

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 116978
 Seq: 1
 Gender: U

 Reported:
 22/04/1997
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medelion Details.			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Rash erythematous			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: Started: 01/04/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Ck: 400, (ckmb: 14)

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 117889 Seq: 1 Gender: M
Reported: 27/05/1997 Weight:

Hospitalisation: Age: 58Y
Onset Date: 07/05/1997
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

Medicine Details.				
OLANZAPINE (Suspected)		Reason:	Schizophrenia	
Oral application	10.0 Milligram	Daily	Oral	
Batch:	Started: 01/12/1996		Stopped:	
OMEPRAZOLE (Suspected)		Reason:	Other diseases of esophagus	
Capsule	40.0 Milligram	Daily	Oral	
Batch:	Started: 01/12/1996		Stopped:	
SODIUM VALPROATE (Suspected)		Reason:		
Tablet	1.2 Gram	Daily	Oral	
Batch:	Started: 01/04/1997		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 118383 Seq: 1 Gender: F
Reported: 19/06/1997 Weight:
Hospitalisation: Age: 47Y

Onset Date: 26/05/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Influenza like illness		Lethargy,sore throat,muscular aches	
Hepatic function abnormal		Raised liver function enzymes	

Medicine Details:

ZOLOFT (Other drug)		Reason: Depression	
Tablet	100.0 Milligram	Alternating-other Oral	
Batch:	Started: 17/10/1996	Stopped:	
VALIUM (Other drug)		Reason: Anxiety neurosis	
	5.0 Milligram	As necessary	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 05/05/1997	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	0-40 U/L	26/05/1997	127	
	ALT = SGPT	0-40 U/L	05/06/1997	26	
	AST = SGOT	0-40 U/L	26/05/1997	42	
	AST = SGOT	0-40 U/L	05/06/1997	18	
	Bilirubin	0-20	26/05/1997	12	
	Bilirubin	0-20	05/06/1997	5	
	GGT = SGGT =	0-45 U/L	26/05/1997	532	

Additional Information:

White cells normal. no past history of liver problems. substantial improvement without changing medication

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 118383
 Seq: 1
 Gender:
 F

 Reported:
 19/06/1997
 Weight:

Hospitalisation:
Onset Date: 26/05/1997
Age: 47Y
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ZOLOFT (Other drug)		Reason: Depression	
Tablet	100.0 Milligram	Alternating-other Oral	
Batch:	Started: 17/10/1996	Stopped:	
VALIUM (Other drug)		Reason: Anxiety neurosis	
	5.0 Milligram	As necessary	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 05/05/1997	Stopped:	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ſ		GGT = SGGT =	0-45 U/L	05/06/1997	223	
		LDH	100-225	26/05/1997	255	
		LDH	100-225	05/06/1997	196	
		SAP = ALP	30-115 U/L	26/05/1997	306	
		SAP = ALP	30-115 U/L	05/06/1997	135	

Additional Information:

White cells normal. no past history of liver problems. substantial improvement without changing medication

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 118590
 Seq: 1
 Gender: M

 Reported:
 30/06/1997
 Weight:

Hospitalisation: Admitted to hospital Age: 70Y
Onset Date: 15/06/1997
DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

todotion Botano.	vaction betailer								
Preferred Term	Severity	Report Description	Treatment						
Confusional state			After rechallenge olanzapine changed to melleril 10mg nocte.						
Hallucination		Increasing hallucinations							
Agitation									

Medicine Details:

AGON (Other drug)		Re	ason:	Essential benign hyperten	sion
Tablet, modified release	5.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN
SINEMET CR (Other drug)		Re	ason:	Paralysis agitans	
Tablet	1.0	Dose Unspecified	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN
QUININE (Other drug)		Rea	ason:		
Tablet	300.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN
NORMISON (Other drug)		Rea	ason:	Disturbance of sleep	
Oral application	10.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient admitted to hospital 15/6, olanzapine ceased and patient did not have hallucinations. olanzapine restarted 17/6 for 3 days and hallucinations returned. olanzapine ceased.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Details:
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 Case Number:
 118590
 Seq: 1
 Gender: M

 Reported:
 30/06/1997
 Weight:

Hospitalisation: Admitted to hospital Age: 70Y
Onset Date: 15/06/1997
DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected) Reason: 2.5 Milligram Daily Batch: Started: 13/06/1996 Stopped: SINEMET (Suspected) Reason: Paralysis agitans Tablet 1.0 Dose Unspecified Daily Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Additional Information:

Patient admitted to hospital 15/6, olanzapine ceased and patient did not have hallucinations. olanzapine restarted 17/6 for 3 days and hallucinations returned. olanzapine ceased.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 118966 Seq: 1 Gender: F

Reported: 10/07/1997 Weight:
Hospitalisation: Age: 28Y

Onset Date: 10/06/1997 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Oro-buccal dyskinesis/lipsmacking	

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 03/06/1997 **Stopped:** 17/06/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has along history of extrapyramidal side effects to typical antipsychotics.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 119116 Seq: 1 Gender: F

Reported: 16/07/1997 Weight: 48.00 Hospitalisation: Age: 69Y

Onset Date: 06/06/1997 **DOB**:

Outcome: Recovered Causality: Causality certain

Reaction Details:

todotion botanoi			
Preferred Term	Severity	Report Description	Treatment
Myalgia		Muscle aches in arms and legs.	
Pyrexia			Olanzapine ceased

Medicine Details:

 THYROXINE SODIUM (Other drug)
 Reason:

 100.0
 Microgram
 Daily

 Batch:
 Started:
 L TERM
 Stopped:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

5.0 Milligram Daily

Batch: Started: 06/05/1997 **Stopped:** 12/06/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient rechallenged on olanzapine and symptoms reoccurred.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 119297 Seq: 1 Gender: F

 Reported: 21/07/1997
 Weight: 87.00

 Hospitalisation:
 Age: 23Y

Onset Date: 14/07/1997 **DOB**:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

Medicine Details.				
ZYPREXA (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 27/06/1997		Stopped:	2W
CLOZARIL (Suspected)		Reason:	Unspecified schizophrenia	
	150.0 Milligram	Daily		
Batch:	Started: 24/06/1997		Stopped: 01/07/1997	

Laboratory Investigations:

	. <u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	X 10'9/L	14/07/1997	1.4	
	Neutrophils	X 10'9/L	15/07/1997	2.2	
	leucocytes	X 10'9/L	14/07/1997	3.8	

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 119388
 Seq: 1
 Gender: F

 Reported:
 23/07/1997
 Weight:

Hospitalisation: Age: 67Y
Onset Date: 04/06/1997
DOB:

Outcome: Recovered with sequelae Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Headache	Required Visit to Doctor		Reduce dose of olanzapine from 15mg each morning to 10 mg each morning.

Medicine Details:

nealence Details.					
UREMIDE (Other drug)		Rea	son:	Essential benign hypertension	
Tablet	40.0	Milligram	Daily	Oral	
Batch:	Started:	L TERM		Stopped:	
SLOW-K (Other drug)		Rea	son:	Essential benign hypertension	
Tablet	1.0	Dose Unspecified	Daily	Oral	
Batch:	Started:			Stopped:	
SENOKOT (Other drug)		Rea	son:	Constipation	
Tablet	2.0	Dose Unspecified	Daily	Oral	
Batch:	Started:	L TERM		Stopped:	
RIVOTRIL (Other drug)		Rea	son:	Disturbance of sleep	
Tablet	1.0	Milligram	Daily	Oral	
Batch:	Started:	L TERM		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Headaches ceased when olanzapine dose reduced to 10mg daily, but patient's psychotic features are no longer under control.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

anort Datail	e.					
eport Detail Case Number: Reported: espitalisation:		eq : 1			Gender Weight: Age:	
Onset Date:	04/06/1997				DOB	
	Recovered with sec	uelae				Causality possible
action Detai		•			,	, , , , , , , , , , , , , , , , , , ,
ledicine Deta				Reason:	Essential benign hyperter	nsion
Tablet			Milligram		Oral	
	40 d)	Started:				
	ted)	15.0	Milligram			a
				Daily		
Batch: ZYPREXA (Suspec Tablet Batch:	eted)	Started: 15.0 Started: 06	Milligram /05/1997	L TERM Reason: Daily	Stopped: Unspecified schizophrenic Oral Stopped:	a
aboratory In	vestigations:					

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Headaches ceased when olanzapine dose reduced to 10mg daily, but patient's psychotic features are no longer under control.



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 119397 Seq: 1 Gender: M

Reported: 23/07/1997 **Weight:** 86.00

Hospitalisation: Age: 25Y
Onset Date: 03/07/1997
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
		duration	Diazepam 10mg given olanzapine dose reduced from 15mg at night to 10mg

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

15.0 Milligram Daily

Batch: Started: 23/06/1997 **Stopped:** 03/07/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Olanzapine was increased from 10mg at night to 15 mg at night on 23/06/1997.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 119463
 Seq: 1
 Gender:
 F

 Reported:
 28/07/1997
 Weight:

Hospitalisation: Age: 26Y

Onset Date: 05/06/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Increased appetite		Craving for sweet food.	
	Weight increased		Weight gain	

Medicine Details:

Medicine Details.			
ANAFRANIL (Other drug)		Reason:	
	75.0 Milligram	Daily	
Batch:	Started: 01/01/1991	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
	5.0 Milligram	Daily	
Ratch:	Started: 01/06/1997	Stonned:	

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Report Details:

Case Number: 119514

Reported: 28/07/1997

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight:

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

rn S	everity		Report Descri	<u> </u>	: Causality possible Treatment
	everity		Report Descri	<u> </u>	
S	everity		Report Descri	ption	Treatment
	- · • · · · · · ·				
			Reason:		
	300.0	Milligram	Daily	Oral	
5	Started:			Stopped:	CONTIN
			Reason:		
	10.0	Milligram	Daily	Oral	
5	Started:			Stopped:	
ations:	Date Tes	ted Resul	t	Deta	ails
	ations:	Started: 10.0 Started:	10.0 Milligram Started: ations:	300.0 Milligram Daily Started: Reason: 10.0 Milligram Daily Started:	300.0 Milligram Daily Oral Started: Stopped: Reason: 10.0 Milligram Daily Oral Started: Stopped:



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 119663 Seq: 1 Gender: M

Reported: 04/08/1997 Weight: 102.00 Hospitalisation: Age: 32Y

Onset Date: 02/07/1997 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation			

Medicine Details:

ZYPREXA (Suspected) Reason: Paranoia

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/07/1997 **Stopped:** 06/07/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred 12 hours after change to zyprexa. reached maximum irritability at 3 days - maintained while taking zyprexa settled within 2 days of ceasing zyprexa history of tolerance problems with most antipshycotics.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 119732 Seq: 1 Gender: F

Reported: 07/08/1997 Weight:
Hospitalisation: Age: 26Y

Onset Date: 31/07/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Overwhelming hunger resulting in weight increase	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 25.0 Milligram Daily Oral

Batch: Started: 01/06/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient's hunger increased with dose increase. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 120087
 Seq: 1
 Gender: M

 Reported:
 20/08/1997
 Weight:
 76.00

Hospitalisation: Age: 63Y
Onset Date: 16/08/1997
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Reduced b.p.	
Rash maculo-papular		Symetrical rash arms, legs,trunk, face	Phenergan 10mg tds, iv hydrocortisone, prednisolone 60mg daily, i.v. fluid replacement, vitamin k replacement.
Pyrexia			
Syncope			
Vasodilatation			

Medicine Details:

CLONAZEPAM (Suspected)		Reason: Unspecified schizophrenia	
	4.0 Milligram	1 time	
Batch:	Started: 06/08/1997	Stopped:	
HALOPERIDOL (Suspected)		Reason: Unspecified schizophrenia	
	10.0 Milligram	As necessary	
Batch:	Started: 05/08/1997	Stopped:	
BENZTROPINE MESYLATE (Suspected)		Reason: Unspecified schizophrenia	
	2.0 Milligram	As necessary	
Batch:	Started: 05/08/1997	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started: 06/08/1997	Stopped: 16/08/1997	

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 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detail	20/08/1997 16/08/1997 Recovered Is:	Seq: 1		Gender: Weight: Age: DOB: Causality:	76.00 63Y
Medicine Deta	ails:		Danaan Maradama		
CARBIMAZOLE (Su	ispected)	10.0 Milligram	Reason: Myxedema Daily	Oral	
Batch:		Started: 05/08/1997	Stoppe		
Laboratory In	vestigations:				
Additional Info	ormation:				

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 120137
 Seq: 1
 Gender: F

 Reported:
 18/08/1997
 Weight:

Hospitalisation: Age: 37Y
Onset Date: 14/08/1997
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Inappropriate effect "spaced out"	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: **Started**: 01/08/1997 **Stopped**: 14/08/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 120173 Seq: 1 Gender: F

Reported: 22/08/1997 Weight: 77.00 Hospitalisation: Age: 53Y

Onset Date: 16/08/1997 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Involuntary movements of tongue, face distorted	Benztropine
Chest pain		Muscular chest pain	
Myalgia			

Medicine Details:

VIBRA-TABS 50 (Other drug)

Tablet 1.0 Dose Unspecified Daily Oral

Batch: Started: 01/01/1990 Stopped: CONTIN

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Reason:

Other acne of sebaceous glands

Tablet 5.0 Milligram Daily Oral

Batch: Started: 14/08/1997 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Symptoms lasted 12 hours, went as soon as cogentin taken, which had been stopped 3 days previously, zyprexa to continue since patient feels well, the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 120716 Seq: 1 Gender: M

Reported: 12/09/1997 Weight: 74.00 Hospitalisation: Age: 29Y

Onset Date: 28/08/1997 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Dotano			
Preferred Term	Severity	Report Description	Treatment
Leukopenia			
Neutropenia			

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified schizophreniaTablet15.0 MilligramDailyOral

Batch: Started: 29/07/1997 **Stopped:** 28/08/1997

Laboratory Investigations:

	. <u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		08/07/1997	4.75	On discharge - neutrophils 2.32
	Neutrophils		15/07/1997	2.46	On discharge - neutrophils 2.32
	Neutrophils		26/08/1997	1.46	On discharge - neutrophils 2.32
	Neutrophils		28/08/1997	1.06	On discharge - neutrophils 2.32
	Neutrophils		29/08/1997	0.79	On discharge - neutrophils 2.32
	Neutrophils		31/08/1997	1.02	On discharge - neutrophils 2.32

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 120723
 Seq: 1
 Gender: M

 Reported:
 12/09/1997
 Weight:
 65.00

 Hospitalisation:
 Age:
 23Y

Onset Date: 18/05/1997 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Increased temperature to over 42c	
Blood pressure fluctuation		Irregular blood pressure 200/100 to 40/30	
Supraventricular tachycardia		Svt 150-170 bpm	
Agitation			
Blood creatine phosphokinase incr			
Hallucination			
Hyperthermia malignant			

Medicine Details:

PARACETAMOL (Suspected)		Reason:	
Oral application	10.0 Gram	1 time	Oral
Batch:	Started: 17/05/1997	Stopped	:
ZYPREXA (Suspected)		Reason: Unspecified	schizophrenia
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 14/05/1997	Stopped	: 16/05/1997
EPILIM (Suspected)		Reason: Unspecified	schizophrenia
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1997	Stopped	: 17/05/1997
COGENTIN (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1997	Stopped	: 17/05/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		17/05/1997	213	
	Creatine		18/05/1997	161	
	Creatine		19/05/1997	160	
	Creatine		20/05/1997	471	
	Creatine		21/05/1997	754	
	Creatine		22/05/1997	1142	
	Creatine		24/05/1997	361	

Additional Information:

The patient has a history of neuroleptic malignant syndrome on typical antipsyschotics the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 120723 Seq: 1 Gender: M

Reported: 12/09/1997 Weight: 65.00 Hospitalisation: Age: 23Y

Onset Date: 18/05/1997 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Required intubation, ventilation and paralysis and was treated with dantrolene and bromocriptine, admission to intensive care unit for 6 days.
Tremor			

Medicine Details:

	Reason: Adv effect an	iline derivatives
20.0 Gram	Daily	Intravenous
Started: 17/05/1997	Stopped:	20/05/1997
	Reason: Schizophreni	а
8.0 Milligram	Daily	Oral
Started: 01/03/1997	Stopped:	12/05/1997
	Started: 17/05/1997 8.0 Milligram	20.0 Gram Daily Started: 17/05/1997 Stopped: Reason: Schizophreni 8.0 Milligram Daily

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		25/05/1997	144	
	Creatine		26/05/1997	104	

Additional Information:

The patient has a history of neuroleptic malignant syndrome on typical antipsyschotics the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 121194 Seq: 1 Gender: F

Reported: 30/09/1997 Weight: 95.00 Hospitalisation: Age: 36Y

Onset Date: 29/08/1997 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema		Fluid retention	
Hypernatraemia			

Medicine Details:

VENLAFAXINE HYDROCHLORIDE	(Suspected)	Reason: Depre	ession	
Tablet	600.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/1996	St	topped:	
EPILIM (Suspected)		Reason:		
Oral application	100.0 Milligram	Daily	Oral	
Batch:	Started: 01/08/1997	Sf	topped:	
OLANZAPINE (Suspected)		Reason: Depre	ession	
Oral application	10.0 Milligram	Daily	Oral	
Batch:	Started: 01/08/1997	Sí	topped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium				Serum na 147 - 149 mmol/l

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	er: 121220	Seq:	. 1		Gen	der: ∪
	ed: 30/09/199	_			Weig	
ospitalisatio	n:				A	\ge : 29
Onset Dat	te:				D	OB: 21/06/1968
Outcom	e: Unknown				Causa	lity: Causality possible
eaction De						
	erred Term	Se	everity	Repo	ort Description	Treatment
_eukopenia						
Neutropenia						
Medicine D OLANZAPINE (Poo	son:	
OLANZAPINE (Suspected)		0.0	Rea	SOII:	
Batch:		9	tarted:		Stopped:	
Daten.			tarteu.		Stoppeu.	
Laboratory	Investigati	ions:				
Date	Туре	Range	Date Tested	Result		Details
	<u>'</u>					
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Additional	Information	1 :				
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Additional	Information	1 :				



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	er: 121396	S	Seq: 1				Gen	der:	M
Reporte	ed: 03/10/1	997					Wei	ght:	
spitalisatio								_	64Y
	te: 11/07/1							OB:	
	e: Recove	red					Causa	lity:	Causality probable
action De									<u> </u>
	erred Term		Severity	 		ort Desc	cription		Treatment
Somnolence Confusional st	4.4.			Ove	ersedation				
Official Si	late								
	\ - 4 - ¹¹								
ledicine D		ar drug)			Pag	son:			
SODIUW VALP	NUATE (UINE	n urug)	3 0	Gran		son: Daily			
Batch:			Started:	Gian	11	Daily	Stopped:		
ASPIRIN (Othe			Starteu.		Roa	son:	Stopped.		
ASPIININ (Othe	r drug)		150.0	Millic		Daily			
Batch:			Started:	ıvıııııg	grani	Daily	Stopped:		
AMLODIPINE (Otartea.	-	Rea	son:	оторрец.		
, (·	omor arag,		10.0	Millig		Daily			
Batch:	:		Started:		,. w	24,	Stopped:		
CARBAMAZEP	INE (Other dr	rug)			Rea	son:	•••		
	•	•	800.0	Milliç		Daily			
	:		Started:			·	Stopped:		
Batch:									
aboratory			Data Taa	tod	Dogult			Datail	lo.
.aboratory	Investiga Type	ations:	Date Tes	ted	Result			Detail	İs
aboratory			Date Tes	sted	Result			Detail	İs

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:				
Case Number: 121396 Reported: 03/10/1997 Hospitalisation: Onset Date: 11/07/1997 Outcome: Recovered Reaction Details:	Seq: 1		Gender: Weight: Age: DOB: Causality:	64Y
Medicine Details:				
OLANZAPINE (Suspected)	5.0 Milligram	Reason: Daily		
Batch:	Started: 10/07/1997	Daily	Stopped: 14/07/1997	,
Laboratory Investigations:				
Additional Information:				

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 121399
 Seq: 1
 Gender: M

 Reported:
 06/10/1997
 Weight:

Hospitalisation: Age: 65Y
Onset Date: DOB:

Outcome: Death Causality: Causality possible

Reaction Details:

			1
Preferred Term	Severity	Report Description	Treatment
Hypertonia		Increase in muscle tone.	
Sudden death			
Tremor			

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)		Reason:	Schizophrenia
	10.0 Milligram	Daily	
Batch:	Started: 01/08/1997		Stopped:
COGENTIN (Suspected)		Reason:	Abnormal involuntary movement
	500.0 Microgram	Daily	
Batch:	Started: 01/09/1997		Stopped:
NATRILIX (Suspected)		Reason:	Essential benign hypertension
	2.5 Milligram	Daily	
Batch:	Started: 01/09/1997		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient died 09/97. committee comment: include in annual fatality analysis the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 121530 Seq: 1 Gender: F

