender: M
Reported: 15/08/2005 Weight: 60.00
Respitalisation: Required a visit to the dector.

Hospitalisation: Required a visit to the doctor

Onset Date: 15/10/2004

Age: 14

DOB: 03/05/1990

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed		The patient developed acute urinary retention lasting a couple of days when dose of Olanzapine was temporarily increased.	
Urinary retention			

Medicine Details:

HALOPERIDOL (Other drug)		Reason: Unspecified psychosis
Batch:	Started: 15/10/2004	Stopped:
OLANZAPINE (Other drug)		Reason: Unspecified psychosis
	20.0 Milligram	
Batch:	Started:	Stopped:
OLANZAPINE (Suspected)		Reason: Unspecified psychosis
	20.0 Milligram	Daily
Batch:	Started:	Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 210847 Seq: 1 Gender: F

Reported: 17/08/2005 Weight: 47.00 Hospitalisation: Age: 19

Onset Date: 03/08/2005 **DOB**: 28/04/1986

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed		The patient developed acne. A large acneiform lesion first started after increase in dose of Olanzapine from 10mg to 15mg.	

Medicine Details:

Lexapro (Other drug)		Reason: Phobic neurosis	
	10.0 Milligram	Daily Oral	
Batch:	Started:	Stopped: 18/07/	2005
OLANZAPINE (Suspected)		Reason:	
	15.0 Milligram	Daily	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History: Previous treatment with SSRI.

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Case Number: 211097

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

ospitalisation:		Weight: 0.00				
ospitansation.			Α	ge : 46		
Onset Date: 08/08/2005			DOB : 27/02/1959			
Outcome: Unknown		Causality: Causality possible				
eaction Details:						
Preferred Term	Severity	<u> </u>	ort Description	Treatment		
achycardia		elevated creatin	nced tachycardia 90-110, ine kinase reported as neuroleptic malignant	Clopine withheld.		
Blood creatine phosphokinase						
leuroleptic malignant syndron	ne					
Pyrexia						
Medicine Details: LORAZEPAM (Other drug)		Rea	ison:			
Tablet	6.0	Milligram	Oral			
Batch:	Started:	g. s!	Stopped:	0		
CLONAZEPAM (Other drug)	Otarioa.	Reason:				
(Julio Gray)		1,00				
Batch:	Started:		Stopped:			
PARACETAMOL (Other drug)		Rea	son:			
Tablet	4.0	Gram	Oral			
Batch:	Started:		Stopped:			
			son:			
OLANZAPINE (Suspected)		Milligram	Oral			
Tablet				0		
	20.0 Started:		Stopped:	0		
Tablet Batch:	Started:		Stopped:	0		
Tablet	Started:	sted Result		0 Details		

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	211097	Seq: 1				Gender:	M	
Reported:	25/08/2005				1	Neight:	0.00	
Hospitalisation:						Age:	46	
Onset Date:	08/08/2005					DOB:	27/02/1959	
Outcome:	Unknown				Ca	usality:	Causality possible	
Reaction Detai	ils:							
Medicine Det								
Aripiprazole (Susp	pected)			Reason:				
Tablet			Milligram			Oral		
Batch:		Started:			Stopped:		0	
QUETIAPINE (Sus	pected)			Reason:				
Batch:		Started:			Stopped:			
CLOPINE (Suspec	ted)			Reason:				
Tablet			Milligram	Daily		Oral		
Batch:		Started: 26	5/07/2005		Stopped:	09/08/2005	5	
I aboratory In	vestigations:							
Laboratory III	ivostigations.							
Additional Inf	formation:							

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 211157
 Seq: 1
 Gender:
 M

 Reported:
 29/08/2005
 Weight:
 0.00

 Hospitalisation:
 Age: 61Y

Onset Date: 01/03/2005 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	prolonged	The patient experienced rolling of the tongue, tremor of the hands and chest pain.	
Chest pain	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TEMAZEPAM (Other drug)		Reason:	
Tablet	10.0 Milligram		Oral
Batch:	Started: 15/09/2004	Stopped:	
ISOSORBIDE DINITRATE (Other drug)		Reason:	
Tablet	60.0 Milligram		Oral
Batch:	Started: 15/09/2004	Stopped:	
DILTIAZEM HYDROCHLORIDE (Other drug)	Reason:	
Capsule	180.0 Milligram		Oral
Batch:	Started: 15/09/2004	Stopped:	
METOPROLOL TARTRATE (Other drug)		Reason:	
Tablet	50.0 Milligram		Oral
Batch:	Started: 15/09/2004	Stopped:	

Laboratory Investigations:

Edbordtory investigations:							
	Date	Туре	Range	Date Tested	Result	Details	

Additional Information:

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Case Number: 211157

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

ospitalisation:	29/08/2005			Weigh	1. 0.00
ospitalisation.				Age	e: 61Y
Onset Date:	01/03/2005			DOI	3:
	Not yet recovered			Causality	y: Causality possible
action Detai	ls:				
ledicine Deta					
	ECANOATE (Suspected)		Reason:		
Injection		50.0 Milligram	Weekly		
Batch:		Started: 15/09/2004		Stopped:	
	E HYDROCHLORIDE (Sus		Reason:		
Tablet		5.0 Milligram	As neces	ssary Oral	
		Started: 15/09/2004		Stopped:	
Batch:					
	pected)		Reason:		
	pected)	15.0 Milligram	Reason: Daily	Oral	
DLANZAPINE (Sus	pected)	15.0 Milligram Started: 15/09/2004		Oral Stopped:	
OLANZAPINE (Sus Tablet	pected)				
OLANZAPINE (Sus Tablet	pected)				
OLANZAPINE (Sus Tablet	pected)				
OLANZAPINE (Sus Tablet Batch:					
OLANZAPINE (Sus Tablet Batch:	pected)				
OLANZAPINE (Sus Tablet Batch:					
DLANZAPINE (Sus Tablet Batch:					
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Case Number: 211221

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

spitalisation:				= =	eight: 0.00		
			Age: 41Y				
Onset Date: 31/	/07/2005		DOB:				
	ot yet recovered			Caus	sality: Causality possible		
action Details:		O a comita d	D (5	Na a seinti a a	T		
Preferred 1	rerm	Severity	-	Description	Treatment		
iapism		line	e patient experier	iced priapism.			
edicine Details			Reason:				
	- (0						
Batch:		Started:		Stopped:			
ENLAFAXINE HYDRO	OCHLORIDE (Other d	rug)	Reason:				
		.					
Batch:	\	Started: Stopped:			va navahasia		
)	2.5 Milli	Reason: gram Da	•			
ZYPREXA (Suspected)							
ZYPREXA (Suspected) Batch:		Started: 15/07/20		Stopped:			
				-			
		Started : 15/07/20	005	-	Details		

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:211380Seq:1Gender:MReported:06/09/2005Weight:0.00Hospitalisation:Treated in Accident/Emergency DepartmentAge:23

Onset Date: 21/08/2005 **DOB**: 21/09/1981

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		The patient had a seizure, was found frothing at the mouth and had unresponsive pupils approximately four weeks after commencing Clozaril. He had not received his previous evening dose as, according to his mother, he had been in a 'bad mood' and upset.	Taken to casualty department for post-ictal monitoring.
Blood prolactin increased Drug withdrawal syndrome Foaming at mouth			

Medicine Details:

Medicine Details.			
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
CLOZARIL (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 28/07/2005	Stopped: 2	21/08/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
06/09/2005	Other data				Clozapine 0.18, Norclozapine 0.12
06/09/2005	Prolactin	<400	22/08/2005	444	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 211459 Seq: 1 Gender: F

Reported: 05/09/2005 Weight: 45.00 Hospitalisation: Age: 82

Onset Date: 16/08/2005 **DOB**: 18/12/1922

Outcome: Unknown Causality: Causality possible

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
Ī	Liver function test abnormal		Patient experienced increased liver function tests	Ceased Olanzepine

Medicine Details:

HEPARIN SODIUM (Other drug)		Reason:			
Injection	10.0 Thousand Inte	rnat		Subcutaneous	3
Batch:	Started: 07/08/2005	Sto	opped:		
OLANZAPINE (Suspected)		Reason:			
Wafer	2.5 Milligram	Daily		Sublingual	
Batch:	Started: 12/08/2005	Sto	opped:	16/08/2005	0
Hivita Liquivita Tonic (Suspected)		Reason:			
Oral Liquid	30.0 Millilitre	Daily		Oral	
Batch:	Started: 12/08/2005	Sto	opped:	16/08/2005	
PARACETAMOL (Suspected)		Reason:			
	4.0 Gram	Daily			
Batch:	Started: 09/08/2005	Sto	opped:	17/08/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/09/2005	ALT = SGPT		16/08/2005	1200	
05/09/2005	AST = SGOT		16/08/2005	1200	
05/09/2005	Albumin		16/08/2005	33	
05/09/2005	Bilirubin		16/08/2005	16	
05/09/2005	GGT = SGGT =		16/08/2005	65	
05/09/2005	Protein		16/08/2005	62	
05/09/2005	SAP = ALP		16/08/2005	163	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:				
Case Number: 211459 Reported: 05/09/2005 Hospitalisation: Onset Date: 16/08/2005 Outcome: Unknown Reaction Details:	Seq: 1			45.00
Medicine Details: TRIMETHOPRIM (Suspected)		Reason:		
Batch:	300.0 Milligram Started: 07/08/2005	Daily	Stopped: 08/08/2005	
Laboratory Investigations:				
Additional Information:				

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE, ZYPREXA, Zyprexa IM, Zyprexa Zydis

Report Details:

Gender: F Case Number: 211557 Seq: 1 Reported: 09/09/2005 Weight: 83.00

Hospitalisation: Required a visit to the doctor Age: 52

Onset Date: 15/06/2005 **DOB:** 10/03/1953

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal			Stopped Zyprexa and increased fluids.
Abdominal distension			
Dry mouth			
Oedema peripheral			
Thirst			

Medicine Details:

Batch:

Lexapro (Other drug) Reason: Depression

> 30.0 Milligram Oral

> > Stopped:

Batch: Started: 15/02/2005 Stopped:

STILNOX (Other drug) Reason: Specific disorders of sleep

Tablet 10.0 Milligram

Started: Stopped:

Symbicort Turbuhaler 200/6 (Other drug) Reason: Asthma

Inhalation 4.0 Dose Unspecified Inhalation

Started: ZYPREXA (Suspected) Anxiety neurosis Reason:

> 2.5 Milligram Daily

Batch: Started: 09/06/2005 Stopped: 02/09/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	211557	Seq: 1		Gender:	F
_	09/09/2005			Weight:	
Hospitalisation:		o the doctor		Age:	
Onset Date:					10/03/1953
	Not yet recovered	d		Causality:	Causality possible
Reaction Detai	ls:				
Medicine Deta	ails:				
ALPRAZOLAM (Su	spected)		Reason:	Otr respiratory systm disea	ases
Tablet		4.0 Milligram	Daily		
Batch:		Started: 09/06/2005		Stopped:	
Laboratory In	vestigations:				
Additional Inf	ormation:				

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Case Number: 211777

Reported: 20/09/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

spitalisation:			_	e : /0Y		
Onset Date:		DOB:				
Outcome: Not yet reco	vered		Causalit	y: Causality possible		
ction Details:						
Preferred Term	Severity		escription	Treatment		
edation		so severely sedated a chair and cannot ris	eeks after beginning ent deteriorated e of this report, she is that she is slumped in se from the chair. The eloped a urinary tract			
nary tract infection						
edicine Details:		Reason:	Unspecified psychosis			
Tablet			Oral			
Batch:	Started:		Stopped:	Continuing.		
PREXA (Suspected)		Reason:	Unspecified psychosis			
Tablet	5.0	Milligram Dail	y Oral			
Batch:	Started: 15/	07/2005 S TERM	Stopped:	Continuing.		
aboratory Investigatio Date Type	P ns: Range Date Test	ted Result	De	etails		
dditional Information:						
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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 211865
 Seq: 1
 Gender:
 F

 Reported:
 22/09/2005
 Weight:
 0.00

 Hospitalisation:
 Age: 53

Onset Date: 26/07/2005 **DOB**: 27/07/1951

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touotion Dotumor			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation	Developed elevated blood glucose and elevated triglyceride levels	
			Corrective treatment for the event included low doses of titrated Gliclazide and Atorvastatin Calcium. Zyprexa was discontinued and Quetiapine treatment restarted.

Medicine Details:

MEGICINE DETAILS.			
LITHIUM CARBONATE (Other drug)		Reason:	
	1.0 Gram		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	30.0 Milligram	Daily Oral	
Batch:	Started: 15/07/2005	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
22/09/2005	Cholesterol		15/07/2005	6.47	
22/09/2005	Cholesterol		12/08/2005	7.5	
22/09/2005	Serum glucose		15/07/2005	9	
22/09/2005	Serum glucose		12/08/2005	13.3	
22/09/2005	Triglyceride		15/07/2005	2.3	
22/09/2005	Triglyceride		12/08/2005	8.13	

Additional Information:

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Case Number: 211865

Reported: 22/09/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Hospitalisation:			Ag	e: 53		
Onset Date: 26/07/2005		DOB : 27/07/1951				
Outcome: Not yet recovered	ed		Causalit	y: Causality poss	ible	
Reaction Details:						
Preferred Term	Severity	Report Descript	ion	Treatmen	nt	
Blood triglycerides increased	Caused or prolonged inpatient hospitalisation					
Medicine Details:		D				
LITHIUM CARBONATE (Other drug)	1.0 Gram	Reason:				
Batch:	Started:	St	opped:			
ZYPREXA (Suspected)			ecified schizophre	nia		
Tablet	30.0 Milligram		Oral			
Batch:	Started: 15/07/2005	-	opped:			
Laboratory Investigations:	:					
Additional Information:						
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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:211931Seq:1Gender:MReported:23/09/2005Weight:56.00Hospitalisation:Admitted to hospitalAge:43Y

Onset Date: 27/06/2005 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation	·	Olanzapine ceased.

n,	-	101	ne	-	+0:	10:
ıv		16 - 1			141	•

RITONAVIR (Other drug)		Reason:	
Batch:	Started:		Stopped:
Tenofovir disoproxil fumarate (Other drug)		Reason:	
Batch:	Started:		Stopped:
RANITIDINE (Other drug)		Reason:	Other diseases of esophagus
Batch:	Started:		Stopped:
GEMFIBROZIL (Other drug)		Reason:	Othr&unspec metabolic diseases
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
23/09/2005	Neutrophils		27/06/2005	1.25	Neutrophil count - 2.25.
23/09/2005	Neutrophils		28/06/2005	1.31	Neutrophil count - 2.25.
23/09/2005	Neutrophils		29/06/2005	0.93	Neutrophil count - 2.25.

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	211931	Seq: 1		Gender:	M
Reported:	23/09/2005			Weight:	56.00
Hospitalisation:	Admitted to hospi	tal		Age:	43Y
Onset Date:	27/06/2005			DOB:	
Outcome:	Unknown			Causality:	Causality possible
Reaction Detai	ils:				
Madiaina Dat					
Medicine Det			Reason:	Other prophylactic proced	ures
DACTRIM D3 (Oth	er drug)		ixeason.	Other propriyiactic proced	uies
Batch:		Started:		Stopped:	
TRIZIVIR (Other di	rua)	otartea.	Reason:	оторреа.	
TRIZIVIT (Other di	ug,		rtouson.		
Batch:		Started:		Stopped:	
AZITHROMYCIN (Other drug)		Reason:	от реги	
	C.				
Batch:		Started:		Stopped:	
CITALOPRAM HYI	DROBROMIDE (Suspe	ected)	Reason:	Depression	
Tablet		10.0 Milligram	Daily	Oral	
Batch:		Started: 24/06/2005		Stopped: 29/06/2005	5
Laboratory In	vestigations:				
Additional Inf	formation:				

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0	Case Number. 211931	eq. ı			Gender.	
ospitalisation: Admitted to hospital Onset Date: 27706/2005 DOB: Outcome: Unknown Causality: Causality possible paction Details: Medicine Details: OLANZAPINE (Suspected) Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0	Reported: 23/09/2005				Weight:	56.00
Onset Date: 27/06/2005 Outcome: Unknown Causality: Causality possible eaction Details: Medicine Details: Medicine Details: OLANZAPINE (Suspected) Tablet Started: 24/08/2005 Reason: Hallucinations Tablet Started: 24/08/2005 Stopped: 29/08/2005 O Allucine Details: Allucinations Stopped: 29/08/2005 Oral Stopped: 29/08/2005 O Allucine Details: Allucinations Stopped: 29/08/2005 O Allucine Details: OLANZAPINE (Suspected) Tablet Started: 24/08/2005 Tablet Stopped: 29/08/2005 O Allucine Details: Allucinations Oral Oral Oral Oral Oral Allucinations Oral Oral Oral Oral Oral Oral Oral Oral		I				
Outcome: Unknown eaction Details: Medicine Details: OLANZAPINE (Suspected) Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 O						
Medicine Details: OLANZAPINE (Suspected) Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0				С		
Medicine Details: OLANZAPINE (Suspected) Tablet Started: 24/06/2005 Reason: Hallucinations Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0					•	71
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0	action Details.					
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0						
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0						
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0						
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0						
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0						
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0						
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0						
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0						
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0						
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0						
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0						
Tablet 5.0 Milligram Daily Oral						
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0						
Tablet 5.0 Milligram Daily Oral Batch: Started: 24/06/2005 Stopped: 29/06/2005 0 -aboratory Investigations:						
Batch: Started: 24/06/2005 Stopped: 29/06/2005 0 -aboratory Investigations:			Reason:	Hallucinations		
_aboratory Investigations:	Tablet	5.0 Milligram	Daily		Oral	
	Batch:	Started: 24/06/2005		Stopped:	29/06/2005	5 0
	_aboratory Investigations:					
Additional Information:						
Additional Information:						
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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details: Gender: F Case Number: 212056 Seq: 1 Reported: 28/09/2005 Weight: 0.00 Hospitalisation: Age: 70 Onset Date: 14/03/2005 DOB: 20/02/1935 Outcome: Not yet recovered Causality: Causality possible Reaction Details: Preferred Term Severity Report Description Treatment Agitation The patient experienced agitation, fever, Sertraline ceased, Phenergan diaphoresis, shivering, hyperreflexia and restlessness following increasing of Sertraline dose. She was taking 100 mg given for rash. daily on 2 March 2005 and the dose was increased to 125 mg on 4 March 2005. Chills Headache Hyperhidrosis Hyperreflexia Pyrexia Rash **Medicine Details:** LACTULOSE (Other drug) Reason: 20.0 Milligram Batch: Started: 04/03/2005 Stopped: SERTRALINE HYDROCHLORIDE (Other drug) Reason: Depression **Tablet** 125.0 Milligram Daily Oral Started: 02/03/2005 Stopped: 14/03/2005 Batch: **ZOPICLONE** (Suspected) Reason: Tablet 15.0 Milligram Daily Oral Batch: Started: 11/03/2005 Stopped: **OLANZAPINE** (Suspected) Reason: 5.0 Milligram Daily Batch: Started: 11/03/2005 Stopped: **Laboratory Investigations:** Date Type Date Tested Result Details Range

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
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 Case Number:
 212056
 Seq: 1
 Gender:
 F

 Reported:
 28/09/2005
 Weight:
 0.00

 Hospitalisation:
 Age: 70

Onset Date: 14/03/2005 **DOB**: 20/02/1935

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	toaction Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Restlessness			
	Serotonin syndrome			
	Therapy regimen changed			

Medicine Details:

LACTULOSE (Other drug)		Reason:	
	20.0 Milligram		
Batch:	Started: 04/03/2005	Stopp	ed:
SERTRALINE HYDROCHLORIDE (Ot	her drug)	Reason: Depression	on
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 02/03/2005	Stopp	ped: 14/03/2005
ZOPICLONE (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 11/03/2005	Stopp	ed:
OLANZAPINE (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started: 11/03/2005	Stopp	ed:

Laboratory Investigations:

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details	<u>:</u>				
Case Number: Reported:	212062	Seq: 1		Weig	der: F ght: 70.00
ospitalisation:					.ge : 56
Onset Date:	01/09/2005			D	OB : 29/01/1949
Outcome:	Not yet recovered	t		Causa	lity: Causality possible
eaction Detail	s:				
Preferre	d Term	Severity	Repo	ort Description	Treatment
Musculoskeletal s	tiffness		Patient experien sweating, clonus serotonin syndro	ced stiffness, agitation, s ++ increased tone, ome or NMS.	Ceased all medication, ICU.
Agitation					
Clonus					
Hyperhidrosis					
Hypertonia					
Serotonin syndror	ne				
Medicine Deta OLANZAPINE (Susp			Rea	son: Manic-depression ps	ycho,manic
Batch:		Started: 18/0	08/2005	Stopped: 08/09	/2005
DOXEPIN HYDROC	HLORIDE (Suspecte	d)	Rea	son:	
Batch:		Started:		Stopped: 08/09	/2005
AMITRIPTYLINE HY	DROCHLORIDE (Su	spected)	Rea	son:	
Batch:		Started:		Stopped: 08/09	/2005
MELLERIL (Suspec	ted)		Rea	son:	
		Started:		Stopped: 08/09	/2005 0
Batch:					
_aboratory Inv	vestigations:	ge Date Test			
	ted)		Rea	son:	

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	212062	Seq: 1		Gender:	
-	28/09/2005			Weight:	
ospitalisation:				Age:	
Onset Date:					29/01/1949
	Not yet recovered	1		Causality:	Causality possible
eaction Detai	ils:				
<u>ledicine Det</u>					
RISPERIDONE (Su	ispected)		Reason:	Otr spec symp psychopat	nol nec
Batch:		Started: 28/08/2005		Stopped: 08/09/200	5
LITHIUM CARBON	IATE (Suspected)	Started. 20/00/2003	Reason:	Manic-depression psycho	
LITTION OAKBOI	ATE (Gaspeotea)		rtouson.	Marilo acpression psysho	mamo
Tablet		1.0 Gram	Daily	Oral	
Tablet		1.0 Gram Started: 18/08/2005	Daily	Oral	5 0
Tablet Batch:		1.0 Gram Started: 18/08/2005	Daily	Oral Stopped: 08/09/200	5 0
			Daily		5 0
			Daily		5 0
			Daily		5 0
			Daily		5 0
			Daily		5 0
Batch:			Daily		5 0
Batch:	vestigations:		Daily		5 0
Batch:	vestigations:		Daily		5 0
Batch:	vestigations:		Daily		5 0
Batch:	vestigations:		Daily		5 0
Batch:	vestigations:		Daily		5 0
Batch:	vestigations:		Daily		5 0
Batch:	vestigations:		Daily		5 0
Batch:	vestigations:		Daily		5 0
Batch:			Daily		5 0
Batch:			Daily		5 0
Batch:			Daily		5 0
Batch:			Daily		5 0
Batch:			Daily		5 0

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Case Number: 212132

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 04/10/200	5		Weight	: 0.00
spitalisation:			Age	: 99u
Onset Date: 01/06/200	4		DOE	3:
Outcome: Unknown			Causality	: Causality possible
action Details:			1	
Preferred Term	Severity	Report Desc		Treatment
ncreatitis	TI pa	he patient experienced ancreatitis'.	'nephrotic	
ledicine Details: ZYPREXA (Suspected)		Reason:		
			Oral	
Batch:	Started:		Stopped:	
aboratory Investigat		Result	Det	ails
Date Type	Range Date Tested	Result	Det	1115
Additional Informatio	n:			
port Run: 04/06/2007 05:16PN	1 Database: pusime02	ADRS004		Page 366 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	: Details:
--------	------------

 Case Number:
 212133
 Seq: 1
 Gender: M

 Reported:
 04/10/2005
 Weight: 90.00

Hospitalisation:
Onset Date:

DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Weight increased		Approximately six months after initiating Olanzapine treatment the patient gained 10 to 20 kg of weight. He became very depressed because of his weight gain.	Olanzapine ceased, changed to Quetiapine.then to lithium and risperidone

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecifid affective psychosis

15.0 Milligram Daily Oral

Batch: Started: 15/07/2003 **Stopped:** 15/08/2004 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Ren	ort	Deta	ils:
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Case Number: 212135 Seq: 1 Gender: M

Reported: 29/09/2005 Weight: 100.00 Hospitalisation: Age: 21Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Weight increased		Six months after initiating Olanzapine treatment the patient gained 10 to 20 kg of weight. The patient became depressed because of his weight gain.	Olanzapine ceased, changed treatment to Quetiapine.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

15.0 Milligram Daily Oral

Batch: Started: 15/03/2004 **Stopped:** 15/02/2005 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212206 Seq: 1 Gender: M

Reported: 05/10/2005 Weight: 0.00 Hospitalisation: Age: 17

Onset Date: 25/07/2005 DOB: 24/09/1987

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation	(175/90).	Zyprexa was ceased; Antipsychotic medication changed to Seroquel
	Caused or prolonged inpatient hospitalisation		
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ATIVAN (Other drug)		Reason: Anxiety neurosis	
Tablet	2.0 Milligram	3 times Oral	
Batch:	Started: 21/07/2005	Stopped:	0
AROPAX (Other drug)		Reason: Depression	
Tablet	40.0 Milligram	1 time Oral	
Batch:	Started:	Stopped:	0
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	1 time Oral	
Batch:	Started: 22/07/2005	Stopped: 25/07/2005	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
05/10/20			28/07/2005	CK 431U/L,	
05/10/20			30/07/2005	CK 342U/L.	
05/10/20	005 Creatine kinase		25/07/2005	CK 931U/L	

Additional Information:

Report 212222 is the second sequence to this report.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212267 Seq: 1 Gender: M

Reported: 06/10/2005 Weight: 0.00 Hospitalisation: Age: 24

Onset Date: 26/08/2005 **DOB**: 24/09/1980

Outcome: Unknown Causality: Causality possible

Reaction Details:

touction Dotailor			
Preferred Term	Severity	Report Description	Treatment
Convulsion			slowly. Sodium valproate as anticonvulsant
Leukopenia			
Neutropenia			

Medicine Details:

CLOZARIL (Suspected) Reason: Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started**: 25/07/2005 **Stopped**: 15/09/2005 0

OLANZAPINE (Suspected) Reason:

15.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Laborato	boratory investigations.						
Date	Туре	Range	Date Tested	Result	Details		
06/10/2005	Electroencephalog				alpha activity at 8cps was symmetrical and attenuated on eye opening. Widespread slow activity was intermixed at 2-6cps. Generalised paroxysmal episodes of synchronous and symmetrical 3-4cps higher amplitude alow activity seen at reat, accompanied by very low amplitude bilateral spikes which were more prominent bifrontally. Cardiac rhythm strip;tachycarida 120 rising to 132 with hyperventilation		
06/10/2005	Neutrophils		28/11/2005	1.42			

Additional Information:

Febrile convulsion as infant

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212267 Seq: 1 Gender: M

Reported: 06/10/2005 Weight: 0.00 Hospitalisation: Age: 24

Onset Date: 26/08/2005 **DOB**: 24/09/1980

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) Reason: Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: Started: 25/07/2005 **Stopped:** 15/09/2005 0

OLANZAPINE (Suspected) Reason:

15.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range Date Tested Result Details		Details			
06/10/2005	Serum drug level				Sep 2005, Clozapine level 890 ng/ml and Sep 2005 Clozapine level 460 ng/ml.		
06/10/2005	White blood cells		28/11/2005	3.30			

Additional Information:

Febrile convulsion as infant

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212450 Seq: 1 Gender: M

 Reported: 12/10/2005
 Weight: 74.50

 Hospitalisation:
 Age: 55Y

Onset Date: 15/08/2005 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Weight increased		Since commencing Olanzapine treatment the patient has gained 7 kg.	Olanzapine dosage decreased to 2.5 mg daily.

Medicine Details:

ZYPREXA (Suspected)Reason: Unspecifid affective psychosis

5.0 Milligram Daily Oral

Batch: Started: 15/08/2005 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History: Bipolar disorder and diabetes. Taking unspecified medication for the treatment of diabetes.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212511 Seq: 1 Gender: M

Reported: 13/10/2005 Weight: 89.00 Hospitalisation: Age: 27

Onset Date: 16/09/2005 DOB: 16/12/1977

Outcome: Recovered 24/09/2005 Causality: Causality probable

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Blepharospasm		Patient experienced continued muscle spasm in left eyelid.	Discontinued Zyprexa.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

Tablet 10.0 Milligram Daily Oral

Batch: Started: 15/09/2005 **Stopped:** 24/09/2005 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Previously taken Olazapine 4 years ago (duration of therapy then was approx 2-3 months) - unsure of adverse effects at that time but none suspected.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212584 Seq: 1 Gender: M

Reported: 14/10/2005 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 29

Onset Date: 06/09/2005 DOB: 22/07/1976

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	hospitalisation	Doctor was reducing dose from 15mg to 10mg with addition of Aripiprazole 10mg. For three days prior to admission, patient was experiencing increased mood, concentration, energy which gradually developed to pacing at night and reduced sleep. On presentation he had a facial twitch, sweating, bilateral coarse tremor, raised creatinine kinase (1958) and some cognitive impairment.	Withdrawal of all antipsychotics, supportive measures monitioring.

Medicine Details:

ZYPREXA (Suspected)		Reason:	Paranoid type schizophrenia	
	10.0 Milligram	Daily		
Batch:	Started: 15/07/2003		Stopped: 15/09/2005	0
Abilify (Suspected)		Reason:	Paranoid type schizophrenia	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 15/08/2005		Stopped: 15/09/2005	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:						
Case Number: 212584	Seq: 1		Gender: M			
Reported: 14/10/2005	•		Weight: 0.00			
Hospitalisation: Admitted to hosp	oital		Age : 29			
Onset Date: 06/09/2005			DOB : 22/07/1976			
Outcome: Recovered				С	ausality:	Causality possible
Reaction Details:						
Preferred Term	Severity		Report De	scription		Treatment
Blood creatine phosphokinase inc	Caused or prolonged inpatient hospitalisation					
Cognitive disorder	Caused or prolonged inpatient hospitalisation					
Muscle twitching	Caused or prolonged inpatient hospitalisation					
Medicine Details:			D	Danamaid tura		_
ZYPREXA (Suspected)	10.0 N	1illigram	Reason: Daily	Paranoid type	schizophreni	a
Batch:	Started: 15/07	_	Daily	Stonnad:	15/09/2005	0
Abilify (Suspected)	Started: 15/07	72003	Reason:	Paranoid type		
Tablet	10.0 M	1illigram	Daily	i didilola typo	Oral	
Batch:	Started: 15/08	-	,	Stopped:	15/09/2005	0
						-
Laboratory Investigations:						
Additional Information:						

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DOB: 22/07/1976

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Details:
--------	-----------------

 Case Number:
 212584
 Seq: 1
 Gender:
 M

 Reported:
 14/10/2005
 Weight:
 0.00

Hospitalisation: Admitted to hospital **Age**: 29

Outcome: Recovered Causality: Causality possible

Reaction Details:

Onset Date: 06/09/2005

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Micalcinic Details.				
ZYPREXA (Suspected)		Reason:	Paranoid type schizophrenia	
	10.0 Milligram	Daily		
Batch:	Started: 15/07/2003		Stopped : 15/09/2005	0
Abilify (Suspected)		Reason:	Paranoid type schizophrenia	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 15/08/2005		Stopped: 15/09/2005	0

Laboratory Investigations:

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212647 Seq: 1 Gender: M

Reported: 17/10/2005 Weight: 0.00 Hospitalisation: Age: 56

Onset Date: 07/05/2005 **DOB**: 22/03/1949

Outcome: Death Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Death		On 7 May 2005 the patient was found dead, the cause of death was unknown.	

Medicine Details:

SEROQUEL (Suspected)		Reason: Un	specifid affective psychosis	
Tablet	800.0 Milligram	Daily	Oral	
Batch:	Started: 10/06/2004		Stopped : 20/04/2005 0	
LITHIUM CARBONATE (Suspected)		Reason:		
	1.0 Gram	Daily	Oral	
Batch:	Started: 16/08/2004		Stopped:	
OLANZAPINE (Suspected)		Reason:		
	10.0 Milligram	Daily	Oral	
Batch:	Started: 20/04/2005		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:212673Seq: 1Gender:FReported:18/10/2005Weight:0.00Hospitalisation:Required a visit to the doctorAge: 48Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose	Caused or prolonged inpatient hospitalisation	Higher than recommended dose used	Doctors considering switching the patient to Clozapine for efficacy reasons.
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation	The patient experienced tardive dyskinesia, restlessness and was not responding sufficiently to Olanzapine treatment.	
Drug effect decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.				
Risperdal Consta (Other drug)		Reason:	Unspecified schizophrenia	
Batch:	Started: 15/01/2005		Stopped:	Continuing.
ZYPREXA (Suspected)		Reason:	Unspecified schizophrenia	
	30.0 Milligram	Daily	Oral	
Batch:	Started: 15/01/2005		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 212673 Reported: 18/10/2005 Hospitalisation: Required a visit to Onset Date: Outcome: Not yet recovered Reaction Details:				Age DO	t: 0.00 e: 48Y
Preferred Term	Severity	Ren	ort Des	scription	Treatment
Restlessness	Caused or prolonged inpatient hospitalisation	T KOP		33.10.1011	rroddinont
Medicine Details: Risperdal Consta (Other drug)		Rea	son:	Unspecified schizophre	nia
Nisperdal Collista (Other drug)		Nec	ison.	Onspecified scriizophrei	nia .
Batch:	Started: 15/01/2	2005		Stopped:	Continuing.
ZYPREXA (Suspected)				Unspecified schizophre	nia
Batch:	30.0 Milli Started: 15/01/2		Daily	Oral Stopped:	
Laboratory Investigations:					
Additional Information:					

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reason: Intramuscular Intramuscular Batch: Started: STERM Stopped: 15/10/2005 Started: Stopped: St	Onset Date: 18 Outcome: Doutcome: etail Risperdal Consta (Sunjection Batch: SODIUM VALPROATE	5/10/2005 eath, maybe d : Term S: spected)	Se	n P.	Re atient commi	port Desc ted suicido	cription e.	Age: DOB Causality:	: 35Y : Causality possible Treatment
Onset Date: 15/10/2005 Outcome: Death, maybe drug 10/11/2005 Causality: Causality possible action Details: Preferred Term Severity Report Description Treatment ompleted suicide Death Patient committed suicide. Patient committed suicide Patient comm	Onset Date: 15 Outcome: Do action Details Preferred ompleted suicide Detail	eath, maybe d Term S: spected)	Se	n P.	Re atient commi	port Desc ted suicido	cription e.	DOB Causality:	: Causality possible Treatment
Outcome: Death, maybe drug action Details: Preferred Term Severity Report Description Treatment ompleted suicide Death Patient committed suicide. Patient committed suicide Patient committed su	Outcome: Doctails Action Details Preferred Ompleted suicide Idedicine Detail Risperdal Consta (Suicide) Injection Batch: SODIUM VALPROATE	eath, maybe d Term S: spected)	Se	n P.	Re atient commi	port Desc ted suicido	cription e.	Intramusc	Treatment Sular
Action Details: Preferred Term Severity Report Description Treatment ompleted suicide Death Patient committed suicide. Patient committed suicide. Patient	Preferred ompleted suicide ledicine Detail Risperdal Consta (Su Injection Batch: SODIUM VALPROATE	Term S: spected)	Se	n P.	Re atient commi	port Desc ted suicido	cription e.	Intramusc	Treatment
Preferred Term Severity Report Description Treatment Ompleted Suicide Death Patient committed Suicide. Patient committed Suicide. Death Patient committed Suicide. Death Patient committed Suicide. Death Patient committed Suicide. Patient committed Suicide. Reason: Reason: Intramuscular Batch: Started: STERM Stopped: 15/10/2005 SODIUM VALPROATE (Suspected) Reason: Batch: Started: Stopped: DLANZAPINE (Suspected) Reason: Batch: Started: Stopped:	Preferred ompleted suicide ledicine Detail Risperdal Consta (Su Injection Batch: SODIUM VALPROATE	S: spected)	Death	n P.	atient commi	ted suicide	е.		eular
Preferred Term Severity Report Description Treatment Ompleted Suicide Death Patient committed Suicide. Patient committed Suicide. Death Patient committed Suicide. Death Patient committed Suicide. Death Patient committed Suicide. Patient committed Suicide. Reason: Reason: Intramuscular Batch: Started: STERM Stopped: 15/10/2005 SODIUM VALPROATE (Suspected) Reason: Batch: Started: Stopped: DLANZAPINE (Suspected) Reason: Batch: Started: Stopped:	Preferred ompleted suicide ledicine Detail Risperdal Consta (Su Injection Batch: SODIUM VALPROATE	S: spected)	Death	n P.	atient commi	ted suicide	е.		eular
Iedicine Details: Risperdal Consta (Suspected) Reason: Intramuscular Injection Intramuscular Batch: Started: STERM Stopped: 15/10/2005 SODIUM VALPROATE (Suspected) Reason: Batch: Started: Stopped: DLANZAPINE (Suspected) Reason: Batch: Started: Stopped: Batch: Started: Stopped: Stopped: Stopped: Batch: Started: Stopped: Batch: Stopped: Batch: Started: Stopped: Batch: Stopped:	ledicine Detail Risperdal Consta (Su Injection Batch: SODIUM VALPROATE	spected)			R: S TER	eason:			
Risperdal Consta (Suspected) Injection Batch: Started: STERM Stopped: 15/10/2005 SODIUM VALPROATE (Suspected) Reason: Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Batch: Started: Stopped: Stopped: Aboratory Investigations:	Risperdal Consta (Su Injection Batch: SODIUM VALPROATE	spected)	St	tarted:	S TER		Stonned		
Injection Batch: Started: STERM Stopped: 15/10/2005 SODIUM VALPROATE (Suspected) Batch: Started: Stopped: OLANZAPINE (Suspected) Batch: Started: Stopped: Batch: Stopped: Stopped:	Risperdal Consta (Su Injection Batch: SODIUM VALPROATE	spected)	Sí	tarted:	S TER		Stonned		
Batch: Started: STERM Stopped: 15/10/2005 SODIUM VALPROATE (Suspected) Reason: Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Batch: Started: Stopped: St	Batch: SODIUM VALPROATE	E (Suspected)	St	tarted:		M	Stonned:		
Batch: Started: Stopped: CLANZAPINE (Suspected) Batch: Started: Stopped: Batch: Started: Stopped: Batch: Started: Stopped:	SODIUM VALPROATI	E (Suspected)	St	tarted:		M	Stopped		
Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Batch: Started: Stopped: aboratory Investigations:		E (Suspected)			D.		otoppou.	15/10/200)5
DLANZAPINE (Suspected) Batch: Started: Stopped: aboratory Investigations:					K	eason:			
Batch: Started: Stopped: aboratory Investigations:			St	tarted:			Stopped:		
aboratory Investigations:	OLANZAPINE (Suspe	cted)			R	eason:			
aboratory Investigations:									
	Batch:		St	tarted:			Stopped		
Bate Type Range Bate rested Result				Date Tested	Result			Deta	nils

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Case Number: 213519

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 17/11/2005	-		Weigl	ht: 0.00	
Hospitalisation:			_	je : 35Y	
Onset Date:			_)B:	
Outcome: Recovered			Causali	ty: Causality possi	ble
Reaction Details:					
Preferred Term	Severity	Report De	escription	Treatmen	t
Blood glucose increased	prolonged	Patient's Blood glucos MMOL/L, also experie (joint swelling).	se test was 43 enced swollen ankles	Xyprexa was ceased with insulin therapy.	d. Treated
Gravitational oedema	Caused or prolonged inpatient hospitalisation				
Medicine Details: ZYPREXA (Suspected)		Reason:			
Tablet	10.0	Milligram Daily	Oral		
Batch:	Started:		Stopped:		
Laboratory Investigation		1			
Date Type	Range Date Teste	ed Result	D	etails	
Additional Information:	1				
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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 213524 Seq: 1 Gender: F
Reported: 17/11/2005 Weight: 0.00
Hospitalisation: Age: 43

Onset Date: 02/04/2005 **DOB**: 23/08/1961

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Neuroleptic Malignant Syndrome. She had increased temperatures, increased	Withheld neuroleptics initially, monitored temperature, BP, pulse, QID. Olanzapine restarted on 7/4/05.
Blood creatine phosphokinase incr Hallucination, auditory Leukocytosis			
Pyrexia Suicidal ideation			

Medicine Details:

Modifile Botalie				
Aripiprazole (Suspected)		Reason:		
Tablet	15.0 Milligram	Daily Oral		
Batch:	Started: 17/03/2005	Stopped:	Stopped:	
OLANZAPINE (Suspected)		Reason:		
Tablet	5.0 Milligram	Daily Oral		
Batch:	Started:	Stopped:		

Laboratory Investigations:

	.,				
Date	Туре	Range	Date Tested	Result	Details
17/11/2005	ALT = SGPT		02/04/2005	61	
17/11/2005	ALT = SGPT		04/04/2005	51	
17/11/2005	ALT = SGPT		11/04/2005	62	
17/11/2005	AST = SGOT		02/04/2005	36	
17/11/2005	AST = SGOT		04/04/2005	37	
17/11/2005	Creatinine		02/04/2005	0.11	
17/11/2005	Creatinine		11/04/2005	0.09	

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 213524 Seq: 1 Gender: F

Reported: 17/11/2005 Weight: 0.00 Hospitalisation: Age: 43

Onset Date: 02/04/2005 **DOB**: 23/08/1961

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.				
Aripiprazole (Suspected)		Reason:		
Tablet	15.0 Milligram	Daily Oral		
Batch:	Started: 17/03/2005	Stopped:	Stopped:	
OLANZAPINE (Suspected)		Reason:		
Tablet	5.0 Milligram	Daily Oral		
Batch:	Started:	Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/11/2005	GGT = SGGT =		02/04/2005	158	
17/11/2005	GGT = SGGT =		04/04/2005	125	
17/11/2005	GGT = SGGT =		11/04/2005	109	
17/11/2005	Neutrophils		02/04/2005	5.8	
17/11/2005	Neutrophils		11/04/2005	3.7	
17/11/2005	Neutrophils		04/04/2005	4.4	
17/11/2005	Potassium		02/04/2005	4.1	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
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Case Number: 213524 Seq: 1 Gender: F

Reported: 17/11/2005 Weight: 0.00 Hospitalisation: Age: 43

Onset Date: 02/04/2005 **DOB**: 23/08/1961

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.				
Aripiprazole (Suspected)		Reason:		
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 17/03/2005	Stopp	oed:	
OLANZAPINE (Suspected)		Reason:		
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started:	Stopp	oed:	

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ	17/11/2005	Sodium		02/04/2005	142	
١	17/11/2005	White blood cells		02/04/2005	9.0	
١	17/11/2005	White blood cells		04/04/2005	6.8	
Į	17/11/2005	White blood cells		11/04/2005	6.0	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 213565
 Seq: 1
 Gender:
 F

 Reported:
 17/11/2005
 Weight:
 0.00

 Hospitalisation:
 Age: 48Y

Onset Date: 08/08/2005 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis fulminant		Clarithromycin.	Patient intubated and sedated, NGT, NAC and Folinic Acid. Cholestyramine 8g/tds to help with removal of Arava from GIT. Stopped all anti-rheumatoid medications, and psychotropic medications and pill.

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ш	vi	-(1	 	-	.,	eta	-

Micalcinic Details.			
FOLIC ACID (Other drug)		Reason:	
Batch:	Started:		Stopped:
CENTRUM TABLETS (Other drug)		Reason:	
Batch:	Started:		Stopped:
OSTELIN 1000 (Other drug)		Reason:	
Batch:	Started:		Stopped:
NEXIUM (Other drug)		Reason:	·
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
17/11/2005	ALT = SGPT	<34 u/l	04/08/2005	2621	
17/11/2005	ALT = SGPT	<34 u/l	10/08/2005	1583	
17/11/2005	ALT = SGPT	<34 u/l	23/08/2005	1431	
17/11/2005	Bilirubin	<18 mcmol/L	04/08/2005	27	
17/11/2005	Bilirubin	<18 mcmol/L	10/08/2005	50	
17/11/2005	Bilirubin	<18 mcmol/L	23/08/2005	33	
17/11/2005	GGT = SGGT =	<38 u/l	04/08/2005	118	

Additional Information:

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Additional Information:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

eport Deta							
Case Number	: 213565	Seq	: 1			Gender:	
Reported	I: 17/11/200	5				Weight:	0.00
spitalisation	:					Age:	48Y
Onset Date	: 08/08/200	5				DOB:	
Outcome	: Not yet red	covered			(Causality:	Causality possible
action Deta	ails:						
MONOPLUS NO: Batch:	S (Other drug)	\$	Started:	Re	rason: Stopped:		0
MONOPLUS NO: Batch:	S (Other drug)	\$	Started:				0
Batch: Batch: AMOXIL (Other of Batch:	S (Other drug)		Started: Started:		Stopped:		0
MONOPLUS NOS Batch: AMOXIL (Other of Batch:	S (Other drug)			Re	Stopped: eason:		0
MONOPLUS NOS Batch: AMOXIL (Other of Batch:	S (Other drug)			Re	Stopped: eason: Stopped:		0
Batch: AMOXIL (Other of Batch: METHOTREXATI	S (Other drug) drug) E (Suspected)	s	Started:	Re	Stopped: sason: Stopped: weekly		
Batch: AMOXIL (Other of Batch: METHOTREXATI	S (Other drug) drug) E (Suspected)	s	Started: 20.0 Millig	Re Re gram	Stopped: sason: Stopped: weekly	Oral	
Batch: AMOXIL (Other of Batch: METHOTREXATI	S (Other drug) drug) E (Suspected)	s	Started: 20.0 Millig	Re gram	Stopped: Stopped: sason: Weekly Stopped:	Oral	
Batch: AMOXIL (Other of Batch: METHOTREXATION Batch: Batch:	S (Other drug) drug) E (Suspected)	\$	Started: 20.0 Millio Started:	Re gram	Stopped: ason: Stopped: ason: Weekly Stopped: ason: As necessary	Oral 09/08/2008	5
Batch: Batch: Batch: Batch: METHOTREXATI Batch: ALPRAZOLAM (3 Tablet Batch:	S (Other drug) drug) E (Suspected) Suspected)	\$	Started: 20.0 Million Started: 5.0 Million	Re gram	Stopped: ason: Stopped: ason: Weekly Stopped: ason: As necessary	Oral 09/08/2009	5
Batch: Batch: Batch: Batch: METHOTREXATI Batch: ALPRAZOLAM (3 Tablet Batch:	S (Other drug) drug) E (Suspected) Suspected)	\$	Started: 20.0 Million Started: 5.0 Million	Re gram	Stopped: ason: Stopped: ason: Weekly Stopped: ason: As necessary	Oral 09/08/2009	5
Batch: Batch: Batch: Batch: METHOTREXATI Batch: ALPRAZOLAM (: Tablet Batch: Batch: Alprazolam (: Tablet Batch: Batch: GGGT	S (Other drug) drug) E (Suspected) Suspected) rype T = SGGT =	s s ions:	Started: 20.0 Millig Started: 5.0 Millig Started:	Re gram Re gram	Stopped: ason: Stopped: ason: Weekly Stopped: ason: As necessary	Oral 09/08/2008 Oral 09/08/2008	5
Batch: Batch: Batch: Batch: METHOTREXATI Batch: ALPRAZOLAM (3 Tablet Batch: Batch: 17/11/2005 GG 17/11/2005 GG	S (Other drug) drug) E (Suspected) Suspected) Type T = SGGT = T = SGGT = T = SGGT =	s i ons: Range	Started: 20.0 Millig Started: 5.0 Millig Started: Date Tested	Regram Regram Regram	Stopped: ason: Stopped: ason: Weekly Stopped: ason: As necessary	Oral 09/08/2008 Oral 09/08/2008	5
Batch: Batch: Batch: Batch: METHOTREXATI Batch: ALPRAZOLAM (3 Tablet Batch: Batch: 17/11/2005 GG 17/11/2005 Inte	S (Other drug) drug) E (Suspected) Suspected) Investigati Type T = SGGT = THE SGGT	ions: Range <38 u/l <38 u/l	20.0 Millig Started: 5.0 Millig Started: Date Tested 23/08/2005 10/08/2005	Regram Regram Result 153 104	Stopped: ason: Stopped: ason: Weekly Stopped: ason: As necessary	Oral 09/08/2008 Oral 09/08/2008	5
Batch: Batch: Batch: Batch: METHOTREXATI Batch: ALPRAZOLAM (Tablet Batch: Date 17/11/2005 GG 17/11/2005 Intee 17/11/2005 Intee 17/11/2005 SAF	S (Other drug) drug) E (Suspected) Suspected) Type T = SGGT = The SGGT =	ions: Range <38 u/l <38 u/l <38 u/l	20.0 Millig Started: 5.0 Millig Started: Date Tested 23/08/2005 10/08/2005 04/08/2005	Regram Result 153 104 88	Stopped: ason: Stopped: ason: Weekly Stopped: ason: As necessary Stopped:	Oral 09/08/2008 Oral 09/08/2008	5
Batch: Batch: Batch: Batch: ALPRAZOLAM (Tablet Batch: Date 17/11/2005 GG 17/11/2005 GG 17/11/2005 Intel 17/11/2005 SAF 17/11/2005 SAF	S (Other drug) drug) E (Suspected) Suspected) Investigati Type T = SGGT = THE SGGT	ions: Range <38 u/l <38 u/l	20.0 Millig Started: 5.0 Millig Started: Date Tested 23/08/2005 10/08/2005	Regram Regram Result 153 104	Stopped: ason: Stopped: ason: Weekly Stopped: ason: As necessary Stopped:	Oral 09/08/2008 Oral 09/08/2008	5