Reported: 10/10/1997 Weight: 90.00
Hospitalisation: Age: 46Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

-									
	Preferred Term	Severity	Report Description	Treatment					
	Hyperkinesia		Nocturnal restless legs.	Withdrawal of olanzapine.					
	Gravitational oedema								

Medicine Details:

 IMIPRAMINE HYDROCHLORIDE (Other drug)
 Reason:

 150.0
 Milligram
 Daily

 Batch:
 Started:
 L TERM
 Stopped:

OLANZAPINE (Suspected) Reason: Schizophrenia

15.0 Milligram Daily

Batch: Started: 13/08/1997 **Stopped:** 08/10/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient put onto olanzapine because haloperidol not satisfactory because of s.e's. but olanzapine wasn't as effective at 15mg as haloperidol on 5mg and nocturnal restless legs was very distressing.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122368 Seq: 1 Gender: F

 Reported: 17/11/1997
 Weight: 45.00

 Hospitalisation:
 Age: 61Y

 Onset Date: 30/06/1997
 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Catatonia		Withdrawn, mute.	
Blood creatine phosphokinase incr			
Hepatic function abnormal			
Leukocytosis			
Neuroleptic malignant syndrome			
Pyrexia			
Tremor			

Medicine Details:

PANADOL (Other drug)		Reason: Other disturbance of se	ensation
Oral application	1.0 Gram	As necessary Oral	
Batch:	Started: 27/04/1997	Stopped:	CONTIN
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started: 30/04/1997	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 14/05/1997	Stopped: 30/06/1	997

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Similar reaction developped on rechallenge in september.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122454 Seq: 1 Gender: F

Reported: 18/11/1997 Weight:
Hospitalisation: Age:
Onset Date: 31/07/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		Missed 2 periods during this time	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122456 Seq: 1 Gender: F
Reported: 18/11/1997 Weight:

Reported: 18/11/1997 Weight:
Hospitalisation: Age: 17

Onset Date: 22/07/1997 DOB: 13/05/1980

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration		Bleeding tongue lesions	
Tongue discolouration		White streaks in mouth	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 15.0 Milligram Daily Oral

Batch: Started: 01/04/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE, ZYPREXA, Zyprexa IM, Zyprexa Zydis

Report Details:

Case Number: 122458 Seq: 1 Gender: F

Reported: 18/11/1997 Weight: 75.00 Hospitalisation: Age: 47Y

Onset Date: 19/07/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

,	reaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Somnolence		Oversleeping	Haloperidol ceased
	Tremor		Tremulousness	
	Headache			
	Nausea			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)	Reason:	Depression	
---------------------------------------	---------	------------	--

300.0 Milligram Daily

Batch: Started: 01/01/1996 Stopped:

BENZHEXOL HYDROCHLORIDE (Other drug) Reason: Unspecified schizophrenia

2.0 Milligram Daily

Batch: Started: 01/01/1996 Stopped: 17/07/1997

TEMAZEPAM (Other drug) Reason:

20.0 Milligram Daily

Batch: Started: 01/01/1996 Stopped:

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

5.0 Milligram Daily

Batch: Started: 01/01/1996 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122458 Seq: 1 Gender: F

Reported: 18/11/1997 Weight: 75.00 Hospitalisation: Age: 47Y

Onset Date: 19/07/1997 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.		
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia
Tablet	10.0 Milligram	Daily Oral
Batch:	Started: 18/07/1997	Stopped : 21/07/1997
HALOPERIDOL (Suspected)		Reason: Unspecified schizophrenia
Injection	5.0 Milligram	Daily Intravenous
Batch:	Started: 01/01/1996	Stopped : 17/07/1997

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1	V	Gender: M /eight: Age: DOB: usality: Causality possible				
Severity	V Cau	Veight: Age: DOB: usality: Causality possible				
	Сац	Age: DOB: usality: Causality possible				
		DOB: usality: Causality possible				
		DOB: usality: Causality possible				
	Report Description					
Da		Treatment				
Rec	d raw mouth					
Medicine Details: ZYPREXA (Suspected) Reason:						
0.0						
		Oral				
	Result	Details				
J	The blood test was nega					
	0.0 Started:	Started: Stopped:				

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122463 Seq: 1 Gender: F

Reported: 18/11/1997 Weight:
Hospitalisation: Age: 45Y

Onset Date: 31/07/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mania		Manic	The doctor intends to reduce dose every second day.

Medicine Details:

ZYPREXA (Suspected) Reason: Depression

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/07/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has a previous history of alcohol abuse - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122464 Seq: 1 Gender: M

Reported: 18/11/1997 **Weight:** 105.00

Hospitalisation: Age: 27Y
Onset Date: 23/07/1997
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression	Severe		

Medicine Details:

DIAZEPAM (Other drug) Reason: Depression

0.0

Batch: Started: Stopped:

NITRAZEPAM (Other drug) Reason:

0.0

Batch: Started: Stopped:

HALOPERIDOL (Other drug) Reason: Unspecified schizophrenia

150.0 Milligram Daily

Batch: Started: Stopped: 02M

METHADONE HYDROCHLORIDE (Other drug) Reason:

5.0 Milligram Daily

Batch: Started: 23/07/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient has a past history of drug addition (heroin).

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	nn	rt	De	tail	ls:
176	μυ		$\mathbf{D}\mathbf{c}$	tai	.

Case Number: 122464 Seq: 1 Gender: M

 Reported:
 18/11/1997
 Weight:
 105.00

 talisation:
 Age:
 27Y

Hospitalisation: Age:
Onset Date: 23/07/1997
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE	(Other drug)	Reason: Depression	
	150.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ALCOHOL (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 26/06/1996	Stopped:	

Laboratory Investigations:

Additional Information:

The patient has a past history of drug addition (heroin).

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122465 Seq: 1 Gender: U

Reported: 18/11/1997 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Low sodium levels	Zyprexa discontinued

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: 01/06/1997 **Stopped:** 03D

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Electrolytes				123mmol/l (135-145)

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122467 Seq: 1 Gender: F

Reported: 18/11/1997 Weight: 63.00 Hospitalisation: Age: 47

Onset Date: 31/05/1997 **DOB**: 16/11/1949

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Elevated liver enzymes	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 20.0 Milligram Daily Oral

Batch: Started: 01/05/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Late june the ggt reach 251 (0-60), alt 222 (0-55) and ast 179 (0-45). as of 07 july 1997 the alt and the ast have returned to normal but the ggt remains elevated.

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 122473
 Seq: 1
 Gender:
 F

 Reported:
 18/11/1997
 Weight:

Hospitalisation: Age: 38

Onset Date: 26/10/1997 **DOB**: 09/03/1959

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		20 kilos in a matter of weeks	
Increased appetite		Compulsive eating	

Medicine Details:

SOMAC (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
PREPULSID (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec	
	30.0 Milligram	Daily	
Batch:	Started: 01/01/1996	Stopped:	
AROPAX (Other drug)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started: 20/10/1997	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	122473	Seq: 1		Gender:	F
Reported:	18/11/1997			Weight:	
Hospitalisation:				Age:	38
Onset Date:	26/10/1997				09/03/1959
Outcome:	Unknown			Causality:	Causality possible
Reaction Detail	s:				
Medicine Deta	ils:				
ZYPREXA (Suspect	ted)		Reason:		
Tablet		15.0 Milligram	Daily	Oral	
Batch:		Started: 26/09/1997	Stop	ped:	
Laboratory Inv	voetinatione				
Laboratory in	vestigations.				
Additional Info		Charles the first of a second		0	
the dosage start da	te is not accurate b	ut indicates that start occurr	ea sometime during	tne year.	

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Gender: F Case Number: 122475 Seq: 1 Weight: 76.00 Reported: 18/11/1997

Hospitalisation: Age: 46

Onset Date: 07/08/1997 **DOB**: 01/02/1951 Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Flatulence		Bloating	
Eructation		Burping	
Hyperglycaemia		Elevated fasting morning glucose	
Hyperprolactinaemia		High prolactin levels	
Hypertonia		Muscle stiffness	
Constipation			
Dry mouth			
Hyperkinesia			
Increased appetite			
Psoriasis			

Medicine Details: OROXINE (Other drug)

	200.0	Milligram	Daily		
Batch:	Started:			Stopped:	
PROCYCLIDINE HYDROCHLORIDE (Other drug)			Reason:	Other psoriasis	
	10.0	Milligram	Daily		
Batch:	Started:			Stopped:	
NEOTIGASON (Other drug)			Reason:	Other psoriasis	

Reason:

Myxedema

25.0 Milligram Daily

Batch: Stopped: Started:

PROZAC (Suspected) Reason:

> Tablet 20.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin		04/10/1997	35.5	
	Prolactin		22/10/1997	45.3	
	Serum glucose		06/08/1997	7.3	
	Serum glucose		09/08/1997	7.8	
	Serum glucose		16/08/1997	8.3	
	Serum glucose		26/08/1997	9.8	
	Serum glucose		06/09/1997	9.8	

Additional Information:

Patient was rechallenged on zyprexa with same reaction occurring.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122475 Seq: 1 Gender: F

Reported: 18/11/1997 Weight: 76.00 Hospitalisation: Age: 46

Onset Date: 07/08/1997 **DOB:** 01/02/1951

Outcome: Recovered Causality: Causality certain

Reaction Details:

Medicine Details:

ZYPREXA (Suspected) Reason: Myxedema

Tablet 10.0 Milligram Daily Oral

Batch: **Started**: 06/08/1997 **Stopped**: 12/09/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Serum glucose		09/09/1997	9.8	
	Serum glucose		09/09/1997	10.6	
	Serum glucose		14/09/1997	12.5	
	Serum glucose		30/10/1997	4.8	

Additional Information:

Patient was rechallenged on zyprexa with same reaction occurring.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 122476				
Demonts d. 40/44/4	Seq: 1		Gend	er: F
Reported: 18/11/1	1997		Weigh	nt:
lospitalisation:			Ag	e : 0
Onset Date: 01/08/1	1997		DC	B : 20/05/1997
Outcome: Unknow	wn		Causali	ty: Causality possible
eaction Details:				
Preferred Term	n Severity	Report Desc	ription	Treatment
Face oedema				
Medicine Details:				
ZYPREXA (Suspected)		Reason:		
Tablet		Dose Unspecified Daily	Oral	214
	1.0 I Started: 28/0	Dose Unspecified Daily	Oral Stopped:	ЗМ
Tablet Batch :	Started: 28/0	Dose Unspecified Daily		ЗМ
Tablet	Started: 28/0	Dose Unspecified Daily	Stopped:	3M etails

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

ase Mullibe		Seq.	1			muer. F
_	d: 18/11/1997	7				eight:
spitalisatior						Age: 25Y
Onset Dat						DOB:
	: Unknown				Caus	sality: Causality possible
ction Det						
	rred Term		verity	Repo	rt Description	Treatment
sh		Severe)			
edicine Do			0.0	Reas	on:	
Batch:		Sta	arted:		Stopped:	
boratory	<u>Investigati</u>	ons:				
Date	Туре		Date Tested	Result		Details
lditional l	nformatior	1:				
ort Run : 04/06/	2007 04·26PM	Database: nus	sime02	ΔΙ	DRS004	Page 46 of 526

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 122478 Seq: 1 Gender: M

Reported: 18/11/1997 Weight: 85.00 Hospitalisation: Age: 37

Onset Date: 12/08/1997 **DOB**: 02/12/1959

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Sleeps 14 to 16 hours.	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 20.0 Milligram Daily Oral

Batch: Started: 12/08/1997 Stopped:

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

100.0 Milligram Daily

Batch: Started: 12/08/1997 **Stopped:** 19/08/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 122479
 Seq: 1
 Gender:
 F

 Reported:
 18/11/1997
 Weight:

Hospitalisation: Age: 50

Onset Date: 15/08/1997 **DOB:** 03/08/1947

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botans.			
Preferred Term	Severity	Report Description	Treatment
Arthralgia			
Hepatic function abnormal			
Myalgia			
Osteoarthritis			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/04/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Details:
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Case Number: 122480 Seq: 1 Gender: F

Reported: 18/11/1997 Weight: 80.00 Hospitalisation: Age: -1

Onset Date: 22/07/1997 **DOB**: 04/09/1997

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Visual disturbance	Severe		

Medicine Details:

CLOZAPINE (Other drug)		Reason:	
	600.0 Milligram	Daily	
Batch:	Started: 19/07/1997	Stopped:	
ZYPREXA (Suspected)	F	Reason:	

5.0 Milligram Daily

Batch: Started: 21/07/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122481 Seq: 1 Gender: F

Reported: 18/11/1997 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Somnolence			Dose of zyprexa reduced from 5mg daily to 2.5mg daily.

Medicine Details:

ZYPREXA (Suspected)

Reason:

5.0 Milligram Daily

Batch: Started: 01/01/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122482 Seq: 1 Gender: M
Reported: 18/11/1997 Weight:

Hospitalisation: Age: 26Y
Onset Date: 31/07/1997
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

-	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Extrapyramidal disorder		Severe parkinsonism	
	Speech disorder			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: 04/06/1997 **Stopped:** 28/08/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 122483
 Seq: 1
 Gender: M

 Reported:
 18/11/1997
 Weight:

Hospitalisation: Age: 33

Onset Date: 27/08/1997 **DOB**: 21/01/1964

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Muscle movement in calf, abdomen, shoulder, face	

Medicine Details:

LOSEC (Other drug)		Reason: Peptic ulcer nos w/o ment perf
	20.0 Milligram	Daily
Batch:	Started:	Stopped:
RISPERIDONE (Other drug)		Reason:
	6.0 Milligram	Daily
Batch:	Started: 01/04/1997	Stopped: 14/08/1997
ZYPREXA (Suspected)		Reason:
	15.0 Milligram	Daily
Batch:	Started: 16/08/1997	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 122484 Seq: 1 Gender: M

Reported: 18/11/1997 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Muscle twitching in legs	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/09/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122506 Seq: 1 Gender: M

Reported: 18/11/1997 **Weight:** 120.00

Hospitalisation: Age: 29

Onset Date: DOB: 20/07/1968
Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Sinus tachycardia	Zyprexa ceased

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 15.0 Milligram Daily Oral

Batch: Started: 11/08/1997 **Stopped:** 22/09/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was reintroduced to zyprexa at a low dose but two days later the patient's heart rate was 120 bpm again.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 122507 Seq: 1 Gender: F

Reported: 18/11/1997 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion			

Medicine Details:

ZYPREXA (Suspected) Reason:

0.0

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient has previously experienced excessive salivation with other antipsychotics. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122508 Seq: 1 Gender: U

Reported: 18/11/1997 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Twitching of the mouth	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 15.0 Milligram Daily Oral

Batch: Started: 01/01/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient is also taking an antidepressant. - the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122509 Seq: 1 Gender: F

Reported: 18/11/1997 Weight:
Hospitalisation: Age: 28Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary retention			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason:	
	50.0 Milligram	Daily	
Batch: S	tarted: 09/09/1997		Stopped:
ZYPREXA (Suspected)	,	Reason:	Unspecified schizophrenia

Tablet 15.0 Milligram Daily Oral

Batch: Started: 28/08/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Symptoms eased off when patient missed one days medication only to increase again when she resumed zyprexa.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122512 Seq: 1 Gender: M
Reported: 18/11/1997 Weight:

Hospitalisation: Age: 30Y
Onset Date: 08/09/1997
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Alanine aminotransferase increase		Elevated alt	
Gamma-glutamyltransferase increa		Elevated gamma gt	
Leukocytosis		Elevated white blood cells	
Hypertonia		Muscle stiffness	
Monocytosis	Required Specialist Consultation		

Medicine Details:

ZYPREXA (Suspected)		Reason:	Unspecified schizophrenia
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 01/09/1997		Stopped: 08/09/1997

Laboratory Investigations:

	. <u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	1-21	08/09/1997	89	
	GGT = SGGT =		08/09/1997	71	
	White blood cells	4.5-11	08/09/1997	17.9	

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 122528
 Seq: 1
 Gender:
 F

 Reported:
 18/11/1997
 Weight:

Hospitalisation: Age:

Onset Date: 31/05/1997 DOB:
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

100.01.01.1 2010	41101			
Prefei	red Term	Severity	Report Description	Treatment
Dyspnoea				The dose was reduced to 5mg daily

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Report Details:

Case Number: 122531

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 18/11/1997			Weigh	nt:				
ospitalisation:				e: 38Y				
Onset Date:			DO					
Outcome: Unknown		Causality: Causality possible						
action Details:								
Preferred Term	Severity	Report Descri		Treatment				
sturbance in attention		Impairment of analytical al						
inking abnormal		Inability to collect thoughts	3					
edicine Details: YPREXA (Suspected)		Reason:						
Tablet	0.0	Reason.	Oral					
Batch:	Started:		Stopped:	04W				
aboratory Investigation		d Brook		-4-9-				
Date Type	Range Date Teste	ed Result	De	etails				
dditional Information:								
ort Run : 04/06/2007 04:26PM I	Database: pusime02	ADRS004		Page 60 of 526				



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122532 Seq: 1 Gender: M

Reported: 18/11/1997 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amnesia		Memory loss	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/01/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:				
Case Number: 122534	Seq: 1		Gender	F
Reported: 18/11/1997			Weight:	63.00
espitalisation:			Age:	57
Onset Date: 17/03/1997			DOB	: 01/05/1939
Outcome: Unknown			Causality	Causality possible
action Details:				
Preferred Term	Severity	Report De	scription	Treatment
ruritus ash erythematous				
acii ci yiiiciiiateae	l l		I	
Medicine Details: CLONAZEPAM (Other drug)		Reason:		
CLONAZEFAM (Other drug)	1.0 Mi			
Batch:	Started:	g.a	Stopped:	
ZYPREXA (Suspected)		Reason:	Unspecified schizophrenia	a
	10.0 Mi	lligram Daily		
Batch:	Started: 14/03/	1997	Stopped: 08/04/199	7
_aboratory Investigatior				
Date Type	Range Date Tested	Result	Deta	ils
		1		
Additional Information:				

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122537 Seq: 1 Gender: M

Reported: 18/11/1997 Weight:

 Hospitalisation:
 Age: 29

 Onset Date: 15/04/1997
 DOB: 07/06/1967

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Pins and needles in the feet	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 5.0 Milligram Daily Oral

Batch: Started: 15/04/1997 **Stopped:** 16/04/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient has complained of other medications causing this sensation.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	122543	Seq: 1		Ger	ider: U
Reported	: 18/11/199	7		Wei	ght:
ospitalisation:					Age:
Onset Date					OOB:
	Unknown			Causa	ality: Causality possible
action Deta		 			<u> </u>
	red Term	Severity		ort Description	Treatment
/luscle twitching	9		Facial twitching		
Medicine De ZYPREXA (Suspe Tablet		0.0	Rea	son: Oral	
Batch:		Started:		Stopped:	
aboratory I	nvestigati Type	Range Date Teste	ed Result		Details
Date	Турс	Trange Date reste	id Result		Details
Additional In	formation	ղ:			
oort Run: 04/06/20	007 04:26PM	I Database: pusime02		DRS004	Page 64 of 526

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	122546	Seq:	. 1				Gender: ા	J	
Reported:	-	Weight:							
spitalisation:							Age:		
Onset Date:							DOB:		
Outcome:						Ca	usality: (Causality poss	ible
action Deta									
	ed Term	Se	everity	Rep	ort Des	cription		Treatmer	nt
inary incontine	nce								
edicine Det			20.0 Milli		son:		Oral		
Batch:		e	tarted:	gram	Dally	Stopped:	Jiai	03W	
aboratory Ir	Type	Range	Date Tested	Result	l		Details		
Buto	1,700	rango	Date Footed	rtocuit			Dotalio		
dditional In	formatio	n:							
ort Run: 04/06/20	07 04:26PM	1 Database: pu	usime02	,	ADRS004			Page 65	of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122547 Seq: 1 Gender: M

Reported: 18/11/1997 Weight:
Hospitalisation: Age: 40Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Increased negative symptoms	
Drug ineffective		Lack of drug effect	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: **Started**: 01/05/1997 **Stopped**: 28/06/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has a 15 year history of schizophrenia and was previously treated by modecate and stelazine the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Gender: M Weight: Age: DOB: Causality: Causality possible Report Description Treatment
Age: DOB: Causality: Causality possible Report Description Treatment
Age: DOB: Causality: Causality possible Report Description Treatment
Causality: Causality possible Report Description Treatment
Report Description Treatment
Report Description Treatment
Reason:
Reason:
Reason:
lligram Daily
Stopped:
Reason: Unspecified schizophrenia
lligram 1 time Oral
1997 Stopped:
Result Details

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122553 Seq: 1 Gender: F

Reported: 18/11/1997 Weight:
Hospitalisation: Age: 43Y

Onset Date: 21/04/1997 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Dermatitis bullous		Rash vesiculobullous on face and appendages.	

Medicine Details:

wedicine Details:			
THYROXINE SODIUM (Other drug)		Reason:	
	50.0 Microgram	Daily	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	15.0 Milligram	Daily Oral	
Batch:	Started: 08/04/1997	Stopped: 24/04/1997	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

P/h: neutropenia with clozapine.

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DOB:

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122557 Seq: 1 Gender: F

Reported: 18/11/1997 Weight:
Hospitalisation: Age: 22Y

Outcome: Recovered Causality: Causality probable

Reaction Details:

Onset Date:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Oro-buccal dyskinesia, lip smacking	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/01/1997 **Stopped:** 28/06/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient has a history of these adverse events occurring, these reactions also occurred with risperidone, but since the patient has been transferred to clozapine they have not reoccurred. the dosage start date is not accurate but indicates that start occurred sometime during the year, the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 122560
 Seq: 1
 Gender: M

 Reported:
 18/11/1997
 Weight:

Hospitalisation: Age: 33

Onset Date: 31/05/1997 DOB: 22/08/1963

Outcome: Recovered Causality: Causality probable

Reaction Details:

	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Myalgia		Aching in arms and legs		
Pain		Generalised aches and flu-like pain in the limbs			
	Osteoarthritis		Stiffness in arms and legs		
	Influenza like illness				

Medicine Details:

ZYPREXA (Suspected)		Reason:	Unspecified schizophrenia
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 28/05/1997		Stopped: 26/06/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine	(0-195)	24/06/1997	42	

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122564 Seq: 1 Gender: F

Reported: 18/11/1997 Weight:
Hospitalisation: Age: AD
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension	Severe	Bp 110/75 fell to 75/unrecordable.	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/04/1997 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122565 Seq: 1 Gender: M
Reported: 18/11/1997 Weight:

Reported: 18/11/1997 Weight:
Hospitalisation: Age: 58Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension Severe		Bp 145/95 fell to 85/50		

Medicine Details:

 EFEXOR (Other drug)
 Reason:
 Depression

 150.0
 Milligram
 Daily

 Batch:
 Started: 01/04/1997
 Stopped:
 CONTIN

ZYPREXA (Suspected)Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/04/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122574 Seq: 1 Gender: F

Reported: 18/11/1997 Weight:
Hospitalisation: Age: 23Y
Onset Date: 01/05/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Sedated	

Medicine Details:

Medicine Details.				
STELAZINE (Other drug)		Reason:		
	5.0 Milligram	Daily		
Batch:	Started: 01/03/1997		Stopped:	
COGENTIN (Other drug)		Reason:		
	2.0 Milligram	Daily		
Batch:	Started: 01/03/1997		Stopped:	
ZYPREXA (Suspected)		Reason:		
Tablet	5.0 Milligram	1 time	Oral	
Batch:	Started: 30/04/1997		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Severity Inc		Gende Weigh Ag DO Causalit ort Description s/hallucinations auditory	t: e:
		Ag DO Causalit ort Description	e: B: y: Causality possible
		DO Causalit ort Description	B: y: Causality possible
		Causalit ort Description	y: Causality possible
		ort Description	
			Treatment
			rrodunone
ļi i i	reading voice	ornandonianono additory	
		•	
Date Tested	Result	De	etails
	Started: 03/04/1	20.0 Milligram Started: 03/04/1997	Started: 03/04/1997 Stopped:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 122641 Seq: 1 Gender: M

Reported: 20/11/1997 **Weight:** 100.00

Hospitalisation: Age: 30Y
Onset Date: 24/10/1997
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Cachon Details.			
Preferred Term	Severity	Report Description	Treatment
Hypertonia		Stiff arms and sense of restlessness.	
Hyperkinesia			

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

0.0

Batch: Started: Stopped: 22/10/1997

ZYPREXA (Suspected)Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 23/10/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 122977 Seq: 1 Gender: M

Reported: 03/12/1997 **Weight:** 100.00

Hospitalisation: Age:
Onset Date: 23/10/1997
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

EPILIM (Other drug)		Reason:	
	1.7 Gram	Daily	
Batch:	Started: 01/01/1995	Stopped:	
TEGRETOL (Other drug)		Reason:	
	300.0 Milligram	Daily	
Batch:	Started: 01/01/1995	Stopped: 29/10/1997	
VALIUM (Other drug)		Reason: Specific disorders of sleep	
	15.0 Milligram	Daily	
Batch:	Started: 01/01/1995	Stopped:	
ZYPREXA (Suspected)		Reason: Schizophrenia	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started: 13/08/1997	Stopped: 29/10/1997	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		23/10/1997	1.7	
	Neutrophils		27/10/1997	1.8	
	Neutrophils		30/10/1997	2.88	
	White blood cells		23/10/1997	3.9	
	White blood cells		27/10/1997	3.8	
	White blood cells		30/10/1997	4.8	

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Gender: M Weight: Age: 62Y DOB: Causality: Causality ity Report Description Tre	possible atment
Age: 62Y DOB: Causality: Causality	
DOB: Causality: Causality	
Causality: Causality	
ity Report Description Tre	atment
Reason:	
4.0 Milligram Daily	
d: Stopped:	
Reason:	
0.5 Dose Unspecified Daily	
d: Stopped:	

te Tested Result Details	
	4.0 Milligram Daily d: Stopped: Reason: 0.5 Dose Unspecified Daily d: Stopped: Reason: 16.0 Dose Unspecified Daily d: Stopped: Reason: 2.5 Milligram Daily

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 123109 Seq: 1 Gender: F

Reported: 04/12/1997 Weight: 93.00 Hospitalisation: Age: 37

Onset Date: DOB: 27/01/1960

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Increase in muscle tone	
Pyrexia		Increased temperature	
Somnolence		Sedation	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug) Reason: Depression

70.0 Milligram Daily

Batch: Started: 01/01/1997 Stopped: 28/11/1997

CLONAZEPAM (Other drug) Reason: Anxiety neurosis

1.0 Milligram Daily

Batch: Started: Stopped:

LOSEC (Other drug) Reason:

2.0 Dose Unspecified Daily

Batch: Started: Stopped:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 20.0 Milligram Daily Oral

Batch: Started: 01/08/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details	:
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 Case Number:
 123142
 Seq: 1
 Gender:
 F

 Reported:
 04/12/1997
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	todotion Botans.				
	Preferred Term	Severity	Report Description	Treatment	l
	Rash maculo-papular				l

Medicine Details:

ZYPREXA (Suspected) Reason:

0.0

Batch: Started: 01/10/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 123143 Seq: 1 Gender: F

Reported: 04/12/1997 Weight:
Hospitalisation: Age: 50Y

Onset Date: 31/10/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence			

Medicine Details:

Medicine Details.							
LIPEX (Other drug)		Reason:					
	20.0 Milligram	Daily					
Batch:	Started: 01/04/1997	Stop	ped:				
ZYPREXA (Suspected)		Reason:					
Tablet	20.0 Milligram	Daily	Oral				
Batch:	Started: 01/10/1997	Stop	ped:				

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was taking fluphenazine until oct 97 when they switched to 20mg zyprexa. patient was also taking 20mg of lipex. the patient experienced excessive sedation and the doctor feels there may be an interaction between the simvastatin and olanzapine. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 123148
 Seq: 1
 Gender:
 F

 Reported:
 04/12/1997
 Weight:

Hospitalisation: Age: 60

Onset Date: 31/12/1997 **DOB**: 16/12/1937

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Extrapyramidal side effts/restless legs/athetosis	
Hypokinesia		Movement disorder	Congentin once daily.
Choreoathetosis			
Hyperkinesia			

Medicine Details:

CYANOCOBALAMIN (Other drug)		Reason:
	1.0	Dose Unspecified Monthly
Batch:	Started:	Stopped:
FOLIC ACID (Other drug)		Reason:
	1.0	Dose Unspecified Daily
Batch:	Started:	Stopped:
TRANSIDERM-NITRO (Other drug)		Reason: Chron isch heart dis no hyper
	25.0) Milligram Daily
Batch:	Started:	Stopped:
CARTIA (Other drug)		Reason: Chron isch heart dis no hyper
	1.0	Dose Unspecified Daily
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details	s:					
Hospitalisation: Onset Date:	04/12/1997 31/12/1997 Recovered	Seq: 1				
Medicine Deta						
ORUDIS (Other dro	ug)	200.0	Milligram	Reason: Daily	Unspecified arthritis	
Batch:		Started:	wiiiigiaiii	Dally	Stopped:	
ZYPREXA (Suspec	cted)			Reason:		
		5.0	Milligram	Daily		
Batch:		Started:			Stopped:	
Laboratory In	vestigations:					
Additional Inf	formation: t is not accurate but	indicates that or	nset occuri	red sometime	e during the year.	

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Hospitalisati Onset D Outcor	ate: ne: Unknown		: 1		С	Gender: Weight: Age: DOB: ausality:	
Reaction D	etails: eferred Term		overity.	Done	art Description		Treatment
Hypotension		36	everity	Керс	ort Description	Ce	ased melleril.
Medicine							
MELLERIL (O	ther drug)			Reas	son:		
B-4 1	. .	•	0.0		04		
CLONAZERA	h: M (Other drug)	Started:			Stopped:		
OLUMAZEPA	m (Outer urug)	0.0			oui.		
Batc	h:	S	Started:		Stopped:		
EPILIM (Othe					son:		
			0.0				
Batc	h:	S	Started:		Stopped:		
ZYPREXA (Su				Reas	son:		
Table			0.0		Stopped:	Oral	
Batc	h:	S	Started:				
Laborator	y Investigat	ions:					
Date	Туре	Range	Date Tested	Result		Detai	s
Additiona Patient is a dia	l Informatio	n:					

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 123154 Seq: 1 Gender: F

Reported: 04/12/1997 Weight:
Hospitalisation: Age: 28

Onset Date: 15/11/1997 **DOB**: 30/08/1969

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Epistaxis			

Medicine Details:

Medicine Details.			
ZOLOFT (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 13/11/1997	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has developed nose bleeds since commencing zyprexa, not previously suffered from this.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	port	Detail	ls:
----	------	--------	-----

 Case Number:
 123156
 Seq: 1
 Gender:
 F

 Reported:
 04/12/1997
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypokinesia		Movement disorder of face	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced worsened severity of movement of face when treated with zyprexa.