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Details:
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 Case Number:
 213565
 Seq: 1
 Gender:
 F

 Reported:
 17/11/2005
 Weight:
 0.00

Hospitalisation: Age: 48Y
Onset Date: 08/08/2005
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ARAVA (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 12/01/2005	Stopped:	09/08/2005
MOBIC (Suspected)		Reason:	
	7.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	09/08/2005
ZYPREXA (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	09/08/2005
PLAQUENIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 12/12/2001	Stopped:	09/08/2005

Laboratory Investigations:

Additional Information:

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Case Number: 213565

Reported: 17/11/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

				Age:	TO 1
Onset Date: 08/08/2005				DOB:	
Outcome: Not yet recovered			С	ausality:	Causality possible
action Details:					
edicine Details:					
ARTANE (Suspected)		Reason:			
Tablet	1.0 Milligram	Daily		Oral	
Batch:	Started:		Stopped:	09/08/2005	
FEXOR (Suspected)		Reason:			
	450.0 Milligram	Daily		Oral	
Batch:	Started:		Stopped:	09/08/2005	
(LACID (Suspected)		Reason:			
	500.0 Milligram	Daily		Oral	
Batch:	Started: 31/07/2005		Stopped:	08/08/2005	
Batch:			Stopped:	08/08/2005	
aboratory Investigations:					
aboratory Investigations:					
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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

tails:						
per: 213743 red: 24/11/2005 on: ate: me: Unknown	Seq: 1				Weight: Age: DOB:	70.00
	Severity	,	Penort Desc	rintion		Treatment
npt	Life	Suicide att		триоп		rreatment
Details:			Reason:			
	3	7.5 Milligram	Daily		Oral	
ո։	Started:	S		M Stopped:		
Suspected)	22	5.0 Milligram	Reason: Daily		Oral	
n:	Started:			Stopped:		
			Reason:			
(Suspected)	1	0.0 Milligram	Daily			
(Suspected)	1 Started:			Stopped:		
n: y Investigation	Started:		Daily TERM	Stopped:	Detail	s
n: y Investigation:	Started:	S	Daily TERM	Stopped:	Detail	s
	ed: 24/11/2005 on: ate: me: Unknown etails: eferred Term npt Details: spected) n: Suspected)	red: 24/11/2005 on: ate: me: Unknown etails: eferred Term Severity hpt Life threatening Details: epected) 3 Started: Suspected)	ced: 24/11/2005 con: cate: cone: Unknown cetails: cferred Term conpt Life threatening Details: cpected) 37.5 Milligram cons: cons: Started: red: 24/11/2005 on: ate: me: Unknown etails: eferred Term	red: 24/11/2005 on: ate: me: Unknown retails: referred Term Severity Report Description retails: referred Term Severity Report Description retails: referred Term Suicide attempt. Suicide attempt. Reason: 37.5 Milligram Daily re: Started: Started: Started: Started: Started: Started: Suicide attempt. Reason: 225.0 Milligram Daily	red: 24/11/2005 on: Age: ate: DOB: me: Unknown Severity Ferred Term Age: atered Term Age:	

Report Run: 04/06/2007 05:16PM Database: pusime02 ADRS004 Page 389 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:213886Seq: 1Gender:MReported:29/11/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 29

Onset Date: 15/11/2005 DOB: 30/10/1976

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myalgia	prolonged	weakness, soreness both legs, developed abnormal gait and tremor.	Cogentin.
Muscular weakness	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Wafer	10.0 Milligram	Daily	Oral
Batch:	Started: 13/11/2005	Stopped:	13/11/2005
VALIUM (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 13/11/2005	Stopped:	13/11/2005
ZYPREXA (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 13/11/2005	Stopped:	13/11/2005
MIDAZOLAM (Suspected)		Reason:	
Injection	1.0 Milligram	Daily	Intravenous
Batch:	Started: 13/11/2005	Stopped:	13/11/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 05:16PM Database: pusime02 ADRS004 Page 390 of 530



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	213886	Seq: 1		Gender:	M
Reported:	29/11/2005			Weight:	0.00
Hospitalisation:	Admitted to hosp	ital		Age:	29
Onset Date:	15/11/2005			DOB:	30/10/1976
Outcome:	Not yet recovered	d		Causality:	Causality possible
Reaction Detai	ls:				
Medicine Deta	ails:				
VALIUM (Suspecte	ed)		Reason:		
Tablet		10.0 Milligram	n Daily	Oral	
Batch:		Started: 13/11/2005		Stopped: 13/11/2005	5
1 -1	4! 4!				
Laboratory in	vestigations:				
Additional Inf	ormation:				

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 213952 Seq: 1 Gender: M

Reported: 02/12/2005 Weight: 0.00 Hospitalisation: Age: 24

Onset Date: 07/09/2005 **DOB**: 11/01/1981

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	prolonged	Raised liver function tests: alkaline phosphatase 195 U/L, ALT 988U/L, Gamma GT 129U/L	Zyprexa & Epilim were ceased
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.					
EPILIM (Suspected)			Reason:		
Tablet	700.0	Milligram	2 times		Oral
Batch:	Started:			Stopped:	07/09/2005
ZYPREXA (Suspected)			Reason:		
Tablet	20.0	Milligram	1 time		Oral
Batch:	Started:			Stopped:	07/09/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repo							
•	rted: 02/12/2005	5			Weigh	t: 0.00	
spitalisat	tion:				Age	e: 32	
Onset D	Date: 26/02/2005	5			DO	B : 15/01/1973	
Outco	ome: Death, mag	ybe drug		26/02/2000	Causalit	y: Causality possible	
action D	Details:						
Pr	referred Term	Se	everity	Rep	ort Description	Treatment	
Orug level in	ncreased	Death	an	ateint died pos nd valproic aci teraction.	sibly due to olanzapine d, possibly due to a drug		
Orug interac	ction	Death	ı				
Medicine	Details:						
OLANZAPIN	IE (Interaction)			Rea	son:		
Bate	ch:	S	started:	Stopped:			
FLUVOXAMI	INE MALEATE (Inte	raction)		Rea	son:		
	Batch: Started: Sto						
			itai teu.		•••		
	LPROATE (Interacti		tarteu.	Rea	son:		
SODIUM VA	LPROATE (Interacti	on)		Rea	son:		
SODIUM VA	LPROATE (Interacti	on) S	started:		Stopped:		
SODIUM VA	LPROATE (Interacti	on) S			son:		
SODIUM VA	LPROATE (Interacti ch: THIXOL ACETATE (on) S Other drug)			Stopped:		
SODIUM VAI Bate ZUCLOPENT	LPROATE (Interacti ch: THIXOL ACETATE (ch:	on) S Other drug) S	started:		Stopped:		
SODIUM VA Bate ZUCLOPENT Bate .aborato	LPROATE (Interacti ch: THIXOL ACETATE (ch: ry Investigati	on) SOther drug) SONS:	itarted: itarted:	Rea	Stopped: Stopped: Stopped:		
Bate Bate Bate Bate Date	ch: THIXOL ACETATE (ch: ry Investigati Type	on) S Other drug) S	started:		Stopped: Stopped: De	otails	
Bate Bate Bate Bate Date	LPROATE (Interacti ch: THIXOL ACETATE (ch: ry Investigati	on) SOther drug) SONS:	itarted: itarted:	Rea	Stopped: Stopped: Stopped: De	bloodlevels of 0.58 mg/l of inconsistent with terapeutic use oic Acid. 0.04 mg/l of	

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 214294 Seq: 1 Gender: F

Reported: 14/12/2005 Weight: 58.00 Hospitalisation: Age: 28

Onset Date: 29/11/2005 DOB: 25/06/1977
Outcome: Recovered Causality: Causality certain

Reaction Details:

caction betails.			
Preferred Term	Severity	Report Description	Treatment
Acne		year and started to get pimples. Once the Zyprexa was ceased mid-year, the	Patient treating pimples with over the counter measures such as Benzoly Peroxide gels. Zyprexa ceased.

Medicine Details:

ZYPREXA (Suspected)	R	Reason: Depression	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started: 21/11/2005	Stopped:	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Suspect drug certain rechallenge.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	214501	Seq: 1		Gende	er: F		
Reported:	23/12/2005		Weight: 0.00				
lospitalisation:	Admitted to hos	pital	Age : 16Y				
Onset Date:		'		DOB:			
Outcome:	Not yet recovere	ed	Causality: Causality possible				
eaction Deta	ils:						
	red Term	Severity	Rep	ort Description	Treatment		
Neuroleptic mali	gnant syndrome	Caused or prolonged inpatient hospitalisation	syndrome, bloo increased and r	roleptic malignant d creatine phosphokinase renal impairment.			
Blood creatine p	hosphokinase ind	cr Caused or prolonged inpatient hospitalisation					
Renal impairmei	nt	Caused or prolonged inpatient hospitalisation					
Medicine Det							
LORAZEPAM (Otl	ner drug)		Rea	ason:			
Batch:		Started:		Stopped:			
DIAZEPAM (Other	r drug)		Rea	ason:			
Detales		Otantada		Otania			
Batch: MAXOLON (Other	drug)	Started:	Re	Stopped:			
`	C,						
Batch:		Started:		Stopped:			
ZYPREXA (Suspe	cted)		Rea	ason:			
Tablet				Oral			
Batch:		Started:		Stopped:			
l aboratory li	nvestigations						
			ted Result	l Do	etails		
		go Date Foot					
Date 23/12/2005 Crea		nge Date Test	ted Result	CPK=8500 units and dates not	etails reported.		

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Case Number: 214539

Reported: 04/01/2006

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Severity	The pa	atient develo		DB: 09/09/1959 ty: Causality possible Treatment	
Severity	The pa	atient develo	t Description		
Severity	The pa	atient develo	oped chronic serotonin	Treatment	
Severity	The pa	atient develo	oped chronic serotonin	Treatment	
	The pa syndro	atient develo	oped chronic serotonin vere akathisia.		
g)		Reaso	on:		
Otented			Otamo de		
Started	1	Reaso			
Started	Reason:				
Started	!		Stopped:		
RIDE (Suspected)		Reaso			
	Oral				
Started	Started:		Stopped:		
Range Date	Tested	Result	De	etails	
•	Started: Started: PRIDE (Suspected) Started:	Started: Started: Started: Started: Started: Started:	Started: Reaso Started: Started: PRIDE (Suspected) Started: Started:	Started: Stopped: Reason: Started: Stopped: Reason: Started: Stopped: Oral Started: Stopped:	

Report Run: 04/06/2007 05:16PM Database: pusime02 ADRS004 Page 396 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:				
Case Number: 214539 Reported: 04/01/2006 Hospitalisation: Onset Date: Outcome: Unknown Reaction Details:	Seq: 1			0.00
Medicine Details:				
Lexapro (Suspected)		Reason:	Oral	
Batch:	Started:		Stopped:	
ZYPREXA (Suspected)		Reason:		
Batch:	Started:		Stopped:	
Laboratory Investigations	:			
Additional Information:				

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Hospitalisation:

Case Number: 214541

Reported: 04/01/2006

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Weight: 0.00

Age: 30

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Outcome: Unknown action Details: Preferred Term kathisia	Severity	The supe	Repo	Causali	ty: Causality possible
Preferred Term	Severity	The supe	Repo		
	Severity	The supe	Repo		
kathisia		supe		ort Description	Treatment
		acce ques aggr temp amir and expe delir viole threa	ersensitivity pritively impaiss his memotions. He exercises his memotions. He exercises his memotion, developmental everature, alterno-transferase elevated creerienced a grium. He hadence and ma	rienced akathisia and osychosis. He was red and was unable to ories in response to perienced agitation and eloped elevations in erations in alanine se, aspartate transferase atinine kinase levels. He rand mal seizure and many episodes of de homicidal and suicidal rienced visual, tactile and ations.	
ledicine Details:					
LITHIUM CARBONATE (Suspected)			Rea	son:	
Tablet				Oral	
Batch:	Started:			Stopped:	
ZYPREXA (Suspected)			Rea	son:	
Batch:	Started:			Stopped:	
_aboratory Investigations	s:				
Date Type F	Range Date	Tested	Result	De	etails
Additional Information:					



Case Number: 214541

Reported: 04/01/2006

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Hospitalisation:		Age: 30			
Onset Date:		DOB : 26/08/1975			
Outcome: Unknown			Causa	ality: Causality possible	
Reaction Details:					
Preferred Term	Severity	Report Des	cription	Treatment	
Aggression					
Amnesia					
Cognitive disorder					
Delirium					
Homicidal ideation					
Psychotic disorder					
Suicidal ideation					
Medicine Details: LITHIUM CARBONATE (Suspected) Tablet		Reason:	Oral		
Batch:	Started:		Stopped:		
ZYPREXA (Suspected)		Reason:			
Batch:	Started:		Stopped:		
Laboratory Investigations	:				
Additional Information:					
Report Run : 04/06/2007 - 05:16PM - Dai	tahase: nusime02	ADRS004	l	Page 300 of 530	

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 214552
 Seq:
 1
 Gender:
 F

 Reported:
 04/01/2006
 Weight:
 0.00

Hospitalisation: Age: 21

Onset Date: **DOB**: 25/09/1984

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		The patient experiences some restlessness. She becomes agitated and suicidal. She thinks her parents in the next room are talking about her. She believes in magic and clairvoyance and thinks she has clairvoyance. She believes in telepathy and sixth sense. She experiences hallucinations and fulfils all the criteria for schizotypal personality disorder.	
Hallucination			
Personality disorder			
Psychotic disorder			

Medicine Details:

Medicine Details.			
AROPAX (Suspected)		Reason:	
Tablet	40.0 Milligra	am	Oral
Batch:	Started:	Stop	pped:
ZYPREXA (Suspected)		Reason:	
	20.0 Milligra	am Daily	
Batch:	Started:	Stop	pped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report 214550 is the first sequence to this report.

A half an hour after she takes the Zyprexa tablets she sees visions, sees something fly past and then goes away. She like the Zyprexa.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 214552 Seq: 1 Gender: F

Reported: 04/01/2006 Weight: 0.00 Hospitalisation: Age: 21

Onset Date: DOB: 25/09/1984

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Restlessness			
Suicide attempt			

Medicine Details:

AROPAX (Suspected)		R	eason:		
Tablet	40.0 Mi	lligram		Oral	
Batch:	Started:			Stopped:	
ZYPREXA (Suspected)		R	eason:		
	20.0 Mi	lligram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

Additional Information:

Report 214550 is the first sequence to this report.

A half an hour after she takes the Zyprexa tablets she sees visions, sees something fly past and then goes away. She like the Zyprexa.

Report Run: 04/06/2007 05:16PM Database: pusime02 ADRS004 Page 401 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 214558 Seq: 1 Gender: M Weight: 0.00 Howelight: 0.00	Report De	tails:				
Age: 21 Onset Date: Outcome: Unknown eaction Details: Preferred Term Akathisia Akathisia Medicine Details: VALIUM (Other drug) Batch: CANNABIS PREPARATION (Other drug) Batch: Started: Started: Stopped: ZYPREXA (Suspected) Batch: Started: Started: Stopped: CIPRAMIL (Suspected) Batch: Started: Stopped: CIPRAMIL (Suspected) Reason: Reason: CIPRAMIL (Suspected) Reason: Reason: CIPRAMIL (Suspected) Reason: Reason: CIPRAMIL (Suspected) Reason: CIPRAMIL (Suspected) Reason: Reason: CIPRAMIL (Suspected) Reason: CIPRAMIL (Suspected) Reason: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Batch: Stopped: CLIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Oral Batch: Stopped: Laboratory Investigations:	Case Numb	er: 214558	Seq: 1		Gende	r: M
Onset Date: Outcome: Unknown Causality: Causality possible eaction Details: Preferred Term Severity Report Description Treatment Akathisia Report Description Treatment The patient attempted to kill himself. He was seeing things and hearing things and was violent. If he missed a pill he became restless and energetic. Homicidal ideation Suicide attempt Medicine Details: VALIUM (Other drug) Reason: Batch: Started: Stopped: CANNABIS PREPARATION (Other drug) Reason: Batch: Started: Stopped: ZYPREXA (Suspected) Reason: 2.5 Milligram Daily Batch: Started: Stopped: CIPRAMIL (Suspected) Reason: 1 Abolet 40.0 Milligram Daily Oral Batch: Started: Stopped: CIPRAMIL (Suspected) Reason: Aboratory Investigations:	Report	ed: 04/01/200	6		Weight	: 0.00
Outcome: Unknown Preferred Term Preferred Term Severity Report Description Treatment Akathisia Akathisia Report Description Treatment The patient attempted to kill himself. He was seeing things and hearing things and was violent. If he missed a pill he became restless and energetic. Homicidal ideation Suicide attempt Medicine Details: VALIUM (Other drug) Reason: Batch: Started: Started: Stopped: ZYPREXA (Suspected) Reason: 2.5 Milligram Daily Batch: Started: Stopped: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Batch: Stopped: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Daily Oral Batch: Stopped: Cappada Stopped: Cappada Stopped: Cappada Stopped: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Daily Daily Daily Daily Stopped: Cappada Stopped: Cappad	ospitalisati	on:			Age	: 21
Preferred Term Severity Report Description Treatment Akathisia The patient attempted to kill himself. He was seeing things and hearing things and was violent. If he missed a pill he became restless and energetic. Homicidal ideation Suicide attempt Medicine Details: VALIUM (Other drug) Reason: Batch: Started: Stopped: CANNABIS PREPARATION (Other drug) Reason: Batch: Started: Stopped: ZYPREXA (Suspected) Reason: 2.5 Milligram Daily Batch: Started: Stopped: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Oral Batch: Started: Stopped: Caboratory Investigations:	Onset Da	ate:			DOE	3 : 10/09/1984
Preferred Term Severity Report Description Treatment Akathisia The patient attempted to kill himself. He was seeing things and hearing things and was violent. If he missed a pill he became restless and energetic. Homicidal ideation Suicide attempt Medicine Details: VALIUM (Other drug) Reason: Batch: Started: Stopped: CANNABIS PREPARATION (Other drug) Reason: Batch: Started: Stopped: ZYPREXA (Suspected) Reason: 2.5 Milligram Daily Batch: Started: Stopped: CIPRAMIL (Suspected) Reason: Tablet 4.0.0 Milligram Daily Oral Batch: Started: Stopped: CIPRAMIL (Suspected) Reason: Tablet Started: Stopped:	Outcor	ne: Unknown			Causality	: Causality possible
The patient attempted to kill himself. He was seeing things and hearing things and was violent. If he missed a pill he became restless and energetic. Medicine Details: VALIUM (Other drug) Batch: Started: Stopped: CANNABIS PREPARATION (Other drug) Reason: Batch: Started: Stopped: ZYPREXA (Suspected) Reason: 2.5 Milligram Daily Batch: Started: Stopped: CIPRAMIL (Suspected) Reason: 1 ablet 40.0 Milligram Daily Oral Batch: Started: Stopped: CIPRAMIL (Suspected) Reason: 2.5 Milligram Daily Oral Batch: Started: Stopped: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Oral Batch: Started: Stopped:						
Was seeing things and hearing things and was violent. If he missed a pill he became restless and energetic. Medicine Details: VALIUM (Other drug) Batch: CANNABIS PREPARATION (Other drug) Batch: Started: Stopped: ZYPREXA (Suspected) Reason: 2.5 Milligram Daily Batch: Stopped: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Oral Batch: Stopped: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Oral Batch: Stopped: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Oral Batch: Stopped: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Oral Batch: Stopped: CIPRAMIL (Suspected) Reason: Tablet Stopped: CIPRAMIL (Suspected) Tablet Stopped: CIPRAMIL (Suspected) Tablet Stopped: CIPRAMIL (Suspected) Reason: Tablet Stopped: CIPRAMIL (Suspected) Tablet Stopped:		ferred Term	-		·	Treatment
Medicine Details: VALIUM (Other drug) Batch: Started: Stopped: CANNABIS PREPARATION (Other drug) Reason: Batch: Started: Stopped: ZYPREXA (Suspected) Reason: 2.5 Milligram Daily Batch: Stopped: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Oral Batch: Stopped:	Akathisia			was seeing thing was violent. If he	s and hearing things and missed a pill he became	
Reason: Batch: Started: Stopped: CANNABIS PREPARATION (Other drug) Reason: Batch: Stopped: ZYPREXA (Suspected) Reason: Batch: Stopped: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Oral Batch: Stopped: -aboratory Investigations:						
Reason: Stopped: CANNABIS PREPARATION (Other drug) Reason:						
CANNABIS PREPARATION (Other drug) Batch: Started: Stopped: ZYPREXA (Suspected) Reason: 2.5 Milligram Daily Batch: Stopped: CIPRAMIL (Suspected) Tablet 40.0 Milligram Daily Oral Batch: Started: Stopped: Audition Daily Oral Batch: Stopped: Additional Daily Oral Batch: Stopped:				Rea	son:	
CANNABIS PREPARATION (Other drug) Batch: Started: Stopped: ZYPREXA (Suspected) Reason: 2.5 Milligram Daily Batch: Started: Stopped: CIPRAMIL (Suspected) Tablet 40.0 Milligram Daily Oral Batch: Started: Stopped:	Batch	n:	Started:		Stopped:	
ZYPREXA (Suspected) 2.5 Milligram Daily Batch: Started: Stopped: CIPRAMIL (Suspected) Tablet 40.0 Milligram Daily Oral Batch: Started: Stopped:	CANNABIS PI	REPARATION (Ot	her drug)	Rea		
Batch: Started: Stopped: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Oral Batch: Started: Stopped:	Batch	n:	Started:		Stopped:	
Batch: Started: Stopped: CIPRAMIL (Suspected) Reason: Tablet 40.0 Milligram Daily Oral Batch: Started: Stopped:	ZYPREXA (Su	spected)		Reas	son:	
CIPRAMIL (Suspected) Tablet 40.0 Milligram Daily Oral Batch: Started: Stopped: aboratory Investigations:			2.5	Milligram	Daily	
Tablet 40.0 Milligram Daily Oral Batch: Started: Stopped: _aboratory Investigations:	Batch	1:	Started:		Stopped:	
Batch: Started: Stopped: _aboratory Investigations:	CIPRAMIL (Su	ispected)		Reas	son:	
_aboratory Investigations:				Milligram	•	
	Batch	1:	Started:		Stopped:	
	aborator	y Investigat	ions:			
				ed Result	Det	ails
				eport 214557 is t	he second sequence.	
Additional Information: Report 214555 is the first sequence to this report and report 214557 is the second sequence.						