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Report Details:

Case Number: 123159

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 04/12/199	7	Weight:					
ospitalisation:		Age : 36Y					
Onset Date: 03/11/199	7		DO				
Outcome: Unknown			Causalit	ty: Causality possible			
eaction Details:				- , ,			
Preferred Term	Severity	Report De	scription	Treatment			
Photosensitivity reaction Rash							
Medicine Details:		Danas					
TEGRETOL (Other drug)	0.0	Reason:					
Batch:	Started:		Stopped:				
ZYPREXA (Suspected)	Starteu.	Reason:	Stopped.				
Tablet	5.0 Mil		Oral				
Batch:	Started: 27/10/1	-	Stopped:				
aboratory Investigat	iono						
Laboratory Investigat Date Type	Range Date Tested	Result	D ₁	etails			
Date Type	Trange Date rested	recount		Stallo			
Additional Informatio	n:						
eport Run: 04/06/2007 04:26PN	1 Database: pusime02	ADRS00	<u> </u>	Page 86 of 526			



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 123160
 Seq: 1
 Gender: F

 Reported:
 04/12/1997
 Weight:

Hospitalisation: Age: 45Y

Onset Date: 14/10/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Pitting oedema of arms, legs, fingers and toes.	
Weight increased		Weight gain of 15kg.	
Dyspnoea			
Hyperhidrosis			

Medicine Details:

Batch:

CLOZAPINE (Other drug)		Reason:	Schizophrenia	
	350.0 Milligram	Daily		
Batch:	Started: 01/09/1996		Stopped: 12/10/1997	
ZYPREXA (Suspected)		Reason:		
Tablet	10.0 Milligram	Daily	Oral	

Stopped:

Started: 09/10/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 123161 Seq: 1 Gender: F

Reported: 04/12/1997 Weight:
Hospitalisation: Age: 18Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/10/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 123162 Seq: 1 Gender: F

Reported: 04/12/1997 Weight:
Hospitalisation: Age: 24Y

Onset Date: 01/11/1997

Outcome: Unknown

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Twitching of muscles, mainly in legs.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: 01/07/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 123163
 Seq: 1
 Gender:
 F

 Reported:
 04/12/1997
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cataract		Posterior cortical cataracts in both eyes.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: 01/09/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Prosterior cortical cataracts.

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 123263 Seq: 1 Gender: F

Reported: 10/12/1997 Weight: 0.00 Hospitalisation: Age: 32

Onset Date: 08/10/1997 **DOB**: 27/10/1964

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			

Medicine Details:

ZYPREXA (Suspected)Reason: Unspecified schizophrenia

10.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Time to onset: 2 months. Doctor to review patient in 3 months time to see if periods have returned.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Mulliber.		Seq	. !			nder. O		
	: 12/12/1997			ight:				
ospitalisation: Admitted to hospital					Age:			
Onset Date	:			DOB:				
Outcome:	Unknown				Caus	ality: Causality possib	le	
action Deta	ıils:							
	red Term	S	everity	Rep	ort Description	Treatment		
leuroleptic mali	ignant syndr	ome						
Medicine De ZYPREXA (Suspe			0.0	Rea	son:			
Batch:			Started:		Stopped:			
_aboratory I	nvestigati	ons:						
Date	Туре	Range	Date Tested	Result		Details		
Crea		-			Ck levels reached 1300.			
Additional In	formation	1 :						
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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 123522
 Seq: 1
 Gender: M

 Reported:
 18/12/1997
 Weight:

Hospitalisation: Admitted to hospital Age: 54Y
Onset Date: 20/11/1997
DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Gravitational oedema		Oedema-bilateral pitting oedema to knees.	Fluid restriction.
Speech disorder		Slurred speech	
Albuminuria			
Hypoproteinaemia			
Nephrotic syndrome			

Medicine Details:

OLANZAPINE (Suspected) Reason: Schizophrenia

20.0 Milligram Daily

Batch: Started: 07/09/1997 **Stopped:** 26/11/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was restarted on olanzapine and symptoms returned. patient to be managed on lithium and risperidone. see original report for other drugs.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Ren	ort	Deta	ils:
-----	-----	------	------

Case Number: 123537 Seq: 1 Gender: F
Reported: 18/12/1997 Weight:

Hospitalisation: Age: 23

Onset Date: 14/07/1997 **DOB**: 21/09/1973

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Olanzepine dose halved, then increased slowly over several weeks.

Medicine Details:

OLANZAPINE (Suspected) Reason: Schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 24/06/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	(2.0-7.5)	14/07/1997	1.4	

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 123602 Seq: 1 Gender: M
Reported: 23/12/1997 Weight:

Hospitalisation: Treated in outpatient department only. **Age:** 54Y **Onset Date:** 25/11/1997 **DOB:**

Outcome: Recovered Causality: Causality certain

Reaction Details:

todotion Dotailo.			
Preferred Term	Severity	Report Description	Treatment
Albuminuria			
Gravitational oedema			
Hypoproteinaemia			Fluid restriction and frusemide

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:		
Tablet	1.2 Gram	Daily	Oral	
Batch:	Started:		Stopped: 26/11/1997	
METFORMIN HYDROCHLORIDE (Other dru	ıg)	Reason: Dia	abetes mellitus	
Tablet	1.0 Gram	Daily	Oral	
Batch:	Started:		Stopped:	
POTASSIUM CHLORIDE (Other drug)		Reason:		
POTASSION CHECKIDE (Other drug)		Reason.		
FOTASSION CHECKIDE (Other drug)	600.0 Milligram	Daily		
Batch:	600.0 Milligram Started: 20/11/1997	Daily	Stopped: 26/11/1997	
ζ,	ğ	Daily	Stopped: 26/11/1997 r&nos infec¶sit diseases	
Batch:	ğ	Daily Reason: Otr	•••	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				25/11/97 hypoalbuminaemia 32 g/l.
	Pharmacokinetics			28/11/97 lithium levels toxic 2.8 mmol/l.	

Additional Information:

Treatment with olanzapine was restarted on 4/12/97 and oedema returned and hypoalbuminaemia and proteinuria worsened. olanzapine ceased again on 9/12/97.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Detail	s:				
Case Number:	123602	Seq: 1		Gender:	M
Reported:	23/12/1997			Weight:	
Hospitalisation:	Treated in outpat	ient department only.		Age:	54Y
Onset Date:	25/11/1997			DOB:	
Outcome:	Recovered			Causality:	Causality certain
Reaction Detai	ils:				
Medicine Det	ails:				
ZYPREXA (Suspec	cted)		Reason:	Jnspecified schizophrenia	
Tablet		20.0 Milligram	Daily	Oral	
Batch:		Started: 07/09/1997		Stopped: 26/11/1997	,
					_
	41. 41				
Laboratory In	vestigations:				
Additional Inf	formation:				
Treatment with ola		ed on 4/12/97 and oedema	returned and	hypoalbuminaemia an	d proteinuria worsened.
	J				

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124010 Seq: 1 Gender: F

Reported: 16/01/1998 Weight: 72.00 Hospitalisation: Age: 72Y

Onset Date: 27/10/1997 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Elevated Ift's	

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason: Unspecified psychosis
	750.0 Milligram	Daily
Batch:	Started: 01/01/1992	Stopped: CONTIN
COGENTIN (Suspected)		Reason: Unspecified psychosis
	2.0 Milligram	Daily
Batch:	Started: 15/09/1997	Stopped: 29/10/1997
OLANZAPINE (Suspected)		Reason: Unspecified psychosis
	10.0 Milligram	Daily
Batch:	Started: 15/09/1997	Stopped : 29/10/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	5-40 U/L	27/10/1997	623	
	ALT = SGPT	5-40 U/L	24/11/1997	26	
	ALT = SGPT	5-40 U/L	12/01/1998	22	
	AST = SGOT	5-40 U/L	27/10/1997	363	
	AST = SGOT	5-40 U/L	24/11/1997	22	
	AST = SGOT	5-40 U/L	12/01/1998	22	
	Bilirubin	3 - 21 UMOL/L	27/10/1997	66	

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124010 Seq: 1 Gender: F

Reported: 16/01/1998 Weight: 72.00 Hospitalisation: Age: 72Y

Onset Date: 27/10/1997 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	Unspecified psychosis	
	750.0 Milligram	Daily		
Batch:	Started: 01/01/1992		Stopped:	CONTIN
COGENTIN (Suspected)		Reason:	Unspecified psychosis	
	2.0 Milligram	Daily		
Batch:	Started: 15/09/1997		Stopped: 29/10/1997	
OLANZAPINE (Suspected)		Reason:	Unspecified psychosis	
	10.0 Milligram	Daily		
Batch:	Started: 15/09/1997		Stopped: 29/10/1997	

Laboratory Investigations:

Da	ate	Туре	Range	Date Tested	Result	Details
		Bilirubin	3 - 21 UMOL/L	24/11/1997	9	
		Bilirubin	3 - 21 UMOL/L	12/01/1998	9	
		GGT = SGGT =	<65 U/L	27/10/1997	709	
		GGT = SGGT =	<65 U/L	12/01/1998	19	
		GGT = SGGT =	<65 U/L	24/11/1997	112	
		SAP = ALP	30-115 U/L	27/10/1997	337	
		SAP = ALP	30-115 U/L	24/11/1997	127	

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124010 Seq: 1 Gender: F

Reported: 16/01/1998 Weight: 72.00 Hospitalisation: Age: 72Y

Onset Date: 27/10/1997 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason: Unspecified psychosis
	750.0 Milligram	Daily
Batch:	Started: 01/01/1992	Stopped: CONTIN
COGENTIN (Suspected)		Reason: Unspecified psychosis
	2.0 Milligram	Daily
Batch:	Started: 15/09/1997	Stopped: 29/10/1997
OLANZAPINE (Suspected)		Reason: Unspecified psychosis
	10.0 Milligram	Daily
Batch:	Started: 15/09/1997	Stopped : 29/10/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	30-115 U/L	12/01/1998	104	

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 124030
 Seq: 1
 Gender: U

 Reported:
 15/01/1998
 Weight:

Hospitalisation: Age:
Onset Date: 27/11/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Ceased olanzapine

Medicine Details:

OLANZAPINE (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: 18/11/1997 **Stopped:** 07/12/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		05/11/1997	2.8	
	Neutrophils		03/12/1997	1.9	
	White blood cells		05/11/1997	4.2	
	White blood cells		03/12/1997	2.52	

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Rei	nort	: De	tai	ls:

 Case Number:
 124164
 Seq: 1
 Gender: U

 Reported:
 19/01/1998
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight increase of 20kg	

Medicine Details:

ZYPREXA (Suspected)

Reason:

20.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced weight gain after dose of zyprexa titrated quickly from 10mg to 20mg daily. patient does not wish to continue treatment.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 124165	Seq: 1		Gene	der: U
Reported: 19/01/1998			Weig	ıht:
spitalisation:				ge:
Onset Date:				OB:
Outcome: Unknown			Causa	lity: Causality possible
action Details:				
Preferred Term	Severity	Report Des	scription	Treatment
eight increased	Wei	ght gain of 12kg		
edicine Details:	0.0	Reason:		
Batch:	Started:		Stopped:	CONTIN
		Result		Details
Date Type	range Bate restea	recount	•	Setano
Date Type Additional Information:	Range Date Tested	Result		Details



Date Range: 1 Jan 1960 To 31 Dec 1999 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: 124169 Seq: 1 Gender: U

Reported: 19/01/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

ZYPREXA (Suspected) Reason:

10.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced lowering of seizure threshold leading to shaking. patient is also taking anticonvulsant medication. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 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: 124170 Seq: 1 Gender: M

Reported: 19/01/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

ZYPREXA (Suspected) Reason:

10.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Young patient experienced lowering of seizure threshold leading to shaking. patient was also taking an anticonvulsant and using marijuana. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 124171	_		_
	Seq: 1		Gender: F
Reported: 19/01/1998			Weight:
spitalisation:			Age: 42
Onset Date:			DOB : 20/05/1955
Outcome: Unknown			Causality: Causality possible
ection Details:			
Preferred Term	Severity	Report Des	· · · · · · · · · · · · · · · · · · ·
emor		Nervous tremor	Given propanolol to treat side effect
edicine Details:			
(PREXA (Suspected)	-		Jnspecified schizophrenia
Tablet Batch:	5.0 Started: 0	D Milligram Daily	Oral Stopped:
boratory Investigation	1S: Range Date Te	ested Result	Details

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Report Details:

Case Number: 124172

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

ospitalisation: Onset Date:				Wei	ght:			
	Reported: 19/01/1998 lospitalisation: Onset Date:				Age: DOB:			
O. d								
Outcome: Unknown		Causality: Causality possible						
eaction Details:					_			
Preferred Term	Se	verity	Repo	ort Description	Treatment			
nfluenza like illness								
Malaise ^P yrexia								
Medicine Details:								
ZYPREXA (Suspected) Tablet		0.0	Rea	son:				
Batch:	04	0.0 arted:		Oral Stopped:				
aboratory Investigation	Range	Date Tested	Result		Details			

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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Case Number: 124173 Seq: 1 Gender: M
Reported: 19/01/1998 Weight:

Hospitalisation: Age: 18Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Libido decreased		Sexual dysfunction	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has experienced the same reaction when previously on haloperidol & risperidone.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124174 Seq: 1 Gender: M

Reported: 19/01/1998 Weight: 120.00 Hospitalisation: Age: 31Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			

Medicine Details:

RISPERIDONE (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	

Tablet 10.0 Milligram Daily Oral

Batch: Started: 15/07/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Ck baseline 120, peaked at 700, took 3 weeks to return to 120

Additional Information:

Previous exposure to zyprexa in november 1996 produced same reaction.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124175 Seq: 1 Gender: F

Reported: 19/01/1998 Weight:

Hospitalisation: Hospitalisation prolonged
Onset Date: 31/12/1997
DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrasystoles		Etopic cardiac attack	Zyprexa discontinued.

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

After re-introduction of zyprexa patient experienced another ectopic episode. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124177 Seq: 1 Gender: F

Reported: 19/01/1998 Weight: Hospitalisation: Age:

Onset Date: 31/12/1997 **DOB:**

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Headache	Severe		

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 15.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced severe headache after dose of zyprexa was increased from 10mg to 15mg daily. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124178 Seq: 1 Gender: F

Reported: 19/01/1998 Weight: 65.00 Hospitalisation: Age: 28

Onset Date: 23/11/1997 **DOB**: 22/10/1969

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral			

Medicine Details:

Medicine Details.							
ZYPREXA (Suspected)		Reason:					
Tablet	7.5 Milligram	7.5 Milligram Daily					
Batch:	Started: 13/11/1997	Started: 13/11/1997 Stopped:					
PROZAC (Suspected)		Reason:					
Oral application	40.0 Milligram	Daily	Oral				
Batch:	Started: 11/06/1997	Sto	opped:				

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

The patient has a history of schizophrenia with morbid paranoia.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124179 Seq: 1 Gender: M

Reported: 19/01/1998 Weight: Hospitalisation: Age:

Onset Date: 31/12/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination		Auditory hallucinations	
Drug ineffective		Lack of drug effect	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 20.0 Milligram Daily Oral

Batch: Started: 01/12/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 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: 124180 Seq: 1

Weight: Reported: 19/01/1998 **Hospitalisation:** Age: Onset Date: 31/12/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Decreased neutrophils	Zyprexa ceased.

Medicine Details:			
VALPRO (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				Patient experienced decreased neutrophils after second dose of zyprexa. patient initially treated with clozapine for 2 weeks and neutrophil levels decreased to 1.1 clozapine treatment ceased and patient's neutrophils recovered to a level of 1.8.

Additional Information:

Patient will be rechallenged with treatment. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Ren	ort	Deta	ils:
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Case Number: 124181 Seq: 1 Gender: F

Reported: 19/01/1998 Weight:
Hospitalisation: Age: 65Y

Onset Date: 31/12/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Very drowsy	

Medicine Details:

Micarcine Betans.			
DIAZEPAM (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient previously tolerated diazepam alone. patient also has parkinson's disease. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:	Rei	port	Deta	ils:
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Case Number: 124182 Seq: 1 Gender: M

Reported: 19/01/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral			

Medicine Details:

ZYPREXA (Suspected) Reason:

0.0

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE, ZYPREXA, Zyprexa IM, Zyprexa Zydis

Report Details:

Case Number: 124183 Seq: 1 Gender: M

Reported: 19/01/1998 Weight:
Hospitalisation: Age: 25

Onset Date: 10/12/1997 DOB: 27/07/1972

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia			

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug)		Reason:	Unspecified psychosis
100.0	Milligram	Daily	

Batch: Started: 16/09/1997 Stopped:

BENZTROPINE MESYLATE (Other drug) Reason:

1.0 Milligram Daily

Batch: Started: 16/09/1997 Stopped:

MIDAZOLAM (Other drug) Reason:

10.0 Milligram Daily

Batch: Started: 26/11/1997 Stopped:

DROPERIDOL (Other drug) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 26/11/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced tachycardia when previously treated with clozapine patient has history of cardiomyopathy secondary to clozapine (investigated 18 november 1997 with electrocariogram). patient commenced zyprexa 10mg and was increased to 15mg. pulse rate increased from 84-90 bpm to 100-128 bpm. dose reduced to 10mg. pulse now 84-94 bpm.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:				
Case Number: 124183 Reported: 19/01/1998 Hospitalisation:	Seq: 1		Gender: M Weight: Age: 25	
Onset Date: 10/12/1997			DOB : 27/0	07/1972
Outcome: Recovered			Causality: Cau	sality possible
Reaction Details:				
Medicine Details:		Reason:		
I ZVDDEYA (Suchacted)				
ZYPREXA (Suspected) Tablet			Oral	
Tablet Batch:	15.0 Milligram Started: 24/11/1997	Daily	Oral pped:	
Tablet	15.0 Milligram	Daily		
Tablet	15.0 Milligram	Daily		
Tablet	15.0 Milligram	Daily		
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Tablet	15.0 Milligram	Daily		
Tablet	15.0 Milligram Started: 24/11/1997	Daily		
Tablet Batch:	15.0 Milligram Started: 24/11/1997	Daily		
Tablet Batch:	15.0 Milligram Started: 24/11/1997	Daily		
Tablet Batch:	15.0 Milligram Started: 24/11/1997	Daily		
Tablet Batch:	15.0 Milligram Started: 24/11/1997	Daily		
Tablet Batch:	15.0 Milligram Started: 24/11/1997	Daily		
Tablet Batch:	15.0 Milligram Started: 24/11/1997	Daily		
Tablet Batch:	15.0 Milligram Started: 24/11/1997	Daily		
Tablet Batch: Laboratory Investigations Additional Information:	15.0 Milligram Started: 24/11/1997	Daily Sto	pped:	
Tablet Batch: Laboratory Investigations	15.0 Milligram Started: 24/11/1997	Daily Sto	istory of cardiomyopa	thy secondary to

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 124184 Seq: 1 Gender: U

Reported: 19/01/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Leg stiffness	

Medicine Details:

ZYPREXA (Suspected) Reason:

0.0

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Leg stiffness has occurred in the past while patient treated with lithium and another older generation antipsychotic. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124186 Seq: 1 Gender: F

Reported: 19/01/1998 Weight: 0.00 Hospitalisation: Age: 99U

Onset Date: 31/12/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Dotanoi		-	
Preferred Term	Severity	Report Description	Treatment
Eructation		Burping	
Obstruction gastric		Puloric stenosis	
Psoriasis			

Medicine Details:

ZYPREXA (Suspected)

Reason:

10.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124324 Seq: 1 Gender: F

Reported: 22/01/1998 Weight: 44.00
Hospitalisation: Admitted to hospital Age: 40

Onset Date: 05/01/1998 **DOB:** 30/01/1957

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Urinary incontinence			Had to be catheterised.	