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Case Number: 214561

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 04/01/2006			Weigh	it: 0.00
ospitalisation:			Ag	e: 99u
Onset Date:			DO	B:
Outcome: Unknown			Causalit	y: Causality possible
eaction Details:		_		
Preferred Term	Severity	Repo	ort Description	Treatment
Akathisia		delirium. He suff agitation and wa	erienced akathisia and ered depression and kes after sleeping only eping no more after that.	
Delirium				
Medicine Details:				
ZYPREXA (Suspected)		Reas	son:	
Batch:	Started:		Stopped:	
RISPERIDONE (Suspected)		Reas	• • • • • • • • • • • • • • • • • • • •	
Batch:	Started:		Stopped:	
	Started:	Reas		
	Started:	Reas		
MIRTAZAPINE (Suspected)	Started:	Reas	son:	
MIRTAZAPINE (Suspected) Tablet Batch: _aboratory Investigations	Started:		son: Oral Stopped:	etails
MIRTAZAPINE (Suspected) Tablet Batch: _aboratory Investigations	Started:		son: Oral Stopped:	etails

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 214840
 Seq: 1
 Gender: M

 Reported:
 11/01/2006
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 42
Onset Date: 07/07/2005
DOB: 05/02/1963

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	prolonged	Patient developed a high fever (39.4), rigors and gram negative bascilli bacteremia	Olanzapine ceased.
Bacteraemia	Caused or prolonged inpatient hospitalisation		
Chills	Caused or prolonged inpatient hospitalisation		

		-	_		
M	ihد	cin	ו או	Deta	ıile:

Medicine Details.			
LITHIUM CARBONATE (Other drug)		Reason:	
Batch:	Started:		Stopped:
Batcii.	Starteu.		Stopped.
COGENTIN (Other drug)		Reason:	
(g)			
5 / 1	o		0.
Batch:	Started:		Stopped:
DIAZEPAM (Other drug)		Reason:	
DIALLI AIII (Other drug)		ricuson.	
Batch:	Started:		Stopped:
TEMAZEPAM (Other drug)		Reason:	
TEMAZEI AM (Other drug)		Reason.	
	-		
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/01/2006	ALT = SGPT		04/07/2005	419	
11/01/2006	AST = SGOT		04/07/2005	79	
11/01/2006	C-Reactive Protein		04/07/2005	79	
11/01/2006	Creatine		08/07/2005	77	
11/01/2006	Eosinophils		08/07/2005	0.02	
11/01/2006	Erythrocyte		04/07/2005	45	
11/01/2006	GGT = SGGT =		04/07/2005	414	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 214840 Seq: 1 Gender: M

Reported: 11/01/2006 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 42

Onset Date: 07/07/2005 **DOB**: 05/02/1963

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)Reason: Unspecifid affective psychosis

 Tablet
 10.0 Milligram
 1 time
 Oral

 Batch:
 Started: 18/12/2004
 Stopped: 18/12/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
11/01/2006	Lymphocytes		08/07/2005	1.32	
11/01/2006	Monocytes		08/07/2005	0.49	
11/01/2006	Neutrophils		08/07/2005	3.77	
11/01/2006	SAP = ALP		04/07/2005	235	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 214999 Seq: 1 Gender: F

Reported: 17/01/2006 Weight: 57.00 Hospitalisation: Age: 17

Onset Date: 08/08/2005 **DOB**: 04/12/1987

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Patient experienced hyperprolactinaemia.	Changed to Quetiapine.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

15.0 Milligram Daily

Batch: Started: 05/08/2005 **Stopped:** 10/08/2005 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
17/01/2006	Prolactin	85-575			Prolactin 1986 mu/l.

Additional Information:

FSH, LH & TSH normal. CT head scan non-specific hyperdensity of path pituitary gland. History: Heavy Amphetamine and marijuana abuse.

Report Run: 04/06/2007 05:16PM Database: pusime02 ADRS004 Page 406 of 530



Hospitalisation:

Onset Date:

Case Number: 215307

Reported: 27/01/2006

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Age: 41

DOB: 03/10/1964

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Action Details: Preferred Term uicidal ideation kathisia Preferred Term	do at	ne patient develorself and was reported and was partacks, violent drug lag. Reaso	Stopped: on: Stopped:	Treatment
edicine Details: CYPREXA (Suspected) Batch: CANNABIS PREPARATION (Suspected) Batch: FEXOR (Suspected) Batch: FEXOR (Suspected)	Started: Started:	ne patient develorself and was reported and was partacks, violent drug lag. Reaso	oped impulses to kill estless. She could not sit cey. She had panic eams and would sleep on: Stopped: on:	Treatment
athisia edicine Details: YPREXA (Suspected) Batch: ANNABIS PREPARATION (Suspected) Batch: FEXOR (Suspected) Batch:	Started: Started:	Reaso	cey. She had panic eams and would sleep on: Stopped: on:	
edicine Details: YPREXA (Suspected) Batch: ANNABIS PREPARATION (Suspected) Batch: FEXOR (Suspected) Batch:	Started:	Reaso	Stopped: On: Stopped:	
Batch: CANNABIS PREPARATION (Suspected) Batch: FEXOR (Suspected) Batch:	Started:	Reaso	Stopped: On: Stopped:	
Batch: CANNABIS PREPARATION (Suspected) Batch: EFEXOR (Suspected) Batch: Batch:	Started:	Reaso	Stopped: On: Stopped:	
Batch: CANNABIS PREPARATION (Suspected) Batch: EFEXOR (Suspected) Batch: Batch:	Started:	Reaso	Stopped: On: Stopped:	
Batch: CANNABIS PREPARATION (Suspected) Batch: EFEXOR (Suspected) Batch: Batch:	Started:	Reaso	Stopped: On: Stopped:	
Batch: CANNABIS PREPARATION (Suspected) Batch: EFEXOR (Suspected) Batch:	Started:	Reaso	Stopped: On: Stopped:	
Batch: Batch: Batch: Batch: Batch: Batch:	Started:	Reaso	Stopped:	
Batch: EFEXOR (Suspected) Batch: aboratory Investigations:	175.0 Mi	Reaso	Stopped:	
EFEXOR (Suspected) Batch: aboratory Investigations:	175.0 Mi		on:	
Batch: aboratory Investigations:				
aboratory Investigations:		lligram I	Daily Oral	
aboratory Investigations:	Started:		,	
			Stopped:	
	Date Tested	Result	Detai	ils
	<u> </u>	<u> </u>		
dditional Information:				
ort Run: 04/06/2007 05:16PM Database:				



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:		
Case Number: 215345	Seq: 1	Gender: F
Reported: 30/01/2006		Weight: 0.00
Hospitalisation:		Age : 81

Onset Date: 10/10/2005 **DOB**: 03/12/1923 Causality: Causality possible

Outcome: Not yet recovered

Reaction Details:

П	leaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Muscle twitching		Patient experienced intermittent twitching - generalized twitching after 4 days of Olanzapine.	Ceased Olanzapine.

_	-			D	• •
N	ЛΩС	אור	IN A	Deta	ne.

COLOXYL WITH SENNA (Other drug)		Reason:	Constipation	
Batch:	Started:		Stopped:	0
PARACETAMOL (Other drug)		Reason:	Pain	
Batch:	Started:		Stopped:	
ASPIRIN (Other drug)		Reason:	Other coagulation defects	
Batch:	Started:		Stopped:	
PRAVASTATIN SODIUM (Other drug)		Reason:	Othr&unspec metabolic disease	s
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report 215345 is the first sequence to this report.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Detail	3.					
Hospitalisation: Onset Date:	30/01/2006 10/10/2005 Not yet recovered	Seq: 1		С		0.00
Madiaina Dat	oilo					
Medicine Det PINDOLOL (Other			Reason:	Essential beni	gn hyperten:	sion
Batch:		Started:		Stopped:		
OLANZAPINE (Oth	ner drug)		Reason:	Unspecified so	hizophrenia	
Batch:		Started:		Stopped:		
OLANZAPINE (Sus	spected)		Reason:			
Tablet		5.0 Milligram	Daily		Oral	
Batch:		Started: 06/10/2005		Stopped:	10/10/2005	5
Laboratory In	vestigations:					
Additional Inf		this report.				
	formation: he first sequence to	this report.				

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Hospitalisation:

Onset Date:

Case Number: 215351

Reported: 30/01/2006

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

DOB:

Weight: 0.00

Age: 99u

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Outcome: Death, may	be drug	15/07/2005	Causalit	y: Causality possible	
eaction Details: Preferred Term	Severity	Report De	escription	Treatment	
ggression	Death	The patient became v Zyprexa. If he did not manifested supersens withdrawal akathisia. Iran out, he went akath homicidal and suicidal suicide by hanging in	iolent and suicidal on take a dose he sitivity psychosis or At one time, when he nisic violent, I. He committed		
kathisia	Death				
completed suicide	Death				
rug withdrawal syndrome	Death				
lomicidal ideation	Death				
sychotic disorder	Death				
Indinina Dataila:					
ledicine Details: ZYPREXA (Suspected)		Reason:			
, , , , , , ,	40.0	Milligram Daily			
Batch:	Started:		Stopped:	0	
aboratory Investigation Date Type	ons: Range Date Test	ed Result	De	etails	
, ye	- J. J.		-		
dditional Information:					



Case Number: 215351

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 30/01/2006			Weigh	nt: 0.00
ospitalisation:				je : 99u
Onset Date:				B:
Outcome: Death, mayb	e drug 1	5/07/2005	Causali	ty: Causality possible
eaction Details:				
Preferred Term	Severity	Report Desc	ription	Treatment
Suicidal ideation	Death			
uicidal ideation	Death			
edicine Details:				
YPREXA (Suspected)		Reason:		
	40.0 Millig	ram Daily		
Batch:	Started:		Stopped:	0
boratory Investigation	ns:			
dditional Information:				
oort Pup : 04/06/2007 05:16PM	Database: pusimo02	VDB6004		Daga 444 of E0

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 215506
 Seq: 1
 Gender: M

 Reported:
 02/02/2006
 Weight:
 0.00

Hospitalisation: Age: 35Y
Onset Date: 01/01/2006 DOB:

Outcome: Death, maybe drug 06/01/2006 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Death	Patient received Zyprexa 20mg intramuscularly and intramuscular clonazepam 6mg, reporter stated that Zyprexa 20mg should not have happened, it was not provided whether this was an accidental or prescribed overdose. The patient experienced cardiac arrest and died.	

Medicine Details:

Modifile Botalies		
CLONAZEPAM (Suspected)		Reason:
Injection		Intramuscular
Batch:	Started:	Stopped:
ZYPREXA (Suspected)		Reason: Otr spec symp psychopathol nec
Injection	20.0 Milligram	Daily Intramuscular
Batch:	Started: 01/01/2006	Stopped: 0

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Medical history included diabetes, obesity and was generally poor in health.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 215506
 Seq: 1
 Gender: M

 Reported:
 02/02/2006
 Weight:
 0.00

 Hospitalisation:
 Age: 35Y

Onset Date: 01/01/2006 DOB:

Outcome: Death, maybe drug 06/01/2006 Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Death	Patient received Zyprexa 20mg intramuscularly and intramuscular clonazepam 6mg, reporter stated this should not have happened, it was not provided whether this was an accidental or prescribed overdose. The patient experienced cardiac arrest and died.	
Overdose	Death		

Medicine Details:

Micalcinic Details.		
CLONAZEPAM (Suspected)		Reason:
Injection		Intramuscular
Batch:	Started:	Stopped:
ZYPREXA (Suspected)		Reason: Otr spec symp psychopathol nec
Injection	20.0 Milligram	Daily Intramuscular
Batch:	Started: 01/01/2006	Stopped: 0

Laboratory Investigations:

Additional Information:

Medical history included diabetes, obesity and was generally poor in health.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 215538 Seq: 1 Gender: F

Reported: 03/02/2006 Weight: 40.00 Hospitalisation: Age: 12

Onset Date: 20/09/2005 **DOB**: 14/05/1993

Outcome: Recovered 15/12/2005 Causality: Causality possible

Reaction Details:

teaction Details.	louotion Botano.					
Preferred Term	Severity	Report Description	Treatment			
Urinary incontinence						
Urinary incontinence		The child experienced urinary incontinence, stress incontinence and nocturnal incontinence.				
Enuresis						

Medicine Details:

Medicine Details.					
ASCORBIC ACID (Other drug)	Re	eason:			
Tablet	500.0 Milligram			Oral	
Batch:	Started: 15/07/2005		Stopped:		
ZYPREXA (Suspected)	Re	eason:	Anorexia		
	5.0 Milligram	Daily	,		
Batch:	Started: 12/08/2005		Stopped:	30/11/2005	0
F.G.F. (Suspected)	Re	eason:			
	1.0 Dose Unspecified	d Daily	,		
Batch:	Started: 15/07/2005		Stopped:	30/10/2005	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 05:16PM Database: pusime02 ADRS004 Page 414 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 215794 Seq: 1 Gender: F

Reported: 13/02/2006 Weight: 0.00 Hospitalisation: Age: 57

Onset Date: DOB: 04/12/1948

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Tardive dyskinesia	Incapacity/dis ability	The patient developed tardive dyskinesia.	Olanzapine ceased, changed to Seroquel.	

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
LITHICARB (Other drug)		Reason: Unspecifid affective psychos	is
	1.2 Gram	Daily Oral	
Batch:	Started:	Stopped:	0
EFEXOR-XR (Other drug)		Reason: Unspecifid affective psychos	is
	300.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecifid affective psychos	is
	2.5 Milligram	Daily	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 215795 is the second sequence to this report.

Report Run: 04/06/2007 05:16PM Database: pusime02 ADRS004 Page 415 of 530



Case Number: 215896

Reported: 16/02/2006

Hospitalisation: Admitted to hospital

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Age: 89

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Outcome: Reconstanting Preferred Televirum Preferred Televirum	erm Capring	Severity aused or olonged soatient ospitalisation Started:	Delirium secono superimposed u vagueness and	ort Description lary to Olanzapine, upon dementia, confidecreased mobility. ason: Stopped:	Dose usion,	Treatment reduced to 5mg daily.	
Preferred Telelirium edicine Details: SODIUM VALPROATE (Compared to the compared to the c	Ca pro inp ho Other drug)	aused or olonged oatient ospitalisation	Delirium secono superimposed u vagueness and	dary to Olanzapine, ipon dementia, conf decreased mobility.	usion, Dose		
Preferred Telirium edicine Details: ODIUM VALPROATE (C Batch: ALOXIFENE (Other dru	Ca pro inp ho Other drug)	aused or olonged oatient ospitalisation	Delirium secono superimposed u vagueness and	dary to Olanzapine, ipon dementia, conf decreased mobility.	usion, Dose		
edicine Details: ODIUM VALPROATE (C Batch: ALOXIFENE (Other dru Batch:	pring ho	patient pspitalisation	Rea	sson:	usion, Dose	reduced to 5mg daily.	
ODIUM VALPROATE (C Batch: ALOXIFENE (Other dru Batch:	Other drug)	Started:		Stopped:			
Batch: Batch: Batch: Batch: Batch:	Other drug)	Started:		Stopped:			
Batch: ALOXIFENE (Other dru Batch:		Started:		Stopped:			
ALOXIFENE (Other dru	ıg)	Started:	Rea				
Batch:	ng)		Rea		Stopped:		
				19011.			
OKBITOL (Other arug)		Started:	Davi	Stopped:			
			Kea	ison:			
Batch:		Started:		Stopped:			
ARACETAMOL (Other	drug)		Rea	ison:			
-				0.			
Batch:		Started:		Stopped:			
boratory Inves				_			
Date Type	Range	Date Teste	d Result		Details		



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	215896	Seq: 1				Gender:	F	
Reported:	16/02/2006					Weight:	0.00	
Hospitalisation:	Admitted to hosp	ital				Age:	89	
Onset Date:	10/03/2005					DOB:	25/04/1915	
Outcome:	Recovered				C	ausality:	Causality possible	
Reaction Detai	ils:							
Medicine Det								
ZYPREXA (Suspec	cted)			Reason:				
Tablet			Milligram	1 time		Oral		
Batch:		Started: 09/0)3/2005		Stopped:	09/03/2005		
ZYPREXA (Suspec	cted)			Reason:				
Tablet			Milligram	Daily		Oral		
Batch:		Started: 09/0)3/2005		Stopped:	10/03/2005	i	
ZYPREXA (Suspec	cted)			Reason:				
Tablet			Milligram	Daily		Oral		
Batch:		Started:			Stopped:			
l aboratory in	voctigations							
Laboratory III	vestigations:							
Additional Inf	formation:							

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 216307 Seq: 1 Gender: F

Reported: 07/03/2006 Weight: 0.00 Hospitalisation: Age: 24Y

Onset Date: 15/02/2006 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
	prolonged	thrombosis that she had experienced in all major blood vessels of her legs.	Ceased Zyprexa

Medicine Details:

MICROGYNON (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
	1.3 Milligram	Daily Oral	
Batch:	Started:	Stopped : 15/02/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had a history of brain damage at birth and mild cerebral palsy.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 216346
 Seq: 1
 Gender:
 M

 Reported:
 09/03/2006
 Weight:
 0.00

 Hospitalisation:
 Age: 40

 Onset Date: 16/08/2005
 DOB: 04/08/1965

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	prolonged inpatient	Patient experienced neuroleptic malignant syndrome, tachycardia, blood pressure increased, hypertonia and complaining of stiffness.	Stopped neuroleptics on 16/08/05.
Blood pressure increased	Caused or prolonged inpatient hospitalisation		
Hypertonia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
Tablet	2.0 Gram	Oral	
Batch:	Started: 16/08/2005	Stopped:	
CLONAZEPAM (Other drug)		Reason: Anxiety neurosis	
Tablet	4.0 Milligram	Daily Oral	
Batch:	Started: 16/08/2005	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason: Unspecified psychosis	
Injection	200.0 Milligram	1 time	
Batch:	Started: 11/08/2005	Stopped: 12/08/2005	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
09/03/2006	Creatine		19/08/2005	300	
09/03/2006	Serum drug level		12/08/2005	140	

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	216360	Seq: 1				Gender:	F	
Reported	: 09/03/200	6				Weight:	0.00	
ospitalisation:						Age:		
Onset Date		6				DOB:		
	Unknown				C	ausality:	Causality poss	sible
eaction Deta		<u> </u>						
	red Term	Severity		ort Desc			Treatme	nt
Alopecia			Hair falling out in	clumps				
Medicine De Zyprexa Zydis (Si			Rea	son.				
Zypiexa Zydis (O	uspecteu,		Nou.	1 time		Oral		
Batch:		Started:			Stopped:	0.0.		
_aboratory II	nvestigat Type	ions: Range Date Teste	ed Result			Detai	lo.	
Date	туре	Range Date reste	d Result			Detai	15	
Additional In	formatio	n:						
eport Run: 04/06/20	007 05:16PM	Database: pusime02		DRS004			Page 420	of 530

Rep



Hospitalisation:

Case Number: 216399

Reported: 10/03/2006

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Weight: 0.00

Age: 19

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Onset D	ate:		DOB: 09/10/1986						
Outcor	me: Unknown			Causality: Causality possible					
eaction D	etails:								
Pre	eferred Term	Se	verity	Rep	ort Description	Treatmen	t		
Suicidal idea	tion		Wh so wi ph ha wa Ex	nich made him meone else, the feelings of hysical damagned thoughts of as walking fas operienced agos feeling high	ights about killing himself violent, tried to hit ried to hit ried to hit a security guard killing and tried to do e. Tried to hurt himself and hurting other people. He ter than normal. gression, insomnia and on Prozac. Also felt on more than 20kg.				
Aggression									
Akathisia									
		I	I						
Medicine									
ZYPREXA (Su	uspected)			Rea	son:				
Batc	h:	St	arted: 19/02/2	2004	Stopped: 19/01/	2006			
PROZAC (Su	spected)			Rea	son: Depression				
			10.0 Mil	ligram	Daily				
Batc	h:	St	Started: Stopped:						
L aborator Date	y Investigati Type	ons: Range	Date Tested	Result	Γ	Details			
	l Information								
port Run: 04/0	06/2007 05:16PM	Database: pu	sime02	,	ADRS004	Page 421	of 530		



Case Number: 216399

Reported: 10/03/2006

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

ospitalisation:			Age: 19				
Onset Date:		DOB : 09/10/1986					
Outcome: Unknown		Causality: Causality possible					
eaction Details:							
Preferred Term	Severity	Report Description	Treatment				
Anxiety							
Euphoric mood							
nsomnia							
ntentional self-injury							
Veight increased							
Medicine Details:							
ZYPREXA (Suspected)		Reason:					
Batch:	Started: 19/02/2004	Stopped: 1	9/01/2006				
PROZAC (Suspected)	40.0	Reason: Depression					
	10.0 Milligram	Daily					
Batch:	Started:	Stopped:					
.aboratory Investigations:							
Additional Information:							
ort Run: 04/06/2007 05:16PM Data	abase: pusime02	ADRS004	Page 422 of 530				



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 216669 Seq: 1 Gender: M

Reported: 24/03/2006 Weight: 96.00 Hospitalisation: Age: 44

Onset Date: 17/03/2006 **DOB**: 25/08/1961

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	prolonged inpatient	severe withdrawal from the medication.	Doctor has resumed Zyprexa at 2.5mg inconjuction with 25mg of Tryptanol.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecifid affective psychosis

Tablet 5.0 Milligram Daily Oral

Batch: Started: 10/09/2005 **Stopped:** 17/03/2006 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 216731
 Seq: 1
 Gender:
 M

 Reported:
 28/03/2006
 Weight:
 0.00

 Hospitalisation:
 Age: 50

Onset Date: 11/03/2006 **DOB**: 09/04/1955

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Body temperature increased	prolonged innatient	Patient had been found non-responsive, unconscious, sedated and with frothing at mouth, increased body temperature and an increased CK.	
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Loss of consciousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (S	Suspected)	Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	700.0 Milligram	Daily Oral	
Batch:	Started: 30/08/1995	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
27/03/2006	Creatine		11/03/2006	63000	

Additional Information:

No muscle rigidity.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report D	etails:					
Case Num	nber: 216787	Seq: 1		Ge	ender: M	
Repo	rted: 29/03/2006		Weight: 90.00			
ospitalisa	tion:				Age: 50	
-	Date: 12/03/2006				DOB : 09/04/1955	
Outco	me: Recovered		23/03/2006	Caus	sality: Causality possible	
eaction E	Details:				3	
	referred Term	Severity	Rep	ort Description	Treatment	
Neuroleptic	malignant syndro	me Life threatening	Patient in hoste from chair- no cas frorhing from consciousness awoke- agitatat for airway prote In ICU, elevated failure, febrile.	I was observed to slump	bed to maintain urine output; dantrolene and bromocript ed CU.	
Aggression		Life threatening				
Agitation		Life threatening				
Medicine	Details:					
	IE (Suspected)		Rea	ason:		
	,					
Bat	ch:	Started:		Stopped:	0	
PAROXETIN	IE HYDROCHLORIDE	(Suspected)	Rea	ason:		
Bat	ch:	Started:		Stopped:	0	
CLOZAPINE	(Suspected)		Rea	ason:		
Tabl	let	600.0	Milligram	1 time Ora	ral	
Bat	ch:	Started: 31/0	03/2005	Stopped: 12/	2/03/2006	
_aborato	ry Investigatio	O NS: Range Date Test	ed Result	T	Details	
	Creatine	nange Date rest	i Nesuit	CK on admission 606 III/I	L and peaked at 63328 on the	
26/03/2000	been believe			13/03/2006. Gradually ded	creased to normal (< 200 IU/L)on all normal. Micro: blood, urine, sputu	
Additiona	al Information	:				

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Case Number: 216787

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Preferred Term vrexia Lit	23/03		Age:	50
Outcome: Recovered action Details: Preferred Term //rexia	23/03			
action Details: Preferred Term prexia Lit	23/03		DOB:	09/04/1955
yrexia Lit		3/2006	Causality:	Causality possible
yrexia Lit			ı	_
ryrexia Lit th	Severity	Report Description		Treatment
	reatening			
ledicine Details:				
OLANZAPINE (Suspected)		Reason:		
Detak	Otanta di	Otama ada		0
Batch:	Started:	Stopped:		0
PAROXETINE HYDROCHLORIDE (Suspec	ted)	Reason:		
Batch:	Started:	Stopped:		0
CLOZAPINE (Suspected)		Reason:		
Tablet	600.0 Milligram	1 time	Oral	
Batch:	Started: 31/03/2005	Stopped:	12/03/2006	3

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Case Number: 216863

Reported: 31/03/2006

Hospitalisation: Admitted to hospital

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00 **Age:** 99U

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Onset Date:		DOB:				
Outcome: Not yet re	covered	Causality: Causality possible				
action Details:						
Preferred Term	Severity	Reno	ort Description	Treatment		
euroleptic malignant syndi	The second secon	Patient experien syndrome.	ced neuroleptic malignant			
edicine Details:		Rea	son:			
Batch:	Started:		Stopped:			
HALOPERIDOL (Suspected)		Rea	son:			
Batch:	Started:		Stopped:			
ALIUM (Suspected)		Rea	son:			
Batch:	Started:		Stopped:			
aboratory Investigat Date Type	ions: Range Date Tes	sted Result	С	Details		
Additional Information	n:					
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Case Number: 216893

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 03/04/2006		Weight: 110.00				
Hospitalisation:		Age : 25Y				
Onset Date:		DOB:				
Outcome: Not yet reco	vered	Causality: Causality possible				
Reaction Details:				_		
Preferred Term	Severity	Rep	ort Description	Treatment		
Incorrect dose administered		Dose used high	er than recommended			
Depression		Experienced de described as a	pression which was "major problem"	citalopram		
Weight increased		Since starting Z five and a half s and prescribed	Typrexa patient has gained stone in weight increased overdose.	Zyprexa discontinued.		
Increased appetite						
Medicine Details: DIAZEPAM (Other drug)		Rea	ason:			
-						
Batch:	Started:		Stopped:			
ZYPREXA (Suspected)		Rea	ason: Unspecified schizophrenia			
Tablet	60	0.0 Milligram	Daily Oral			
-			Daily			
Batch:	Started:	_	Stopped:			
Batch: Laboratory Investigatio Date Type	Started:	_	Stopped:	etails		
Laboratory Investigatio	Started:		Stopped:	retails		
Laboratory Investigatio	Started:		Stopped:	etails		
Laboratory Investigatio Date Type	Started:		Stopped:	Petails		

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

-						
Report Details:						
Case Number: 216894	Seq:	1			Gender:	M
Reported: 03/04/2006					Weight:	0.00
ospitalisation:					Age:	35Y
Onset Date:					DOB:	
Outcome: Unknown				(Causality:	Causality possible
eaction Details:						
Preferred Term	Sev	erity		rt Description		Treatment
Convulsion		Aftı ext	er commencin perienced a se	g Zyprexa pateint eizure.		
Madiaina Dataila.						
Medicine Details: SEROQUEL (Suspected)			Reas	son:		
Tablet					Oral	
Batch:	Sta	rted:				
EFEXOR (Suspected)				Stopped		
			Reas			
			Reas		Oral	
Batch:	Sta	rted:	Reas		Oral	
Batch: LITHIUM CARBONATE (Suspected		rted:	Reas	son: Stopped	Oral	
		rted:		Stopped:	Oral	
LITHIUM CARBONATE (Suspected Tablet Batch:	1)	rted:		Stopped: Stopped:	Oral Oral	
LITHIUM CARBONATE (Suspected Tablet Batch: ZYPREXA (Suspected)	1)	rted:	Reas Reas	Stopped:	Oral Oral	osis
Tablet Batch: ZYPREXA (Suspected) Tablet	l) Sta	rted: 10.0 Milli	Reas Reas	Stopped: Stopped: Stopped: Stopped: Daily	Oral Oral fective psychological	osis
Tablet Batch: ZYPREXA (Suspected)	l) Sta	rted:	Reas Reas	Stopped: Stopped: Stopped: Stopped: Unspecifid af	Oral Oral fective psychological	osis
Tablet Batch: ZYPREXA (Suspected) Tablet	Sta	rted: 10.0 Milli	Reas Reas	Stopped: Stopped: Stopped: Stopped: Daily	Oral Oral fective psychological	osis

Additional Information:

Patient's medical history includes the patient experiencing extreme agitation whilst receiving Lithium. This report 216894 is a duplicate of 216945.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 216944 Seq: 1 Gender: F

Reported: 04/04/2006 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 54

Onset Date: 08/03/2006 DOB: 24/09/1951

Outcome: Recovered 15/03/2006 Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Ceased Olanzapine and monitor with FBC.

Medicine Details:

CEPHALEXIN (Other drug)	Reason: Othr diseases of urinary tract
-------------------------	---

250.0 Milligram

Batch: Started: 19/12/2005 **Stopped:** 0

THIAMINE (Other drug) Reason:

100.0 Milligram

Batch: Started: 15/12/2005 Stopped:

MULTIVITAMINS (Other drug)

Tablet 1.0 Dose Unspecified Oral

Batch: Started: 22/12/2005 Stopped:

ZYPREXA (Suspected) Reason:

Tablet 2.5 Milligram Daily Oral

Batch: Started: 18/10/2004 **Stopped:** 09/03/2006 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
04/04/2006	Neutrophils		08/03/2006	0.85	

Reason:

Additional Information:

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Case Number: 216949

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

			weig	ht: 0.00
Hospitalisation:			A	ge: 34
Onset Date:	DOB : 09/06/1971			
Outcome: Unknown			Causal	ity: Causality possible
Reaction Details:				
Preferred Term	Severity		ort Description	Treatment
Pyrexia		weeks when he hospital. The pa (neuroleptic mal	no Clozaril for 2.5-3 was given Olanzapine in tient then developd NMS ignant syndrome) with a ure and raised CK.	benzodiazapine
Neuroleptic malignant syndrome		Suspected		
Blood creatine phosphokinase ir	ncr	·		
Medicine Details: OLANZAPINE (Suspected)		Poo	son:	
OLANZAPINE (Suspected)		кеа	SUII.	
Batch:	Started: Stopped:			
		ed Result		Details
Laboratory Investigations Date Type F	S: Range Date Teste	ed Result		Details

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 217175 Seq: 1 Gender: F

Reported: 07/04/2006 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 65Y
Onset Date: 15/02/2006 DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Joint swelling	Caused or prolonged inpatient hospitalisation	The patient experienced swollen ankle, pain (location unknown), fever and raised c-reactive protein.	
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected) Reason: Anxiety neurosis

5.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Suspect drug certain rechallenge.

Medical condition: Bipolar disorder and rheumatoid arthritis.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Ren	ort	Deta	ils:
-----	-----	------	------

Case Number: 217175 Seq: 1 Gender: F

Reported: 07/04/2006 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 65Y
Onset Date: 15/02/2006 DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

Cachon Details.			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		

ıvu		Deta	mo.

ZYPREXA (Suspected)

Reason: Anxiety neurosis

5.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Additional Information:

Suspect drug certain rechallenge.

Medical condition: Bipolar disorder and rheumatoid arthritis.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Gender: F Case Number: 217538 Seq: 1

Weight: 48.50 Reported: 20/04/2006 Hospitalisation: Admitted to hospital **Age:** 24

Onset Date: 08/02/2006 **DOB**: 28/07/1981

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion botano			
Preferred Term	Severity	Report Description	Treatment
Deep vein thrombosis	Life threatening	Bilateral femoral, iliac and right popliteal and right calf DVT's on sonogram.	Clexane, then Warfarin.

Medicine Details:

OLANZAPINE (Suspected)		Reason:	Unspecified psychosis
Tablet	1.3 Milligram	Daily	Oral
Batch:	Started: 21/10/2003		Stopped: 08/02/2006
MICROGYNON 30 FD (Suspected)		Reason:	

Tablet 1.0 Dose Unspecified Daily Oral Batch: Started: Stopped: 08/02/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 217552
 Seq: 1
 Gender: M

 Reported:
 20/04/2006
 Weight: 70.00

Hospitalisation: Required a visit to the doctor **Age:** 41

Onset Date: 05/04/2006 **DOB**: 13/06/1964

Outcome: Unknown Causality: Causality possible

Reaction Details:

,	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	ı
	Choreoathetosis		choreo-athetoid movements.	Given Benztropine 2mg IM and Olanzapine was discontinued.	

Medicine Details:

OLANZAPINE (Suspected) Reason: Manic-depression psycho, manic

20.0 Milligram 1 time Oral

Batch: Started: 05/04/2006 Stopped: 05/04/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Case Number: 217840

Reported: 02/05/2006

Onset Date: 17/02/2003

Hospitalisation: Admitted to hospital

Outcome: Not yet recovered

Report Run: 04/06/2007 05:17PM Database: pusime02

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Weight: 0.00

Age: 24

DOB: 27/12/1978

Causality: Causality possible

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Preferred Term	Severity	Report Description	Treatment			
Eye infection	Incapacity/dis ability	Frequent eye infections				
Diabetes mellitus insulin-depende	r Incapacity/dis ability	Patient diagnosed with insulin dependent diabetes. Patient also reported to have experienced difficulty sleeping, anxiety, depression and frequent sweating.				
Anxiety	Incapacity/dis ability					
Depression	Incapacity/dis ability					
Hyperhidrosis	Incapacity/dis ability					
Medicine Details:						
SERTRALINE HYDROCHLORIDE (Other	er drug)	Reason:				
Batch:	Started:	Stopped:				
ZYPREXA (Suspected)		Reason: Unspecified schi	zophrenia			
Tablet	20.0	Milligram Daily Oral				
Batch:	Started: 05/	09/1999 Stopped : 2	0/02/2003 0			
Laboratory Investigations:		ed Result	Details			
		ed Result	Details			
		ed Result	Details			
		ed Result	Details			
		ed Result	Details			
		ed Result	Details			
		ed Result	Details			
Date Type Ra		ed Result	Details			
		ed Result	Details			
Date Type Ra		ed Result	Details			

ADRS004



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Detail	s:					
Case Number: 217840 Seq: 1 Reported: 02/05/2006 Hospitalisation: Admitted to hospital			Gender: M Weight: 0.00 Age: 24			
-	Onset Date: 17/02/2003					: 24 3: 27/12/1978
Outcome: Not yet recovered					: Causality possible	
Reaction Detai		•			Gudsunty	. Oddodnity possible
	ed Term	Severity		Report Desc	cription	Treatment
Insomnia		Incapacity/dis ability		•	'	
Ketoacidosis		Incapacity/dis ability				
Renal impairmen	t	Incapacity/dis ability				
Weight increased	i	Incapacity/dis ability				
Medicine Deta	ails: PROCHLORIDE (Other	r drug)		Reason:	Stopped:	
ZYPREXA (Suspec	eted)	Starteu.		Reason: U	Inspecified schizophren	ia
Tablet	neu)	20.0	Milligram	Daily	Oral	la la la la la la la la la la la la la l
Batch:		Started: 05/0	-	. ,	Stopped: 20/02/200	03 0
Laboratory In	vestigations:					
Additional Inf	formation:					

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Numb	er: 217845	Seq: 1			Ge	nder:	M
	ed: 02/05/200					eight:	
Hospitalisation						Age:	
Onset Da	ite:					DOB:	
Outcon	ne: Unknown				Caus	sality:	Causality possible
Reaction De	tails:						
	ferred Term	Severi	ty	Repo	rt Description		Treatment
Cerebrovasci	ılar accident		Pati	ent experien	ced a stroke.		
Medicine [Ootails:						
ZYPREXA (Su				Reas	son:		
(,						
Batch	:	Starte	d:		Stopped:		
Laboratory							
Date	Туре	Range Dat	e Tested	Result		Detail	S
Additional	Informatio	n:					

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 217948 Seq: 1 Gender: F

Reported: 03/05/2006 Weight: 0.00 Hospitalisation: Age: 20

Onset Date: DOB: 23/04/1986

Outcome: Unknown Causality: Causality possible

Reaction Details:

			-
Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Hyperprolactinaemia - this is symptomatic with amenorrhea (no periods).	Medication ceased. Aripiprazole commenced.
Amenorrhoea			
Therapy regimen changed			

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: **Started**: 27/12/2004 **Stopped**: 13/01/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details	
03/05/2006	Prolactin	<200.		Prolactin level - 2110.		

Additional Information:

Intermittent amenorrhea while on 10mg - worsened on increase to 20mg.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 217987 Seq: 1 Gender: F

Reported: 04/05/2006 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 81

Onset Date: 27/03/2006 **DOB**: 29/06/1924

Outcome: Recovered with sequelae Causality: Causality possible

Reaction Details:

todotion Botanoi									
Preferred Term	Severity	Report Description	Treatment						
Hypothermia	ypothermia								

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis
Batch:	Started:	Stopped:
SEROQUEL (Suspected)		Reason: Unspecified psychosis

Tablet 150.0 Milligram Daily Oral

Batch: Started: Stopped: 06/04/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 217989 is the second sequence to this report.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 218212 Seq: 1 Gender: M
Reported: 10/05/2006 Weight: 70.00

 Hospitalisation:
 Age: 35

 Onset Date: 15/04/2006
 DOB: 26/08/1970

Outcome: Recovered Causality: Causality probable

Reaction Details:

eaction Details.									
Preferred Term	Severity Report Description		Treatment						
Weight increased		Patient experienced weight gain of 3 kg in 1 month. Known stable diabetic, developed BSLs of 15 for duration of use of Zyprexa.	Ceased Zyprexa.						
Blood glucose increased									

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 2.5 Milligram Daily Oral

Batch: Started: 31/03/2006 **Stopped:** 30/04/2006 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 441 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 218299 Seq: 1 Gender: M
Reported: 12/05/2006 Weight: 74.00
Respitalisation: Admitted to bespital

Hospitalisation: Admitted to hospital Age: 62
Onset Date: 24/02/2006 DOB: 10/07/1943

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		Olanzapine ceased. Treated with GCSF s/c for 5/7.
	Caused or prolonged inpatient hospitalisation		

п	v	\sim	 	•	-	 \sim
ı١	vi		 		eta)	•

OMEPRAZOLE (Other drug)		Reason:	Other diseases of esophagus
Batch:	Started:		Stopped:
Valganciclovir (Other drug)		Reason:	Other prophylactic procedures
Batch:	Started:		Stopped:
HALOPERIDOL (Other drug)		Reason:	Unspecified psychosis
Batch:	Started:		Stopped:
CYCLOSPORIN-A (Other drug)		Reason:	
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
12/05/2006	Lymphocytes				Lymp - 0.43.
12/05/2006	Monocytes				Mono- 0.16.
12/05/2006	Neutrophils				Neut - 0.28.
12/05/2006	White blood cells				WCC - 0.9.

Additional Information:

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Case Number: 218299

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported:	12/05/2006				Weight:	74.00
Hospitalisation:	Admitted to hospital				Age:	62
Onset Date:	24/02/2006					10/07/1943
Outcome:	Recovered			C	ausality:	Causality possible
Reaction Detail	ls:					
Medicine Deta			Reason:			
	G,	Otomordi.		Ctampad.		
Batch: OLANZAPINE (Sus	nected)	Started:	Reason:	Stopped: Unspecified ps	vchosis	
Tablet	pociouj	5.0 Milligram	Daily	опореспіси ра	Oral	
Batch:		Started: 17/02/2006	Dany	Stopped:	24/02/2006	,
Laboratory In	vestigations:					
Additional Inf	ormation:					

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
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Case Number: 218366 Seq: 1 Gender: F

Reported: 15/05/2006 Weight: 58.00 Hospitalisation: Age: 37

Onset Date: 20/04/2006 **DOB**: 16/01/1969

Outcome: Recovered 23/04/2006 Causality: Causality probable

Reaction Details:

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Headache		Severe headache, dizziness and loss of memory for one and a half hours after patient took medication.	
Dizziness			

Medicine Details:

<u>Medicine Details:</u>						
FLUOXETINE HYDROCHLORIDE (Other dru	g)		Reason:	Depression		
	50.0	Milligram	Daily		Oral	
Batch:	Started:		L TERM	Stopped:		
ZYPREXA (Suspected)			Reason:	Depression		
Tablet	2.5	Milligram	Daily		Oral	
Batch:	Started: 20	/04/2006		Stopped:	22/04/2006	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report De	tails:				
Case Numb	oer: 218528	Seq: 1		Gen	der: M
Report	ted: 19/05/2006	3		Weig	ght: 0.00
Hospitalisati	on:			Δ.	\ge : 51Y
Onset Da	ate:			D	OB:
Outcor	ne: Not yet red	covered		Causa	lity: Causality possible
Reaction D	etails:				
Pre	eferred Term	Severity	Repor	Description	Treatment
Diabetes me	llitus		Patient developed polydipsia, nausea	diabetes, polyuria, a and vomiting.	On an unknown date, Olanzapine was discontinued. The pateint's mental condition worsened and therefore Olanzapine was restarted.
Polydipsia					
Polyuria					
Vomiting					
AROPAX (Oth		2	Reaso		
Batcl		Started:	B	Stopped:	
XANAX (Othe	r drug)		Reaso	on:	
Batcl	h:	Started:		Stopped:	
ZYPREXA (Su	uspected)		Reaso	n: Unspecifid affective	osychosis
		10.0 M	Milligram [Daily	
Batcl	h:	Started: 15/00	6/2005	Stopped:	
	y Investigati				
Date	Туре	Range Date Teste	d Result		Details

Additional Information:

The patient did not experienced any further problems after restarting Olanzapine. Patient is generally healthy and not overweight.

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 445 of 530



Case Number: 218604

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 23/05/2006			Weigh	t: 0.00	
ospitalisation:			Age	e: 55Y	
Onset Date:			DO	В:	
Outcome: Not yet recove	ered		Causalit	y: Causality possi	ble
action Details:					
Preferred Term	Severity	Report De		Treatmen	t
euroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient developed neu syndrome.	roleptic malignant		
edicine Details:					
ZYPREXA (Suspected)		Reason:			
Tablet		Milligram Daily	Oral		
Batch:	Started:		Stopped:		
aboratory Investigations					
Date Type F	Range Date Test	ed Result	De	tails	
,	1				
dditional Information:					



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: 29/05/2006 Hospitalisation: Onset Date: Outcome: Not yet recovered Reaction Details: Preferred Term Overdose Blood creatine phosphokinase incr Akathisia	F	Higher than reco	ort Description ommended dose	0.00 99u
Outcome: Not yet recovered Reaction Details: Preferred Term Overdose Blood creatine phosphokinase incr Akathisia	l F	Higher than reco	Causality: ort Description ommended dose	Causality possible
Preferred Term Overdose Blood creatine phosphokinase incr Akathisia	l F	Higher than reco	ort Description ommended dose	
Preferred Term Overdose Blood creatine phosphokinase incr Akathisia	l F	Higher than reco	ommended dose	Treatment
Overdose Blood creatine phosphokinase incr Akathisia	l F	Higher than reco	ommended dose	Treatment
Blood creatine phosphokinase incr Akathisia	F	Pateint experien		
	ľ	phosphokinase	vated creatine	
Delirium				
Medicine Details: ZYPREXA (Suspected)		Rea	son:	
Tablet	45.0 N	Milligram	Oral	
_aboratory Investigations: Date Type Range	Date Teste	d Result	Detai	ls
29/05/2006 Creatine	24.0 . 00.0		CPK - >300.	

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Case Number: 218832

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 31/05/2006				Weight:	0.00	
ospitalisation:		Age : 50				
Onset Date: 25/05/2006				DOB	21/04/1956	
Outcome: Unknown		Causality: Causality possible				
eaction Details:						
Preferred Term	Severity	i i	eport Description		Treatmen	
Diabetes mellitus		Patient develo	oped diabetes.		educe the dose of anazepine.	
Medicine Details: OLANZAPINE (Suspected)		R	leason:			
Tablet	15.0) Milligram	Daily	Oral		
<u>_aboratory Investigation</u> Date Type	S: Range Date Te	sted Result		Deta	ils	
Additional Information:						
port Run: 04/06/2007 05:17PM E	Database: pusime02		ADRS004		Page 448	of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:218879Seq: 1Gender:UReported:02/06/2006Weight:0.00Hospitalisation:Admitted to hospitalAge: 73

Onset Date: DOB: 14/12/1932

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cognitive disorder	prolonged	13/04/06: Incontient/Impaired cognition, mobility. 14/04/06: Oedema. 18/04/06: Febrile and dysphagia. 23/04/06: Hyperglycaemia.	Metofrmin, Clomipramine and Ogen ceased.
Dysphagia	Caused or prolonged inpatient hospitalisation		
Hyperglycaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

METFORMIN HYDROCHLORIDE (Se	uspected)	Reason:			
Tablet	500.0 Milligram	Daily		Oral	
Batch:	Started: 25/04/2006		Stopped:	02/05/2006	0
CLOMIPRAMINE HYDROCHLORIDE	(Suspected)	Reason:			
Tablet	50.0 Milligram	Daily		Oral	
Batch:	Started: 18/11/2005		Stopped:	02/05/2006	
OGEN (Suspected)		Reason:			
	1.3 Milligram	Daily			
Batch:	Started: 16/03/2006		Stopped:	02/05/2006	
ATENOLOL (Suspected)		Reason:			
Tablet	25.0 Milligram	Daily		Oral	
Batch:	Started: 26/09/2005		Stopped:	02/05/2006	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:218879Seq: 1Gender:UReported:02/06/2006Weight:0.00Hospitalisation:Admitted to hospitalAge: 73

Onset Date: DOB: 14/12/1932

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mobility decreased	Caused or prolonged inpatient hospitalisation		
Oedema	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	Explosive personality disorder
	10.0 Milligram	Daily	
Batch:	Started: 26/09/2005		Stopped: 02/05/2006 0
EPILIM (Suspected)		Reason:	Explosive personality disorder
	1.5 Gram	Daily	
Batch:	Started: 26/06/2005		Stopped: 02/05/2006
LASIX (Suspected)		Reason:	Edema and dropsy
	80.0 Milligram	Daily	
Batch:	Started: 26/09/2005		Stopped: 02/05/2006
ALDACTONE (Suspected)		Reason:	Edema and dropsy
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 26/09/2005		Stopped: 02/05/2006

Laboratory Investigations:

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

218879	Seq: 1		•	:ender	~
02/06/2006			\	Veight:	0.00
Admitted to hosp	ital			Age:	73
				DOB:	14/12/1932
Not yet recovered	d		Ca	usality:	Causality possible
ls:					
IS:					
aile					
		Reason:	Explosive perso	nality disor	der
scieu)	400 0 Milligram				uei
		Daily			
	Started: 26/09/2005		Stopped: ()2/05/2006	
vestigations:					
vestigations:					
	Admitted to hosp	02/06/2006 Admitted to hospital Not yet recovered Is:	02/06/2006 Admitted to hospital Not yet recovered Is: ails: ected) Reason: 400.0 Milligram Daily	O2/06/2006 Admitted to hospital Not yet recovered Calls: Sails: Sected) Reason: Explosive person 400.0 Milligram Daily	O2/06/2006 Weight: Admitted to hospital Age: DOB: Not yet recovered Causality: Is: Age: DOB: Reason: Explosive personality disor 400.0 Milligram Daily Oral

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 2191	71 Seq	: 1			Gend	der: M
Reported: 15/06	3/2006				Weig	ht: 0.00
ospitalisation:					Α	ge: 15Y
Onset Date: 28/04	1/2006				D	OB:
Outcome: Reco	vered				Causal	ity: Causality possible
action Details:						
Preferred Ter	m Se	everity	Repo	rt Des	cription	Treatment
remor		lyin eye	g on floor, ex	cess sa	shaking, found liva, EPSE, open dystonia, gait,	Given Benztropine imi/oral.
)ystonia						
xtrapyramidal disorde	er					
culogyration						
Salivary hypersecretion	1					
Somnolence						
Medicine Details: DIAZEPAM (Other drug)		2.5 Milli	Reas gram	son: (Otr spec symp psycho	opathol nec
Batch:	\$	Started:	-		Stopped:	
TEMAZEPAM (Other drug	<u>,</u>		Reas	son:	Specific disorders of	sleep
		10.0 Milli	gram			
Batch:	S	Started:			Stopped:	
DIAZEPAM (Other drug)			Reas	son:		
		5.0 Milli	gram			
Batch:	9	Started: 14/04/20	006		Stopped:	
CLOPIXOL-ACUPHASE (S	Suspected)		Reas	son:		
Injection		100.0 Milli	•	1 time		nuscular
Batch:		Started: 28/04/20	006		Stopped:	
	<u>igations:</u>					
aboratory Invest	Range	Date Tested	Result		Г	Details
	igations:	Data Tostad	Result		Г	Details

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:			
Case Number: 219171	Seq: 1	Gender:	M
Reported: 15/06/2006		Weight:	0.00
Hospitalisation:		Age:	
Onset Date: 28/04/2006		DOB:	
Outcome: Recovered			Causality possible
Reaction Details:		oudounty.	Caddanty poddibio
Reaction Details.			
Medicine Details:			
OLANZAPINE (Suspected)		Reason: Otr spec symp psychopath	nol nec
	5.0 Milligram	As necessary	
Batch:	Started: 11/04/2006	Stopped:	0
Laboratory Investigations:			
A - - :4: £4:			
Additional Information:			

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	port	Detai	ls:
----	------	-------	-----

 Case Number:
 219524
 Seq: 1
 Gender:
 F

 Reported:
 27/06/2006
 Weight:
 0.00

 Hospitalisation:
 Age: 24Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
3		g .	Olanzapine was ceased and her Lithium dose was increased to 500mg twice a day.

Medicine Details:

OLANZAPINE (Suspected) Reason: Depression

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report 219520 is the first sequence to this report 219521 is the second sequence and 219525 is the fourth sequence.

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Case Number: 219754

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

eaction Details Preferred Rash	ot yet recovered	Severity	Patient experien legs, arm, trunk,	Causali ort Description ced rash widespread over	ge: 48Y DB: ty: Causality possible Treatment Ceased Zyprexa anc change to Quetiapine, treated with Phenergan.
Outcome: Note the preferred Preferre	ot yet recovered	1	Patient experien legs, arm, trunk,	Causali ort Description ced rash widespread over	ty: Causality possible Treatment Ceased Zyprexa anc change to Quetiapine, treated with
Preferred Rash Medicine Detail PANAMAX (Other dru Batch:	Term	1	Patient experien legs, arm, trunk,	ort Description ced rash widespread over	Treatment Ceased Zyprexa anc change to Quetiapine, treated with
Preferred cash ledicine Detail PANAMAX (Other dru Batch:	Term S:	Severity	Patient experien legs, arm, trunk,	ced rash widespread over	Ceased Zyprexa anc change to Quetiapine, treated with
ledicine Detail PANAMAX (Other dru Batch:	s:	Severity	Patient experient legs, arm, trunk,	ced rash widespread over	Ceased Zyprexa anc change to Quetiapine, treated with
/ledicine Detail PANAMAX (Other dru Batch:			legs, arm, trunk,	ced rash widespread over groin, back.	Ceased Zyprexa anc change to Quetiapine, treated with Phenergan.
PANAMAX (Other dru Batch:			Rea		
PANAMAX (Other dru Batch:			Rea		
				son:	
PRAMIN (Other drug)		Started:		Stopped:	
i italiini (Otiloi arag)			Rea	son:	
Batch:		Started:		Stopped:	
ZOFRAN (Other drug			Rea	son:	
Batch:		Started:	_	Stopped:	
MORPHINE SULPHAT	E (Other drug)		Rea	son:	
Batch:		Started:		Stopped:	
Datcii.		Starteu.		Stopped.	
aboratory Inve		ge Date Tes	4-4 L B#		and a Ma
Date Ty	pe Ran	ge Date les	ted Result	U	etails

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation: Onset Date:	06/07/2006 25/05/2006 Not yet recovered	Seq: 1		Gender: Weight: Age: DOB: Causality:	78.00 48Y
Medicine Deta					
CLEXANE (Other of	lrug)		Reason:		
Batch:		Started:		Stopped:	
CARDIPRIN 100 (C	ther drug)		Reason:		
Batch:		Started:		Stopped:	
NIMOTOP (Other of	lrug)		Reason:		
Batch:		Started:		Stopped:	
COLOXYL WITH S	ENNA (Other drug)		Reason:		
Batch:		Started:		Stopped:	
Laboratory In	vestigations:				
Additional Inf	ormation:				

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation: Onset Date:	06/07/2006 25/05/2006 Not yet recovered	Seq: 1	C	Gender: Weight: Age: DOB: ausality:	78.00 48Y	
Medicine Deta						
LACTULOSE (Other	er drug)		Reason:			
Batch:		Started:	Stopped:			
PANADEINE FORT	E (Other drug)		Reason:			
Batch:		Started:	Stopped:			
Zyprexa Zydis (Su	spected)		Reason: Explosive pers	sonality diso	rder	
Wafer		5.0 Milligram	As necessary	Oral		
Batch:		Started: 24/05/2006	Stopped:	25/05/2006	3 0	
Laboratory In	vestigations:					
Additional Inf	formation:					

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:219778Seq:1Gender:MReported:06/07/2006Weight:0.00Hospitalisation:Admitted to hospitalAge:44Y

Onset Date: 17/03/2006 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	prolonged	long walk on hot day, temp 42.5 and neuroleptic malignant syndrome suspected.	Intubated, fluid resuscitation, ICU management including haemofiltration. Only Phenytoin and BZ used for seizures (no antipsychotics yet).
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

viedicinė Details:			
PHENYTOIN SODIUM (Other drug)		Reason:	
	200.0 Milligram		
Batch:	Started:	Stopped:	
METOPROLOL TARTRATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
	40.0 14:11:	D-31.	
	10.0 Milligram	Daily	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Peak CK - 27,000.
	Potassium				K+ - 7.0.

Additional Information:

NMS developed when patient was very dehydrated. Pineal breain tumour (age 20). Eleven operations for this. Secondary epilepsy and ventricular flow disturbance has VP shunt.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:219778Seq:1Gender:MReported:06/07/2006Weight:0.00Hospitalisation:Admitted to hospitalAge:44Y

Onset Date: 17/03/2006 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Caused or prolonged inpatient hospitalisation		
Convulsion	Caused or prolonged inpatient hospitalisation		
Hyperkalaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

wealcine Details:		
PHENYTOIN SODIUM (Other drug)		Reason:
	200.0 Milligram	
Batch:	Started:	Stopped:
METOPROLOL TARTRATE (Other drug)		Reason:
Batch:	Started:	Stopped:
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia
	10.0 Milligram	Daily
Batch:	Started:	Stopped : 14/03/2006

Laboratory Investigations:

Additional Information:

NMS developed when patient was very dehydrated. Pineal breain tumour (age 20). Eleven operations for this. Secondary epilepsy and ventricular flow disturbance has VP shunt.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:219778Seq:1Gender:MReported:06/07/2006Weight:0.00Hospitalisation:Admitted to hospitalAge:44Y

Onset Date: 17/03/2006 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

faction Details.							
Preferred Term	Severity	Report Description	Treatment				
Pyrexia	Caused or prolonged inpatient hospitalisation						
Renal failure acute	Caused or prolonged inpatient hospitalisation						

Medicine Details:

wealcine Details:			
PHENYTOIN SODIUM (Other drug)		Reason:	
	200.0 Milligram		
Batch:	Started:	Stopped:	
METOPROLOL TARTRATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped: 14/03/2006	

Laboratory Investigations:

Additional Information:

NMS developed when patient was very dehydrated. Pineal breain tumour (age 20). Eleven operations for this. Secondary epilepsy and ventricular flow disturbance has VP shunt.

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Hospitalisation:

Case Number: 219827

Reported: 10/07/2006

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Age: 25Y

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Onset Date: 01/09/20	05		DOB:					
Outcome: Unknown	1				С	ausality: Ca	ausality poss	ible
action Details:								
Preferred Term	Se	everity	Repo	ort Descr	ription		Treatmer	nt
Pericardial effusion			Patient experien hygroma, perica oligohydramnios absent right kidr 01/09/2005.	rdial effus , left kidn	sion, ey dilation	,		
eath neonatal								
ligohydramnios								
enal aplasia								
ledicine Details:								
Amphetamine (Suspected)				son:				
Injection		2.0	Dose Unspecified	Weekly		Intravenous		
Batch:	S	tarted:			Stopped:			
OLANZAPINE (Suspected)					specified p	sychosis		
	_		Milligram	Daily				
Batch:		tarted:			Stopped:			
CANNABIS PREPARATION (S	uspected)		Rea	son:				
Batch:		tarted:	Daily Stopped:					
aboratory Investiga	tions:							
Date Type	Range	Date Test	ted Result			Details		
		<u> </u>	1					
dditional Informatio	n:							
ort Run: 04/06/2007 05:17P	M Database: p	usime02	A	DRS004			Page 461	of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 220030
 Seq: 1
 Gender: M

 Reported:
 14/07/2006
 Weight:
 0.00

Hospitalisation: Age: 79Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Skin reaction			Zyprexa and Tolvon ceased. Given salt tablets 1800mg/bd.

Medicine Details:

ilculcine Details.				
DEPTRAN (Other drug)		Reason:		
	50.0	Milligram	Oral	
Batch:	Started:		Stopped:	
NORMISON (Other drug)		Reason:		
	10.0	Milligram	Oral	
Batch:	Started:		Stopped:	
LIPITOR (Other drug)		Reason:		
Tablet	10.0	Milligram	Oral	
Batch:	Started:		Stopped:	
ZYPREXA (Suspected)		Reason:		
Tablet	2.5	Milligram Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
14/07/2006	Sodium		04/04/2006	137	
14/07/2006	Sodium		11/04/2006	134	
14/07/2006	Sodium		18/04/2006	133	
14/07/2006	Sodium		26/04/2006	129	
14/07/2006	Sodium		14/06/2006	136	
14/07/2006	Sodium		28/06/2006	136	

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:				
Case Number: 220030 Reported: 14/07/2006 Hospitalisation: Onset Date: Outcome: Unknown	Seq: 1		Gender: Weight: Age: DOB: Causality:	0.00 79Y
Reaction Details:				cassamy process
Medicine Details:				
TOLVON (Suspected) Tablet	40.0 Milliaram	Reason:	Oral	
Batch:	40.0 Milligram Started:	Daily Sto i	oped:	
Laboratory Investigations:				
Additional Information:				

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 220234 Seq: 1 Gender: F

Reported: 20/07/2006 Weight: 70.00 Hospitalisation: Age: 43Y

Onset Date: 15/12/2005 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Breast cancer female			Received treatment (unspecified).

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/08/2004 Stopped: 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 464 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 220379 Gender: M Seq: 1

Weight: 68.00 Reported: 26/07/2006 Hospitalisation: Age: 48

Onset Date: 19/07/2006 **DOB**: 10/12/1957

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Therapy regimen changed	ability	Had been on valproate (Epilim) 500mg bd until mid-June; this was reinstated on admission, and the dose escalated to 500mg mane/1000mg nocte on 13 July.	

Medicine Details:

MIRTAZAPINE (Suspected)		Reason:	
	45.0 Milligram		
Batch:	Started:	Stopped:	
OLANZADINE (Supported)		Pagagani	

OLANZAPINE (Suspected) Reason:

10.0 Milligram

Batch: Started: Stopped:

SODIUM VALPROATE (Suspected) Reason: Unspecified neurosis Tablet 1.5 Gram Alternating-other Oral

Batch: unknown Started: 12/07/2006 Stopped: 20/07/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
26/07/2006	Other data				Investigations revealed normal FBC, EUC and LFT, but the valproate level (992 micromol/L, 5h post mane dose) and ammonia level (195 micromol/L) were elevated on 20 July.

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 220379 Seq: 1 Gender: M

Reported: 26/07/2006 Weight: 68.00 Hospitalisation: Age: 48

Onset Date: 19/07/2006 DOB: 10/12/1957

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness	Incapacity/dis ability	subjectively restless, panicky, stiff and shaky, and was observed to have bradykinesia, parkinsonian gait (but normal muscle tone), confusion, mild upper limb ataxia (clumsiness handling dinner plate etc) and a slight flap/tremor. valproate level (992 micromol/L, 5h post mane dose) and ammonia level (195 micromol/L) were elevated on 20 July. Patient was exquisitely sensitive to 5mg diazepam stat dose on 19 July.	Patient was exquisitely sensitive to 5mg diazepam stat dose on 19 July., Valproate was ceased immediately on clinical suspicion and olanzapine reducted to 7.5mg. Carnitine supplementation to be commenced when available, after repeat blood sample for valproate/carnitine levels.
Ammonia increased	Incapacity/dis ability		

Medicine Details:

viedicine Details:			
MIRTAZAPINE (Suspected)		Reason:	
	45.0 Milligram		
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram		
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Suspected)		Reason: Unspecified neurosis	
Tablet	1.5 Gram	Alternating-other Oral	
Batch: unknown	Started: 12/07/2006	Stopped: 20/07/2006 0	

Laboratory Investigations:

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:					
Case Number: 220379	Seq: 1			Gender:	M
Reported: 26/07/2006	•		•	Weight:	68.00
Hospitalisation:				Age:	
Onset Date: 19/07/2006				_	10/12/1957
Outcome: Recovered			Ca	usality:	Causality possible
Reaction Details:				•	, ,
Preferred Term	Severity	Report I	Description		Treatment
Asterixis	Incapacity/dis ability				
Bradykinesia	Incapacity/dis ability				
Confusional state	Incapacity/dis ability				
Coordination abnormal	Incapacity/dis ability				
Drug level above therapeutic	Incapacity/dis ability				
Panic attack	Incapacity/dis ability				
Medicine Details:					
MIRTAZAPINE (Suspected)		Reason	1		
	45.0	Milligram			
Batch:	Started:		Stopped:		
OLANZAPINE (Suspected)		Reason	:		
	10.0	Milligram			
Batch:	Started:		Stopped:		
SODIUM VALPROATE (Suspected)		Reason	•	urosis	
Tablet	1.5	Gram Alt	ernating-other	Oral	
Batch: unknown	Started: 12/0	07/2006	Stopped:	20/07/2006	0
Laboratory Investigations:					
Additional Information:					

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Preferred Term Severity Report Description Treat Parkinsonian gait Incapacity/dis ability	
Onset Date: 19/07/2006 Outcome: Recovered Causality: Causality eaction Details: Preferred Term Parkinsonian gait Parkinsonian gait Preferred Term Parkinsonian gait Preferred Term Prefer	possible
Outcome: Recovered Parkinsonian gait Outcome: Recovered Causality: Causality Report Description Treat Incapacity/dis ability	possible
Parkinsonian gait Severity Report Description Treat Parkinsonian gait Treat Parkinsonian gait Parkinsonian gait Treat Parkinsonian gait	
Preferred Term Severity Report Description Treat Parkinsonian gait Incapacity/dis ability	atment
Parkinsonian gait Incapacity/dis ability	
Restlessness Incapacity/dis	
ability	
Tremor Incapacity/dis ability	
Medicine Details: MIRTAZAPINE (Suspected) Reason:	
45.0 Milligram Batch: Started: Stopped:	
OLANZAPINE (Suspected) Reason:	
10.0 Milligram	
Batch: Started: Stopped:	
SODIUM VALPROATE (Suspected) Reason: Unspecified neurosis	
Tablet 1.5 Gram Alternating-other Oral	
Batch : unknown Started : 12/07/2006 Stopped : 20/07/2006 0	

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Case Number: 220675

Reported: 09/08/2006

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Onset Date:		Age: 13Y			
		DOB:			
Outcome: Not yet rec	overed	Causality: Causality possible			
eaction Details:					
Preferred Term	Severity	Report Description	Treatment		
Diabetes mellitus	prolonged inpatient hospitalisation	Weight gain of 45 kg over a period of six months while on olanzapine treatment, after the weight gain patient became diabetic. Zyprexa takes every feeling away from the patient, has had serious behavioural problems for many years. Worsening of violent outbursts.			
Abnormal behaviour	Caused or prolonged inpatient hospitalisation				
Medicine Details:					
ZYPREXA (Suspected)		Reason: Unspecifid affective psy	rchosis		
Batch:	Started:	Stopped:			
1		and Deput	.toilo		
_aboratory Investigation	ONS: Range Date Teste	ed Result De	etails		
	Range Date Teste	ed Result De	etails		



Case Number: 220675

Reported: 09/08/2006 Hospitalisation: Admitted to hospital

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Age: 13Y

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Onset Date:		DOB:				
Outcome: Not yet reco	vered	Causality: Causality possible				
eaction Details:						
Preferred Term	Severity	Report Description	Treatment			
Aggression	Caused or prolonged inpatient hospitalisation					
Flat affect	Caused or prolonged inpatient hospitalisation					
Weight increased	Caused or prolonged inpatient hospitalisation					
Medicine Details:			_			
ZYPREXA (Suspected)		Reason: Unspecifid affective p	sychosis			
Batch:	Started:	Stopped:				
Laboratory Investigatio	ns:					
Additional Information:						
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DOB: 22/04/1974

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 220741 Seq: 1 Gender: M
Reported: 11/08/2006 Weight: 80.00

Hospitalisation: Required a visit to the doctor **Age**: 32

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Onset Date: 17/07/2006

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Gynaecomastia		Gynaecomestia-swollen areolae, enlarged breast tissue, hyper prolactinaemia - increased to 84. (0-372) on the 18/7/06. Tender nipples.	Stopped Olanzapine, switched to quetiapine.
Hyperprolactinaemia Nipple pain			

Medicine Details:

SODIUM VALPROATE (Other drug) Reason: Manic-depression psycho, manic

2.0 Gram

Batch: Started: 08/06/2006 Stopped:

METHADONE HYDROCHLORIDE (Other drug) Reason:

50.0 Milligram

Batch: Started: 26/05/2006 Stopped:

OLANZAPINE (Suspected) Reason: Manic-depression psycho, manic

Tablet 30.0 Milligram Daily Oral

Batch: Started: 01/05/2006 **Stopped:** 18/07/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Case Number: 220779

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

14 - 11 4	ted: 14/08/200)6	Weight: 0.00				
ospitalisat			Age: 19Y				
Onset D						DOB:	
	me: Not yet re	covered				Causality: Causality possible	
eaction D	etails: eferred Term		avority	Don	ort Description	Treatment	
Veight incre		36	everity	eight gain of 3		Exercising.	
fledicine RISPERIDON	Details: NE (Other drug)			Rea	son:		
Bato	ch:	S	Started:		Stopped	:	
SODIUM VAI	PROATE (Other of	drug)		Rea	son:		
Bato			started:		Stopped	:	
LITHIUM CA	RBONATE (Other	drug)		Rea	son:		
Bato	ch:	S	Started:		Stopped	:	
THYROXINE	SODIUM (Other d	rug)		Rea	son:		
	J.		Manda da		04	ı.	
D-4-	:n:		Started:		Stopped	<u>:</u>	
Bato							
	ry Investigat	tions: Range	Date Tested	Result		Details	

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 472 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:			
Case Number: 220779 Reported: 14/08/2006 Hospitalisation: Onset Date: Outcome: Not yet recovered Reaction Details:	Seq: 1	Gender: Weight: Age: DOB: Causality:	0.00 19Y
Medicine Details:			
ZYPREXA (Suspected)	15.0 Milliorom	Reason: Unspecifid affective psychological	osis
Batch:	15.0 Milligram Started:	Daily Stopped:	
Laboratory Investigations:			
Additional Information:			

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 220962 Seq: 1 Gender: U

Reported: 23/08/2006 Weight: 0.00
Hospitalisation: Age: 99u
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
•	Congenital anomaly / birth defect	Infant born with small cleft palate.	

Medicine Details:

LITHIUM CARBONATE (Suspected)			Reason:	Depression	
Tablet	900.0	Milligram	Daily	(Oral
Batch:	Started:			Stopped:	
OLANZAPINE (Suspected)			Reason:	Depression	
Tablet	5.0	Milligram	Daily	(Oral
Batch:	Started:			Stopped:	
LAMOTRIGINE (Suspected)			Reason:	Depression	
Tablet	200.0	Milligram	Daily	(Oral
Batch:	Started:			Stopped:	
EFEXOR-XR (Suspected)			Reason:	Depression	
Capsule	150.0	Milligram	Daily	(Oral
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Female baby born on 05/06/06.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 221110
 Seq: 1
 Gender: M

 Reported:
 28/08/2006
 Weight:
 85.00

Hospitalisation: Required a visit to the doctor **Age**: 34

Onset Date: 01/03/2006 DOB: 03/05/1971
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caction Details.							
Preferred Term	Severity	Report Description	Treatment				
Swelling		Foot swelling, heartburn, 3 episodes of vomiting at night and 5kg weight gain.	olanzapine and methadone ceased.				
Dyspepsia							
Vomiting							
Weight increased							

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 22/02/2006 Stopped: 01/08/2006

METHADONE HYDROCHLORIDE (Suspected) Reason:

Oral Liquid 50.0 Millilitre Daily Oral

Batch: Started: L TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 475 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 221190 Seq: 1 Gender: F

Reported: 29/08/2006 Weight: 0.00 Hospitalisation: Age: 13

Onset Date: 15/05/2006 **DOB**: 23/04/1993

Outcome: Recovered 15/08/2006 Causality: Causality possible

Reaction Details:

todotion Botans.			
Preferred Term	Severity	Report Description	Treatment
Weight increased	prolonged	weight (30 to 40kg in 3 months) and blood sugar level increased.	Olanzapine and Sodium Valproate stopped. Patient required insulin.
Blood glucose increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)

Reason: Unspecified schizophrenia

15.0 Milligram Daily

Batch: Started: 31/03/2006 Stopped: 17/07/2006

SODIUM VALPROATE (Suspected) Reason:

1.0 Gram Daily

Batch: Started: Stopped: 26/07/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Case Number: 221283

Reported: 01/09/2006

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Hospitalisation:							e: 70Y		
Onset Date: 03/08/20					•	DO		ality nagai	blo
Outcome: Not yet r	ecovered				C	ausanı	y. Caus	ality possi	bie
Reaction Details: Preferred Term	Severity	,	Reno	rt Des	scription			Treatmen	ıt
Myocardial infarction	Caused or prolonged inpatient hospitalisa	Acu	te myocardia					Treatmen	
Medicine Details:									
MIRTAZAPINE (Suspected)			Reas	on:					
Tablet						Oral			
Batch:	Started	:			Stopped:				
OXAZEPAM (Suspected)			Reas	on:					
Tablet						Oral			
Batch:	Started	:			Stopped:				
ZYPREXA (Suspected)			Reas		Depression				
		5.0 Millig		Daily		Oral			
Batch:	Started	: 02/08/20	06		Stopped:				
Laboratory Investiga Date Type		Tested	Result			De	etails		
Additional Information	on:								
eport Run: 04/06/2007 05:17F	PM Database: pusime0)2	A	DRS00	4		F	Page 477	of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 221284
 Seq: 1
 Gender:
 M

 Reported:
 01/09/2006
 Weight:
 0.00

 Hospitalisation:
 Age:
 99u

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation	"passed out". ECG showed a mixed low pulse.	Zyprexa Zydis ceased.
Heart rate decreased	Caused or prolonged inpatient hospitalisation		
Heart rate irregular	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.					
CLONAZEPAM (Other drug)			Reason:		
Batch:	Started:			Stopped:	
Zyprexa Zydis (Suspected)			Reason:	Unspecified psychosis	
Wafer	10.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Medical history included amphetamine induced psychosis and a mild congenital abnormality of mixed/low pulse.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details: Case Number: 221284 Seq: 1 Gender: M Reported: 01/09/2006 Weight: 0.00 Ospitalisation: Age: 99u Onset Date: DOB: Outcome: Recovered Causality: Causality possion Details: Preferred Term Severity Report Description Treatment coss of consciousness Caused or prolonged inpatient hospitalisation	
Reported: 01/09/2006 Spitalisation: Onset Date: Outcome: Recovered Action Details: Preferred Term Severity Report Description Treatment open of consciousness Caused or prolonged inpatient	
Onset Date: Outcome: Recovered action Details: Preferred Term Oss of consciousness Caused or prolonged inpatient Age: 99u DOB: Causality: Causality possion Treatment Treatment Caused or prolonged inpatient	
Onset Date: Outcome: Recovered action Details: Preferred Term Oss of consciousness Caused or prolonged inpatient Age: 99u DOB: Causality: Causality possion Treatment Treatment Caused or prolonged inpatient	
Onset Date: Outcome: Recovered action Details: Preferred Term Severity Report Description Treatment oss of consciousness Caused or prolonged inpatient	
Action Details: Preferred Term Severity Report Description Treatment Description Description Treatment Description Descriptio	
Preferred Term Severity Report Description Treatment Caused or prolonged inpatient	t
oss of consciousness Caused or prolonged inpatient	t
prolonged inpatient	
Tedicine Details: CLONAZEPAM (Other drug) Reason:	
·	
Batch: Started: Stopped:	
Zyprexa Zydis (Suspected) Reason: Unspecified psychosis	
Wafer 10.0 Milligram Daily Oral	
Batch: Started: Stopped:	

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 221486 Seq: 1 Gender: U

Reported: 07/09/2006 Weight: 62.00 Hospitalisation: Age: 17

Onset Date: 04/08/2006 **DOB**: 09/08/1988

Outcome: Recovered 04/08/2006 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Seizure: Grand mal seizure, tonic clonic x 2 in the space of 4-6 hours.	Supporting therapy, IVT, Neuro Obs.
Grand mal convulsion			

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

5.0 Milligram Daily

Batch: Started: 20/07/2006 Stopped: 05/08/2006

FLUOXETINE HYDROCHLORIDE (Suspected) Reason: Depression

40.0 Milligram Daily

Batch: Started: 15/07/2006 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Hospitalisation:

Case Number: 221565

Reported: 12/09/2006

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Age: 32Y

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Onset Date: 06/05/200	6			DOB:	
Outcome: Recovered	t		Causa	ality: Causality po	ssible
eaction Details:				-	
Preferred Term	Severity	Repo	rt Description	Treatm	nent
Intentional overdose	prolonged inpatient hospitalisation	experienced verti grand mal seizure discomfort nause	a, asthenia, palpitations acute renal insufficiency	S.	
Suicide attempt	Caused or prolonged inpatient hospitalisation				
Medicine Details: ALCOHOL (Suspected)		Reas	on:		
Batch:	Started:	_	Stopped:	0	
ZYPREXA (Suspected)		Reas			
Batch:	Started:		Oral Stopped:	0	
EFEXOR-XR (Suspected)	Starteu.	Reas		0	
Capsule	20.0		Total Oral		
Batch:	Started: 06/0	05/2006	Stopped:	0	
Laboratory Investigat Date Type	ions: Range Date Testo	ed Result		Details	
Additional Information	ղ։				
eport Run: 04/06/2007 05:17PM	Database: pusime02	AI	DRS004	Page 48	31 of 530



Hospitalisation:

Case Number: 221605

Reported: 13/09/2006

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Age: 61

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

0	ate: 23/08/200)6				DOB : 31/07/1945
Outco	me: Not yet re	covered			Caus	sality: Causality possible
action D	etails:					
	eferred Term	S	everity	Rep	ort Description	Treatment
lepatic fund	tion abnormal		A	bnormal LFT's	and severe EPSE.	Withdrew promethazine, Lipitor, olanzapine and risperidone. Small doses benztropine prn.
xtrapyrami	dal disorder					
ledicine						
LITHIUM CAF	RBONATE (Other	drug)		Rea	son:	
Batc	h:	5	Started:		Stopped:	
THYROXINE	SODIUM (Other d	rug)		Rea	son:	
Batc	h:	•	Started:		Stopped:	
TEMAZEPAN	I (Other drug)			Rea	son:	
Batc	h:	5	Started:		Stopped:	
ALENDRONA	ATE SODIUM (Oth	er drug)		Rea	son:	
Batc	h:		Started:		Stopped:	
ahorator	y Investigat	ions:				
abulatui		Range	Date Tested	Result		Details
Date	Туре	rtango				

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Case Number: 221605

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported:	13/09/2006						Weight:	0.00
lospitalisation:							Age:	61
Onset Date:	23/08/2006						DOB:	31/07/1945
Outcome:	Not yet recovered					С	ausality:	Causality possible
eaction Detai	ils:							
Medicine Det	aile							
LIPITOR (Suspect				Reas	on:			
Tablet	- · ,						Oral	
Batch:		Started:				Stopped:		
	HYDROCHLORIDE (Susp			Reas	on:	•		
			Milligram		As nece	ssary	Oral	
Batch:		Started:	-	S TERM		Stopped:		
RISPERIDONE (Su	ispected)			Reas	on:			
		1.0	Milligram		Daily		Oral	
Batch:		Started:		S TERM		Stopped:		
OLANZAPINE (Sus	spected)			Reas	on:			
		15.0	Milligram		Daily		Oral	
Batch:		Started:		S TERM		Stopped:		
ala a wata wa Isa								
-aboratory in	vestigations:							
Additional Inf	formation:							
	-							

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	Seq. I		Gender. F
Reported: 25/09/2006			Weight: 0.00
ospitalisation:			Age: 55Y
Onset Date:			DOB:
Outcome: Recovered			Causality: Causality possible
eaction Details:			
Preferred Term	Severity	Report Description	Treatment
Angioedema			
Medicine Details: VENLAFAXINE HYDROCHLORIDE	E (Suspected)	Reason:	
Batch:	Started:	Stopped	ŀ
			···
OLANZAPINE (Suspected)		Reason: Depression	·
	2.5 Mi	Reason: Depression lligram Daily	
OLANZAPINE (Suspected) Batch:	2.5 Mi Started:	Reason: Depression	
	Started:	Reason: Depression lligram Daily	

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:222168Seq: 1Gender: MReported:05/10/2006Weight:0.00Hospitalisation:Admitted to hospitalAge: 26Y

Onset Date: 13/08/2006 DOB:

Outcome: Recovered 14/08/2006 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	prolonged	Admitted after a suicide attempt in which he took 90 or so anti-schizophrenia tablets with alcohol.	
Alcoholism	Caused or prolonged inpatient hospitalisation		
Depression	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason:	Unspecified psychosis	
Tablet			Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Medical condition: Suicide attempt and self mutilation.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number:222168Seq: 1Gender: MReported:05/10/2006Weight:0.00Hospitalisation:Admitted to hospitalAge: 26Y

Onset Date: 13/08/2006 DOB:

Outcome: Recovered 14/08/2006 Causality: Causality possible

Reaction Details:

Veaction Details.			_
Preferred Term	Severity	Report Description	Treatment
Drug dependence	Caused or prolonged inpatient hospitalisation		
Self mutilation	Caused or prolonged inpatient hospitalisation		

M	ed	lic	ine	Dei	tai	ls:
---	----	-----	-----	-----	-----	-----

ZYPREXA (Suspected)		Reason:	Unspecified psychosis	
Tablet			Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Additional Information:

Medical condition: Suicide attempt and self mutilation.

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Hospitalisation:

Onset Date:

Case Number: 222843

Reported: 01/11/2006

Outcome: Not yet recovered

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

DOB:

Weight: 0.00

Age: 31Y

Causality: Causality possible

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

eaction Details:					
Preferred Term	Se	verity	Repo	ort Description	Treatment
Suicidal behaviour		his ho sy	Neuroleptic Malignant Syndrome because his sone has excessive salivation, suicidal, homicidal, akathisia, extrapyramidal symptoms and hives, although GP stated it is acne.		ll,
cne					
kathisia					
xtrapyramidal disorder					
omicidal ideation					
Salivary hypersecretion					
Irticaria					
ledicine Details: AMISULPRIDE (Other drug)			Roa	son:	
AMISOLFRIDE (Other drug)			Nea	50II.	
Batch:	St	arted:		Stopped:	
Zyprexa IM (Suspected)			Rea	nrenia	
Injection	10.0		Milligram As necessary Intramuscular		
Batch:	St	arted:		Stopped:	0
ZYPREXA (Suspected)				son: Unspecified schizopl	nrenia
D 4.1		60.0 Mill	_	Daily Oral	
Batch:	31	arted:	L TERM	Stopped:	
.aboratory Investigat	ions:				
Date Type	Range	Date Tested	Result		Details
Additional Information	n:				
ort Run: 04/06/2007 05:17PN	Database: pu	sime02	A	DRS004	Page 487 of 530
	•				1 23 15. 5. 5. 505



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	etails:					
Dane.	ber: 223047	Seq: 1			Gene	der: M
Repor	ted: 13/11/2006	6			Weig	jht: 0.00
spitalisati	ion:				Α	ge : 22
Onset D	ate:				D	OB : 27/06/1984
Outco	me: Unknown				Causa	lity: Causality possib
action D			1 .		. ,.	
	eferred Term	Severity		Report De	•	Treatment
uicidal idea omicidal id			Suicidal idea	ation, hom	icidal ideation.	
edicine Ithium caf	Details: RBONATE (Other d	lrug)		Reason:		
Batc		Started:			Stopped:	
Strattera (Su	spected)	40.0	MA:III: mma ma	Reason:	Behavior disorders of	childhod
•		10.0	Milligram			
	h·				Stopped:	0
Batc		Started:		Reason:	Stopped: Unspecifid affective p	0 osychosis
Batc		Started:	Milligram		Stopped: Unspecifid affective p	
	uspected)	Started:	Milligram	Reason: Daily		
Batc ZYPREXA (S Batc	uspected)	Started: 5.0 Started:		Daily	Unspecifid affective p	sychosis

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 223069	Seq: 1		Gende	r: F
Reported: 13/11/2006			Weigh	t: 0.00
ospitalisation:				e: 68Y
Onset Date:			DO	
Outcome: Death			Causalit	y: Causality possible
eaction Details:				
Preferred Term	Severity		rt Description	Treatment
Cerebrovascular accident	Death F	Patient experience	ced a stroke and died.	
Medicine Details: ZYPREXA (Suspected)		Reas	on: Unspecified schizophre	nia
Batch:	Started:		Stopped:	0
aboratory Investigation Date Type	Range Date Tested	d Result	Do	tails
Таке Туре	Nange Date restet	d Result	De	lalis
Additional Information:				
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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 223705
 Seq: 1
 Gender: M

 Reported:
 01/12/2006
 Weight:
 0.00

 Hospitalisation:
 Age: 25

Onset Date: 24/10/2006 **DOB**: 12/10/1981

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano			
Preferred Term	Severity	Report Description	Treatment
Alanine aminotransferase increase		Patient had increased Alanine aminotransferase, aspartate amino-transferase and gamma glutamyltransferase.	Olanzapine was stopped and clozapine withheld, Recommenced next day and increased slowly with improvement of liver function
Aspartate aminotransferase increa Gamma-glutamyltransferase increa			

Medicine Details:

Medicine Details.			
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily Oral	
Batch:	Started: 10/10/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/12/2006	ALT = SGPT	<55	23/10/2006	354	baseline: 90
01/12/2006	ALT = SGPT	<55	24/10/2006	306	baseline: 90
01/12/2006	ALT = SGPT	<55	26/10/2006	239	baseline: 90
01/12/2006	ALT = SGPT	<55	29/10/2006	143	baseline: 90
01/12/2006	ALT = SGPT	<55	03/10/2006	105	baseline: 90
01/12/2006	ALT = SGPT	<55	31/10/2006	90	baseline: 90
01/12/2006	AST = SGOT	<50	23/10/2006	153	Baseline: normal

Additional Information:

Patient has hepatitis B.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 223705 Seq: 1 Gender: M

Reported: 01/12/2006 Weight: 0.00 Hospitalisation: Age: 25

Onset Date: 24/10/2006 **DOB**: 12/10/1981

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		Reason:					
Batch:	Started:	Sto	ppped:				
CLOZARIL (Suspected)		Reason:					
Tablet	12.5 Milligram	Daily	Oral				
Batch:	Started: 10/10/2006	Sto	opped:				

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
01/12/2006	AST = SGOT	<50	24/10/2006	85	Baseline: normal
01/12/2006	AST = SGOT	<50	26/10/2006	66	Baseline: normal
01/12/2006	Bilirubin	<19	03/10/2006	20	
01/12/2006	Bilirubin	<19	26/10/2006	19	
01/12/2006	GGT = SGGT =	<50	23/10/2006	192	baseline: 90
01/12/2006	GGT = SGGT =	<50	24/10/2006	181	baseline: 90
01/12/2006	GGT = SGGT =	<50	26/10/2006	161	baseline: 90

Additional Information:

Patient has hepatitis B.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 223705 Seq: 1 Gender: M

Reported: 01/12/2006 Weight: 0.00 Hospitalisation: Age: 25

Onset Date: 24/10/2006 **DOB**: 12/10/1981

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		Reason:				
Batch:	Started:	Stop	ped:			
CLOZARIL (Suspected)		Reason:				
Tablet	12.5 Milligram	Daily	Oral			
Batch:	Started: 10/10/2006	Stop	ped:			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =	<50	31/10/2006	132	baseline: 90
	GGT = SGGT =	<50	03/10/2006	119	baseline: 90
01/12/2006	Ultrasound				24 Oct: fatty liver

Additional Information:

Patient has hepatitis B.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 224127 Seq: 1 Gender: M

Reported: 15/12/2006 Weight: 49.00 Hospitalisation: Age: 13

Onset Date: 09/12/2006 **DOB**: 27/12/1992

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano			
Preferred Term	Severity	Report Description	Treatment
Dystonia		acute dystonic reaction	Benztropine 2mg IM and then regular benztropine 1mg orally since as well as reduction in dose

Medicine Details:

vieuicine Details.				
OLANZAPINE (Suspected)		Reason: Unspecified	psychosis	
Tablet	10.0 Milligram	1 time	Oral	
Batch:	Started: 20/11/2006	Stoppe	d: 08/12/2006	0
RISPERIDONE (Suspected)		Reason: Unspecified	psychosis	
Tablet	4.0 Milligram	Daily	Oral	
Batch:	Started: 07/12/2006	Stoppe	d: 09/12/2006	0
RISPERIDONE (Suspected)		Reason: Unspecified	psychosis	
Injection	25.0 Milligram	Alternate weeks	Intramuscular	
Batch:	Started: 08/12/2006	Stoppe	d:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
15/12/2006	Other data				genetic testing for CYP2D6 phenotyping maybe done

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	port l	Detai	ils:
----	--------	-------	------

Case Number: 224128 Seq: 1 Gender: M
Reported: 15/12/2006 Weight: 69.00

Hospitalisation: Required a visit to the doctor
Onset Date:

Age: 27Y
DOB:

Outcome: Recovered 01/09/2006 Causality: Causality possible

Reaction Details:

1	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Polydipsia		Experiencing extreme thirst and drinking 9-10 L fluid daily	
		Required Visit to Doctor		

Medicine Details:

<u>Medicine Details.</u>							
OLANZAPINE (Suspected)			Reason:	Unspecified ps	sychosis		
	5.0	Milligram	Daily		Oral		
Batch:	Started:			Stopped:		0	
EDRONAX (Suspected)			Reason:	Depression			
Tablet	12.0	Milligram	Daily		Oral		
Batch:	Started:			Stopped:		0	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Case Number: 224162

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

		DC	ge: 46Y DB:		
			· - ·		
		Caucali			
		Causan	ty: Causality possible		
Severity	Repo	ort Description	Treatment		
Caused or prolonged inpatient hospitalisation			IV Frusemide		
Caused or prolonged inpatient hospitalisation					
Caused or prolonged inpatient hospitalisation					
	Rea	ison:			
Batch: Started:					
er arug)	Rea	ison:			
Started:		Stopped:			
	Reason:				
Started:	Stopped:				
	Rea	ison:			
Started:		Stonned:			
	Stoppeu.				
	.1	T -			
ige Date Teste	ea Result	<u>D</u>	etails		
1	1	L			
	prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Started: Started: Started: Started:	prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Rea Started: Rea Started: Rea Started:	prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Reason: Started: Stopped: Reason: Started: Stopped: Reason: Started: Stopped: Reason: Started: Stopped:		

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Case Number: 224162

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 18/12/2006					Weight	t: 0.00	
Hospitalisation:						e: 46Y	
Onset Date: 05/10/2006					DO	3:	
Outcome: Recovered				С	ausality	y: Causality pos	sible
Reaction Details:							
Preferred Term	Severity		Report Des	cription		Treatme	nt
Oedema peripheral	Caused or prolonged inpatient hospitalisation						
Medicine Details:							
ZYPREXA (Suspected)				Unspecifid affe		chosis	
Tablet Batch:	2.5 N Started: 01/10	Milligram	Daily	Stopped:	Oral		
Laboratory Investigations							
Additional Information:							
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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation Onset Da	ed: 18/12/200 on: te: ne: Unknown	Seq: 1		Gender: Weight: Age: DOB: Causality:	0.00 40Y		
	erred Term	Severity	Rep	ort Description	Treatment		
Cardiomyopa	thy		Cardyomyoptha				
Medicine D							
ZYPREXA (Sus	spected)		Rea	son:			
Batch	:	Started:		Stopped:	Stopped:		
Laboratory	ı Investigat	ions:					
Date	Туре	Range Date T	ested Result	Detai	ls		
Additional	Information	n:					

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 224400 Seq: 1 Gender: F

Reported: 05/01/2007 Weight: 60.00 Hospitalisation: Age: 77

Onset Date: 05/12/2006 DOB: 10/10/1929

Outcome: Recovered 07/12/2006 Causality: Causality probable

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Neuroleptic malignant syndrome	Life threatening	Neuroceptic Malignant Syndrome	Supportive

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Tablet 5.0 Milligram Daily Oral

Batch: Started: 30/11/2006 **Stopped:** 06/12/2006

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Ran	ort	Deta	ile:
Reb	DIL	Deta	115.

Case Number:224483Seq: 1Gender:FReported:09/01/2007Weight:0.00Hospitalisation:Admitted to hospitalAge: 99u

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Reaction Details.			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		Drug discontinued.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecifid affective psychosis

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient's medical history included depression and had taken antidepressant.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:224526Seq: 1Gender:MReported:10/01/2007Weight:0.00Hospitalisation:Required a visit to the doctorAge: 39

Onset Date: 24/09/2006 DOB: 12/12/1966

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
	Photosensitivity reaction		Photo sensitive reaction, rash on foot exposed parts.	Ceased Zyprexa
	Rash			

Medicine Details:

ilculcine Details.				
SEROQUEL (Other drug)		Reason:	Unspecified schizophrenia	
	600.0	Milligram		
Batch:	Started:		Stopped:	
Valpam (Other drug)		Reason:		
	30.0	Milligram		
Batch:	Started:		Stopped:	
FUNGILIN (Other drug)		Reason:		
Lozenge	3.0	Dose Unspecified	Oral	
Batch:	Started:		Stopped:	
COGENTIN (Other drug)		Reason:		
	4.0	Milligram		
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	224526	Seq: 1			Gender:	M
Reported:	10/01/2007				Weight:	0.00
Hospitalisation:	Required a visit to	the doctor			Age:	39
Onset Date:	24/09/2006				DOB:	12/12/1966
Outcome:	Not yet recovered	I			Causality:	Causality possible
Reaction Detai					_	
Medicine Det						
CLOPIXOL DEPOT	(Other drug)			Reason:		
Batch:		Started:			Stopped:	
ZYPREXA (Suspec	cted)			Reason:	Unspecified schizophrenia	
Tablet			Milligram	Daily	Oral	
Batch:		Started:			Stopped:	
Laboratory In	vestigations:					
•	3					
Additional Inf	ormation:					

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 224568 Reported: 10/01/200 ospitalisation: Onset Date: Outcome: Not yet re eaction Details: Preferred Term Veight increased	covered Severity	Wei	nder: F ight: 0.00 Age: 99U DOB: ality: Causality possible Treatment	
ospitalisation: Onset Date: Outcome: Not yet reaction Details: Preferred Term	covered Severity	Causa Report Description	Age: 99U DOB: ality: Causality possible	
Onset Date: Outcome: Not yet re action Details: Preferred Term	Severity	Causa Report Description	DOB: ality: Causality possible	
Outcome: Not yet re action Details: Preferred Term	Severity	Causa Report Description	ality: Causality possible	
action Details: Preferred Term	Severity	Report Description		
Preferred Term			Treatment	
			Treatment	
/eight increased	W	/eight gain,		
ledicine Details:				
RISPERIDONE (Other drug)		Reason:		
Batch:	Started:	: Stopped:		
ZYPREXA (Suspected)		Reason: Unspecified psycho	sis	
Batch:	Started:	Stopped:	Contin	
aboratory Investigat	ions:			

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 502 of 530

The reporting psychiatrist was concerned that the patient's obesity may be affecting her absorption, as the patient still had some

psychotic symptoms. He was aslo concerned about drug efficacy due to the stomach banding. Procedure Gastric banding.



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	ber: 224569 ted: 10/01/2007	Seq: 1		Gender: F Weight: 0.00		
lospitalisat Onset D				Ag DO	e: 35Y B:	
	me: Not yet red	overed			y: Causality possible	
eaction D	etails:					
Pr	eferred Term	Severity	Repo	ort Description	Treatment	
Gamma-glu	tamyltransferase	increa	Gamma- glutam	yltransferase increased.		
Medicine						
OLANZAPINI	E (Suspected)	40.0	Reas	·	nia	
Bato	.h.	10.0 Started:	Milligram	Daily Oral Stopped:		
	ry Investigati		tod Dogult	Do	stoile.	
Date	Туре	Range Date Tes	ted Result	De	etails	
Additional Information:						
eport Run:04/	06/2007 05:17PM	Database: pusime02	Α	DRS004	Page 503 of 530	



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 224715
 Seq: 1
 Gender: M

 Reported:
 16/01/2007
 Weight:
 76.00

Hospitalisation: Required a visit to the doctor **Age:** 22

Onset Date: 09/10/2006 **DOB**: 02/02/1984

Outcome: Recovered 31/10/2006 Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Asymptomatic neutropenia.	Cessation of drug.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

 Tablet
 20.0 Milligram
 Daily
 Oral

 Batch:
 Started: 14/09/2006
 Stopped: 27/10/2006

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ſ	16/01/2007	Neutrophils		09/10/2006	1.7	
	16/01/2007	Neutrophils		12/10/2006	1.9	
	16/01/2007	Neutrophils		23/10/2006	1.7	
l	16/01/2007	Neutrophils		31/10/2006	5.0	

Additional Information:

Suspected cause-olanzapine previous neutropenia on clozapine.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 224770 Seq: 1 Gender: M

Reported: 17/01/2007 Weight: 85.00 Hospitalisation: Age: 36

Onset Date: 05/12/2006 **DOB**: 17/11/1970

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia, Asymptomatic.	

Medicine Details:

MIRTAZAPINE (Suspected) Reason:

Tablet 30.0 Milligram Daily Oral

Batch: Started: 29/11/2006 Stopped: 02/12/2006

OLANZAPINE (Suspected) Reason: Unspecified psychosis

5.0 Milligram Daily

Batch: Started: 02/12/2006 Stopped: 06/12/2006

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
Ī	17/01/2007	Neutrophils				Neutophils 1.0.

Additional Information:

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 505 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: 18/01/2007 Weight: 0.00 ospitalisation: Admitted to hospital Onset Date: Outcome: Unknown Causality: Causality poss paction Details: Preferred Term Severity Report Description Treatment Salivary hypersecretion Caused or prolonged inpatient hospitalisation Crooling Caused or prolonged inpatient hospitalisation Caused or Batch: Started: Stopped:				
Onset Date: Outcome: Unknown action Details: Preferred Term Caused or prolonged inpatient hospitalisation rooling Caused or prolonged inpatient hospitalisation	Case Number: 224836	Seq: 1	(Gender: F
Onset Date: Outcome: Unknown action Details: Preferred Term Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or Patient not chewing or swallowing, experiencing increased saliva and drooling. Caused or prolonged inpatient hospitalisation Reason:	Reported: 18/01/20	07	V	Veight: 0.00
Outcome: Unknown action Details: Preferred Term Caused or prolonged inpatient hospitalisation Reason: Causality: Causality possible in possible in patient prolonged inpatient hospitalisation Reason:	ospitalisation: Admitted	to hospital		
Preferred Term Severity Report Description Treatment Report Description Tr				
Preferred Term Severity Report Description Treatment alivary hypersecretion Caused or prolonged inpatient hospitalisation Redicine Details: OLANZAPINE (Suspected) Reason:		1	Са	usality: Causality possible
Alivary hypersecretion Caused or prolonged inpatient hospitalisation Reason:		Cavarity	Donard Dagariation	Tuestanent
prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Iedicine Details: OLANZAPINE (Suspected) Reason:			· · · · · · · · · · · · · · · · · · ·	
prolonged inpatient hospitalisation Medicine Details: OLANZAPINE (Suspected) Reason:	allivary hypersecretion	prolonged inpatient	experiencing increased saliva and drooling.	l etrabenazine was initiated
OLANZAPINE (Suspected) Reason:	Drooling	prolonged inpatient		
Batch: Started: Stopped:				
Salon Carton Stoppen	OLANZAPINE (Suspected)		Reason:	
aboratory Investigations:		Started:		
Date Type Range Date Tested Result Details	Batch:	țions:	Stopped:	

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 506 of 530



Hospitalisation:

Onset Date:

Case Number: 224876

Reported: 19/01/2007

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

DOB:

Age: 18Y

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

action Details:							
Preferred Term	S	everity	Repo	rt Description	Treatment		
)ysphagia	Caus prolo inpat	ed or P	•	le swallowing and	Drug discontinued, started Escitalopram oxalate		
Aastication disorder	prolo inpat						
Salivary hypersecretion	prolo inpat	ed or nged ient italisation					
Medicine Details:							
RISPERDAL (Suspected)			Reas	on:			
Batch:	5	Started:		Stopped: 08/	12/2006		
TETRABENAZINE (Suspecte	ed)		Reas	on:			
Batch:		Started:		Stopped:			
ZYPREXA (Suspected)			Reason: Other atyp forms schizophrenia				
Tablet		7.5 M	Milligram Daily Oral				
Batch:		Started: 01/08/	2000	Stopped: 07/	122000		
aboratory Investig	ations:						
_aboratory Investig	ations:	Date Tested	Result		Details		



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 225026 Seq: 1 Gender: F

Reported: 24/01/2007 Weight: 62.00 Hospitalisation: Age: 18

Onset Date: 29/12/2006 **DOB**: 06/02/1988

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Acute onset Diabetes with Keto Acidosis	Insulin
Acidosis			
Diabetes mellitus insulin-depender			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 2.5 Milligram Daily Oral

Batch: Started: 15/06/2006 Stopped: 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
24/01/2007	Other data				Urine Ketones
24/01/2007	Serum glucose				

Additional Information:

History: relatives diabetes. BSL fasting normal in June before starting olanzapine.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls	:
----	----	----	----	-----	----	---

Case Number:225326Seq: 1Gender: MReported:02/02/2007Weight:80.00Hospitalisation:Required a visit to the doctorAge: 40

Onset Date: 27/12/2006 DOB: 24/07/1966

Outcome: Not yet recovered Causality: Causality probable

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Tremor			Reduce olanzapine to 10mg, Benztropine.
Akathisia			
Parkinsonism			

n	л	\sim	 	_	. 1	^+^	\sim
ш	vi	-(1	 	-	.,	eta	-

OLANZAPINE (Suspected) Reason: Othr&unspec metabolic diseases

20.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 225541 Seq: 1 Gender: M

Reported: 07/02/2007 Weight: 85.00 Hospitalisation: Age: 31

Onset Date: 21/12/2006 DOB: 20/07/1975

Outcome: Recovered 07/01/2007 **Causality:** Causality probable

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Patient with normal baseline LFT's. Commenced Olanzapine, titrated to 10mg tds, after 3 weeks, LFTs - in particular. ALT high 21 to 395. All other LFT's remained in normal range.	

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:
	900.0 Milligram	
Batch:	Started: 30/11/2006	Stopped:
ATIVAN (Other drug)		Reason: Otr spec symp psychopathol nec
	1.5 Milligram	Daily
Batch:	Started: 30/11/2006	Stopped:
ZYPREXA (Suspected)		Reason: Unspecified psychosis
	30.0 Milligram	Daily
Batch:	Started: 30/11/2006	Stopped: 21/12/2006 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
07/02/2007	ALT = SGPT				ALT up from 21 to 395
	GGT = SGGT =				GGT up from 13 to 84

Additional Information:

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 225583 Seq: 1 Gender: M

Reported: 08/02/2007 Weight: 107.00 Hospitalisation: Age: 38Y

Onset Date: 19/11/2006 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Caction Dotaile			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation	%	Metformin

Medicine Details:

DIAZEPAM (Other drug)		Reason: Unspecifid affective psychosis	
Tablet	5.0 Milligram	As necessary Oral	
Batch:	Started:	Stopped:	
Lexapro (Other drug)		Reason: Unspecifid affective psychosis	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecifid affective psychosis	
	20.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
08/02/2007	Other data		19/11/2006	7.5	HBAIC
08/02/2007	Serum glucose		19/11/2006	16.7	

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reportalisat Onset E	Date: ome: Recovered			Ag DC	er: F nt: 0.00 ge: 34 DB: 29/07/1972 ty: Causality possible
eaction D	Details: referred Term	Severity	Report D	escription	Treatment
Ovarian cys			rarian cyst.	Compact	Hoamon
Medicine OLANZAPIN	Details: E (Suspected)		Reason:	Unspecified psychosis	
Bate	ch:	Started:	L TERM	Stopped: 15/04/2	2001
	ry Investigatio				
Date	Туре	Range Date Tested	Result	D	etails
Additiona	al Information	:			
eport Run: 04/	/06/2007 05:17PM	Database: pusime02	ADRS	004	Page 512 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 225725
 Seq: 1
 Gender: M

 Reported:
 12/02/2007
 Weight:
 0.00

Hospitalisation: Age: 22

Onset Date: 04/12/2006 **DOB**: 31/08/1984

Outcome: Recovered 08/12/2006 Causality: Causality possible

Reaction Details:

cuotion Details.							
Preferred Term	Severity	Report Description	Treatment				
Weight increased	Caused or prolonged inpatient hospitalisation	Patient experienced weight gain and severe sedation.	Clopine withdrawn. Patient intubated and remained in ICU.				
Sedation	Caused or prolonged inpatient hospitalisation						

ı			Detai	

Escitalopram (Other drug) Reason:

20.0 Milligram

Batch: Started: Stopped:

FLUOXETINE HYDROCHLORIDE (Other drug) Reason:

Batch: Started: Stopped:

Metoprolol Succinate (Other drug) Reason:

Batch: Started: Stopped:

ALPRAZOLAM (Suspected) Reason: Anxiety neurosis

Tablet Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient has a history of obesity, alcohol abuse, benzodiazepine abuse.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	port	Detail	ls:
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Case Number: 225725 Seq: 1 Gender: M

Reported: 12/02/2007 Weight: 0.00 Hospitalisation: Age: 22

Onset Date: 04/12/2006 **DOB**: 31/08/1984

Outcome: Recovered 08/12/2006 Causality: Causality possible

Reaction Details:

Medicine Details:

ilculcine Details.			
CLOPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	300.0 Milligram	Daily Oral	
Batch:	Started: 05/10/2006	Stopped: 12/12/2006	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

The patient has a history of obesity, alcohol abuse, benzodiazepine abuse.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:				
Case Number: 225884 Reported: 15/02/2007 ospitalisation: Onset Date: Outcome: Unknown	Seq: 1		C	Gender: M Weight: 0.00 Age: 35Y DOB: Causality: Causality possible
eaction Details:				ausanty. Causanty possible
Preferred Term	Severity	Repo	ort Description	Treatment
Neutrophilia	Caused or prolonged inpatient hospitalisation		commencement of	
Medicine Details: ZYPREXA (Suspected)		Rea	son:	
	10.0	Milligram	Daily	
_aboratory Investigations: Date Type Rar		ed Result		Details
Additional Information:				

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 226279 Seq: 1 Gender: M

Reported: 04/03/2007 Weight: 75.00 Hospitalisation: Age: 32Y

Onset Date: 15/01/2007 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		Hyperglycaemia BSL 15.6	Cease medication

Medicine Details:

OLANZAPINE (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
04/03/2007	Biochemistry				BSL 15.6mmol/L

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repo Hospitalisa Onset I	Date: ome: Unknown	Seq : 1		Age DO	t: 0.00 e: 99u		
	referred Term	Severity	Repo	rt Description	Treatment		
Weight incr			doctor suspected	abdominal distension etension, rapid weight			
Abdominal	distension						
Medicine SEROQUEL	Details: (Suspected)		Reas	on:			
Bat	ch:	Started:	Stopped:				
OLANZAPIN	IE (Suspected)		Reas	on:			
Bat	ch:	Started:	Stopped:				
Laborato Date	ry Investigat Type	ions: Range Date Teste	ed Result	De	tails		
Additions	al Informatio	n·					

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 517 of 530

Abdominal distension and weight gain occured after one week of olanzapine treatment , and worsened on commencement of Seroquel, switched to risperidone but developed " prolcatin issues" and then switched to aripiprazole



Case Number: 226448

Reported: 07/03/2007

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Onset Date: 15/02/2007 Outcome: Unknown eaction Details: Preferred Term				Age			
eaction Details:			DOB : 03/09/1939				
			Causality: Causality p				
Preferred Term							
	Sc	everity	Repo	ort Description	Treatment		
Veight increased		٥٧	atient's weight ver 8 weeks wh eatment.	increased by 10 kilograms ille on Olanzapine			
ledicine Details:							
COUMADIN (Other drug)			Reas	son:			
Batch:	ç	Started:		Stopped:			
METFORMIN HYDROCHLORIDE			Rea	son:			
Batch:	Started:			Stopped:			
DIAMICRON (Other drug)			Reas	son:			
Batch:	Started:			Stopped:			
ZYPREXA (Suspected)	Reas				chosis		
		5.0 Mi	lligram				
Batch:	S	Started: 15/12/2	_	Stopped:	0		
ahoratory Investigatio	ne'						
aboratory Investigation Date Type	NS: Range	Date Tested	Result	De	ails		

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	226589	Seq: 1		Ge	ender: F
	13/03/2007	•			eight: 0.00
ospitalisation:					Age: 99u
Onset Date:					DOB:
Outcome:	Not yet reco	overed		Caus	sality: Causality possible
eaction Detai					
	ed Term	Severity		ort Description	Treatment
Renal failure			Renal failure		Ceased olanzapine
Medicine Deta			Rea	son: Unspecified schize	phrenia
Batch:		Started:		Stopped:	
_aboratory In	vestigation	Pange Date Test	ted Result		Details
Date	туре	Range Date Test	ted Result		Details
Additional Inf	ormation	:			
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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Jase Mullibe		Seq. 1			iei. F
_	i: 13/03/2007			_	ht: 0.00
spitalisatior					ge: 99u
Onset Date				DO	OB:
Outcome	: Unknown			Causal	ity: Causality possible
ction Det	ails:				
Prefe	rred Term	Severity	Report	Description	Treatment
phritis inters	titial	N	ephritis interstitia	l suspected.	Olanzapine discontinued.
edicine De			Reaso	n: Unspecified schizophr	enia
Batch:		Started:		Stopped:	
aboratorv	Investigations	s:			
Date		ange Date Tested	Result	С)etails
dditional l	nformation:				
ort Pup : 04/06/	2007 05:17PM Da	utahase: nusime02	ΔΠΙ	RS004	Page 520 of 530

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 226604 Seq: 1 Gender: M

Reported: 09/03/2007 Weight: 92.00 Hospitalisation: Age: 28

Onset Date: DOB: 22/11/1978

Outcome: Recovered Causality: Causality possible

Reaction Details:

touction Dotailo			
Preferred Term	Severity	Report Description	Treatment
Pruritus		Itchy rash on arms, legs, palms of hands fine macular rash on trunk and limbs-large hives, has persisted for approx 2 months.	
Rash generalised			
Rash macular			
Urticaria			

Medicine Details:

OLANZAPINE (Suspected) Reason: Othr&unspec metabolic diseases

 Tablet
 15.0 Milligram
 Daily
 Oral

 Batch:
 Started: 05/07/2006
 Stopped: 05/01/2007

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No other obvious allergies.

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 521 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 226868
 Seq: 1
 Gender: M

 Reported:
 22/03/2007
 Weight: 0.00

 Hospitalisation:
 Age: 21Y

Onset Date: 20/02/2007 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation		Sedation, catatonia, headache, medication dose increased - Zyprexia 5mg to 10mg daily (19/02/07) and drug ineffective. "It worked well the first day" but "the medication dis not seem to work" on the second day.	
Catatonia			
Drug ineffective			
Headache			
Therapy regimen changed			

		-	_		
M	ihد	cin	ו או	Deta	ıile:

EPILIM (Other drug)		Reason:		
Batch:	Started:		Stopped:	
LITHIUM CARBONATE (Other drug)		Reason:		
Tablet			Oral	
Batch:	Started:		Stopped:	
TEGRETOL CR (Suspected)		Reason:		
Tablet	200.0 Milligram	Daily	Oral	
Batch:	Started: 19/02/2007		Stopped:	
ZYPREXA (Suspected)		Reason:		
	5.0 Milligram	Daily		
Batch:	Started:		Stopped: 18/02/2007	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History: Schizophrenia and bipolar disorder. The reporter believed that the return of catatonia was due to the increased dose of Zyprexia the day before, "which normally increased his catatonia".

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Started: Stopped:	Reported: 23/03/2007								
Reported: 23/03/2007 Weight: 0.00 ospitalisation: Age: 26Y Onset Date: 18/11/2006 DOB: Causality: Causality possible eaction Details: Preferred Term Severity Report Description Treatment Gravitational oedema Fluid retention in ankles, including pain, especially when weight bearing. Treated with frusemide, give as stat pm doses - not a regular order, TED stocking Medicine Details: CITALOPRAM HYDROBROMIDE (Other drug) Reason: Batch: Started: Stopped: LITHIUM CARBONATE (Other drug) Reason: 450.0 Milligram Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: 20.0 Milligram Daily Oral Batch: Started: Stopped: Laboratory Investigations:	Reported: 23/03/2007	Case Numb	er: 226921	Sea:	: 1			Gen	der: F
Onset Date: 18/11/2006 Outcome: Unknown Causality: Causality possible Perferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Report Description Treatment Fluid retention in ankles, including pain, especially when weight bearing. Treated with frusemide, give as stat pm doses - not a regular order, TED stocking Medicine Details: CITALOPRAM HYDROBROMIDE (Other drug) Batch: Started: Stopped: LITHIUM CARBONATE (Other drug) Reason: 450.0 Milligram Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: 20.0 Milligram Daily Oral Batch: Started: Stopped:	Oset Date: 18/11/2006 Outcome: Unknown Causality: Causality possible Preferred Term Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Severity Preferred Term Fluid retention in ankles, including pain, est state true doses - not a regular order, TED stockings Addicine Details: CITALOPRAM HYDROBROMIDE (Other drug) Started: Started: Stopped: LITHIUM CARBONATE (Other drug) Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: 20.0 Milligram Daily Oral Batch: Started: Stopped: Date Type Range Date Tested Result Details			-					
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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 226934
 Seq: 1
 Gender:
 M

 Reported:
 23/03/2007
 Weight:
 0.00

Hospitalisation: Age: 56

Onset Date: DOB: 15/09/1950
Outcome: Unknown Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus non-insulin-depe			Metformin hydrochloride, olanzapine ceased, switched to quetiapine fumarate.
Hyperglycaemia			
Syncope			

Medicine Details:

ZYPREXA (Suspected)Reason: Unspecifid affective psychosis

Tablet 2.5 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
23/03/2007	Serum glucose				His fasting glucose levels rose up to 7.0mmol/L. Prior to starting olanzapine, and when the patient is off the olanzapine, the patient's fasting blood glucose levles were below 6.0 mmol/L.

Additional Information:

Historical AR Malaise

Patient tried lithium and was crook and felt very sick.

Historial AR Hepatitis

Patient tired sodium valproate and developed a hepatitis-like-thing, with elevated liver function tests.

Reporting psychiatrist stated that the patient needs to loose weight and has a family history of diabetes.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Ren	ort	Deta	ils:
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Case Number: 227271 Seq: 1 Gender: M

Reported: 03/04/2007 Weight: 0.00
Hospitalisation: Age: 65Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		Thrombocytopenia. Low platelets	Treatment Discontinued

Medicine Details:

ZYPREXA (Suspected) Reason:

Batch: Started: 15/09/2006 Stopped: 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
03/04/2007	Platelets				Platelet count 70,000 Low.

Additional Information:

Patient experienced symptoms after being on olanzapine for 6 months.

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 525 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 227973 Seq: 1 Gender: M

Reported: 26/04/2007 Weight: 102.00 Hospitalisation: Age: 17

Onset Date: 15/10/2006 **DOB:** 02/11/1988

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Cardiac failure congestive	Life threatening	Patient experienced cardiomyopathy.	Ceased drug.

Medicine Details:

Medicine Details.				
EPILIM (Other drug)		Reason:		
	1.5 Grar	n Daily		
Batch:	Started:	L TERM	Stopped:	
ZYPREXA (Suspected)		Reason:		
	5.0 Millig	gram Daily		
Batch:	Started: 15/07/20	006	Stopped: 21/03/2007	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
26/04/2007	Ejection fraction				

Additional Information:

intellectual disability, midline abnormalities, high palate, hypotonia, exomphalos, normal karyotype.

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 228265
 Seq: 1
 Gender:
 M

 Reported:
 07/05/2007
 Weight:
 0.00

Hospitalisation: Required a visit to the doctor
Onset Date:

Age: 48Y
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abnormal sleep-related event	prolonged inpatient hospitalisation	Patient had apparent hallucinations, during the day would "drive like an idiot" had swerved across 3 lanes of traffic. After a friend hung himself there were several occasions when he would wander near his place "talking to the trees" at night. He had no memory of these events.	
Amnesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MS CONTIN (Other drug)		Reaso	on:	
	60.0 Mi	illigram [Daily	
Batch:	Started:	L TERM	Stopped:	
OXAZEPAM (Other drug)		Reaso	on:	
Tablet	1.0 Do	ose Unspecified [Daily	Oral
Batch:	Started:	L TERM	Stopped:	Continued.
ENDONE (Other drug)		Reaso	on:	
	3.0 Do	ose Unspecified [Daily	
Batch:	Started:	L TERM	Stopped:	Continued.
ZYPREXA (Suspected)		Reaso	on:	
	5.0 Mi	illigram [Daily	
Batch:	Started: 31/05/	2005 L TERM	Stopped:	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No suicidal ideation.

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 527 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 228265
 Seq: 1
 Gender:
 M

 Reported:
 07/05/2007
 Weight:
 0.00

Hospitalisation: Required a visit to the doctor
Onset Date:

Age: 48Y
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination	Caused or prolonged inpatient hospitalisation		
Stereotypy	Caused or prolonged inpatient hospitalisation		
Suicidal behaviour	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.					
STILNOX (Suspected)		F	Reason: S	Specific disorde	ers of sleep
Tablet	10.0	Milligram	Daily		Oral
Batch:	Started:	L TE	RM	Stopped:	15/02/2005
EFEXOR-XR (Suspected)		F	Reason:		
Capsule	150.0	Milligram	Daily		Oral
Batch:	Started: 05/	07/2005 L TEI	RM	Stopped:	

Laboratory Investigations:

Additional Information:

No suicidal ideation.

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 528 of 530



Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 228346
 Seq: 1
 Gender:
 F

 Reported:
 09/05/2007
 Weight:
 0.00

Hospitalisation: Admitted to hospital **Age**: 46

Onset Date: 24/03/2007 DOB: 17/01/1961
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Rhabdomyolysis	threatening	Patient developed rhabdomyolysis, fevers, rigor, suspected URTI and a fall before admission.		
Chills	Life threatening			
Neuroleptic malignant syndrome	Life threatening			
Pyrexia	Life threatening			

Medicine Details:

FLUVOXAMINE MALEATE (Other drug)			Reason:			
Tablet	100.0	Milligram			Oral	
Batch:	Started:			Stopped:		
QUETIAPINE (Other drug)			Reason:			
Tablet	400.0	Milligram			Oral	
Batch:	Started:			Stopped:		
CARBAMAZEPINE (Other drug)			Reason:			
Tablet	400.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		0
Aripiprazole (Suspected)			Reason:			
Tablet	15.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:	24/03/2007	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History: Psychosis, depression, asthma and epilepsy.

Report Run: 04/06/2007 05:17PM Database: pusime02 ADRS004 Page 529 of 530



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation: Onset Date: Outcome: Reaction Detai	09/05/2007 Admitted to hospit 24/03/2007 Not yet recovered Is:				0.00
Medicine Deta			Danasa		
OLANZAPINE (Sus	spectea)	7.5 Milligram	Reason: Daily		
Batch:		Started:	Daily	Stopped : 24/03/2007	
Laboratory In	vestigations:				
Additional Inf History: Psychosis	f ormation: depression, asthma	a and epilepsy.			

Report Run: 04/06/2007 05:18PM Database: pusime02 ADRS004 Page 530 of 530