Medicine Details:

AROPAX (Other drug) Reason: Depression

20.0 Milligram Daily

Batch: Started: 01/06/1997 Stopped: 13/01/1998

ZYPREXA (Suspected) Reason: Schizophrenia

10.0 Milligram Daily

Batch: Started: 21/12/1997 **Stopped:** 13/01/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124336 Seq: 1 Gender: F

 Reported:
 22/01/1998
 Weight:
 70.00

 Hospitalisation:
 Age:
 75Y

Onset Date: 14/01/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Grossly elevated lfts.	Ceased zyprexa.
Fatigue			
Nervousness			

Medicine Details:

OVESTIN (Other drug)		Reason: Vaginitis&vulvitis	
Ointment	5.0 Dose Unspeci	ified Monthly Vaginal	
Batch:	Started: 01/01/1993	Stopped:	CONTIN
FLUANXOL (Other drug)		Reason: Unspecified neurosis	
	5.0 Milligram	Monthly	
Batch:	Started: 01/12/1997	Stopped:	
PROZAC (Other drug)		Reason: Depression	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started: 01/06/1996	Stopped:	CONTIN
THYROXINE SODIUM (Other drug)		Reason: Myxedema	
	50.0 Microgram	Daily	
Batch:	Started: 01/01/1993	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE, ZYPREXA, Zyprexa IM, Zyprexa Zydis

Report Details:

Case Number: 124336 Seq: 1 Gender: F

 Reported:
 22/01/1998
 Weight:
 70.00

 Hospitalisation:
 Age:
 75Y

 Onset Date:
 14/01/1998
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

COLOXYL WITH SENNA (Other drug)	Reason:			Constipation		
	2.0	Oose Unspecifie	d Daily			
Batch:	Started: 01/12	2/1997		Stopped:	CONTIN	
COGENTIN (Other drug)	Reason:					
	0.5	Oose Unspecifie	d Daily			
Batch:	Started:			Stopped:		
ZYPREXA (Suspected)		Re	ason:	Unspecified neurosis		
	5.0 N	Milligram	Daily			
Batch:	Started: 01/12	2/1997		Stopped: 14/01/199	98	

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124541 Seq: 1 Gender: F

 Reported:
 02/02/1998
 Weight:
 40.00

 Hospitalisation:
 Age:
 76Y

Onset Date: 31/12/1997 **DOB**:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia			Antibiotics, supportive care.

Medicine Details:

OLANZAPINE (Interaction)		Reason:	Manic depress	sive psycho, depre
Oral application	10.0 Milligram	Daily		Oral
Batch:	Started:		Stopped:	28/01/1998
FLUCONAZOLE (Interaction)		Reason:	Moniliasis	
Oral application	50.0 Milligram	Daily		Oral
Batch:	Started: 30/12/1997		Stopped:	28/01/1998
NEFAZODONE HYDROCHLORIDE (Int	eraction)	Reason:	Depression	
	500.0 Milligram	Daily		
Batch:	Started:		Stopped:	28/01/1998
CISAPRIDE (Other drug)		Reason:		
Oral application	20.0 Milligram	Daily		Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Profound sedation occurring after commencement of fluconazole. patient previously stable on olazapine and other treatment. patient aspirated, developed bronchopneumonia and died 3/1/98 despite antibiotics and supportive care. drug interaction suspected. olanzapine, fluconazole and cisapride were all administered via a peg tube. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	nn	rt	De	tail	ls:
176	μυ		$\mathbf{D}\mathbf{c}$	tai	.

Case Number: 124541 Seq: 1 Gender: F

 Reported:
 02/02/1998
 Weight:
 40.00

 Hospitalisation:
 Age:
 76Y

 Onset Date:
 31/12/1997
 DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Medicine Details:

MEGICINE DETAILS.					
SODIUM VALPROATE (Other drug)			Reason:	Depression	
	900.0	Milligram	Daily		
Batch:	Started:			Stopped:	28/01/1998
liothyronine sodium (Other drug)			Reason:	Depression	
	20.0	Microgram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

Additional Information:

Profound sedation occurring after commencement of fluconazole. patient previously stable on olazapine and other treatment. patient aspirated, developed bronchopneumonia and died 3/1/98 despite antibiotics and supportive care. drug interaction suspected. olanzapine, fluconazole and cisapride were all administered via a peg tube. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

| Preferred Term Severity Report Description Treatment Exacerbation of acne. Retin - a gel Preferred Term |--|
| Preferred Term Severity Report Description Treatment of acne Exacerbation of acne. Retin - a gel |
| Preferred Term Severity Report Description Treatment of acne Exacerbation of acne. Retin - a gel Retin - a gel |
| Medicine Details: BENZTROPINE MESYLATE (Other drug) Batch: Started: Started: Stopped: Exacerbation of acne. Retin - a gel Retin - a gel Other&unspecified epilepsy Daily Stopped: Stopped: Stopped: |
| ### Medicine Details: BENZTROPINE MESYLATE (Other drug) |
| Batch: Started: Stopped: SERTRALINE HYDROCHLORIDE (Other drug) Reason: Depression 50.0 Milligram Daily Batch: Started: Stopped: |
| Batch: Started: Stopped: SERTRALINE HYDROCHLORIDE (Other drug) Reason: Depression 50.0 Milligram Daily Batch: Started: Stopped: |
| SERTRALINE HYDROCHLORIDE (Other drug) Reason: Depression 50.0 Milligram Daily Batch: Started: Stopped: |
| 50.0 Milligram Daily Batch: Started: Stopped: |
| |
| |
| OLANZAPINE (Suspected) Reason: |
| 0.0 Batch: Started: Stopped: |
| _aboratory Investigations: |
| Date Type Range Date Tested Result Details |

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 124784
 Seq: 1
 Gender: M

 Reported:
 06/02/1998
 Weight:

Hospitalisation: Age: 25Y

Onset Date: 14/01/1998 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Respiratory disorder		Fast breathing	Zyprexa ceased
Muscle twitching		Muscle twitching from hands to feet	
Blood creatine phosphokinase incr			

Medicine Details:

Medicine Details.			
EFEXOR (Other drug)		Reason:	
	150.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
	150.0 Milligram	Daily	
Batch:	Started: 01/12/1997	Stopped: 14/01/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine	< 300	30/01/1998	378	
	SAP = ALP	7 - 56	30/01/1998	83	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124807 Seq: 1 Gender: U

Reported: 10/02/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 124810
 Seq: 1
 Gender:
 F

 Reported:
 10/02/1998
 Weight:

Hospitalisation: Hospitalisation prolonged **Age**: 57

Onset Date: 07/01/1998 **DOB**: 01/11/1940

Outcome: Unknown Causality: Causality possible

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Coma			
Consciousness fluctuating			
Rash maculo-papular			Prednisolone, aristocort, burrows sol.

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:		
	500.0 Milligram	Daily		
Batch:	Started:	St	opped:	
CARBAMAZEPINE (Other drug)		Reason:		
	800.0 Milligram	Daily		
Batch:	Started:	St	opped: 28/01/1998	
CLONAZEPAM (Other drug)		Reason:		
	1.0 Milligram	Daily		
Batch:	Started:	St	opped:	
ZYPREXA (Suspected)		Reason:		
Tablet	15.0 Milligram	Daily	Oral	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

On 07/01/98 zyprexa dose was increased to 20mg. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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Repo)I L	υt	Lai	15.

 Case Number:
 124812
 Seq: 1
 Gender: U

 Reported:
 10/02/1998
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	<u> </u>			1
	Preferred Term	Severity	Report Description	Treatment
	Neurosis		Worsening of obsessive disorder	
	Drug ineffective			

Medicine Details:

ZYPREXA (Suspected) Reason: Obsessive compulsive neurosis

0.0

Batch: Started: Stopped: 4M

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Same reaction occurred when patient was using risperidone about 1 year ego.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 124814
 Seq: 1
 Gender: F

 Reported:
 10/02/1998
 Weight:

Hospitalisation: Age: 27

Onset Date: 31/12/1997 **DOB:** 14/03/1970

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: 01/11/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt has been taking olanzapine for approx. 3 months. she has been titrated up to 20mg for the past 6 weeks - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124824 Seq: 1 Gender: F

Reported: 11/02/1998 Weight: 60.00
Hospitalisation: Admitted to hospital Age: 31Y
Onset Date: 23/01/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity Report Description		Treatment
Neutropenia			Zyprexa ceased

Medicine Details:

ZYPREXA (Suspected) Reason: Paranoid type schizophrenia

 Tablet
 20.0 Milligram
 Daily
 Oral

 Batch:
 Started: 17/07/1997
 Stopped: 23/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		23/01/1998	1.7	
	Neutrophils		27/01/1998	2.8	
	leucocytes		23/01/1998	2.7	
	leucocytes		27/01/1998	4.0	

Additional Information:

Patient was hospitalised with neutropenia on 230198. the patient has thalassaemia minor. no history of haematological disease, hiv, cancer, illicit drug use, collagen vascular disorder or immune suppressive conditions.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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Case Number: 124837 Seq: 1 Gender: F

Reported: 10/02/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/01/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Skin discolouration		Brown spots on skin.	
	Somnolence		Sedation	

Medicine Details:

ZYPREXA (Suspected) Reason:

0.0

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124839 Seq: 1 Gender: M

Reported: 10/02/1998 Weight:

Hospitalisation: Age: 61Y
Onset Date: 31/01/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 15.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt experienced reaction 8-9 months after commencement of zyprexa - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: 10/0	2/1998		Weight:							
spitalisation: Onset Date: 31/0	4/4000						Ag DO			
Outcome: Unki						_			iooliti i nood	sible
action Details:	IOWII						ausaiii	.y. Cat	usality poss	sible
Preferred Te	erm	Severity		Report I	Descrir	tion			Treatme	nt
dema peripheral		coverity	Oedema o	•					110011110	
dema			Swollen a							
adicina Datails:										
		er drug)		Reason	:					
		e r drug) 0.0)	Reason	:					
)	Reason		Stopped:				
ENLAFAXINE HYDROC Batch:		0.0	0	Reason	;	Stopped:				
ENLAFAXINE HYDROC Batch:		0.0			;	Stopped:				
ENLAFAXINE HYDROO Batch: GEN (Other drug) Batch:		0.0 Started:		Reason	; :	Stopped:				
Batch: GEN (Other drug) Batch: YPREXA (Suspected)		0.0 Started: 0.0 Started:)	Reason Reason	:					
GEN (Other drug)		0.0 Started: 0.0 Started:	O Milligram	Reason	: :		Oral			

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124845 Seq: 1 Gender: F

Reported: 10/02/1998 Weight:
Hospitalisation: Age: 35Y

Onset Date: 31/01/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Rash in cnr of mouth and neck	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/01/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 124847
 Seq: 1
 Gender: F

 Reported:
 10/02/1998
 Weight:

Hospitalisation: Age: 17Y
Onset Date: 31/01/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Acne		Worsening of acne	Retin a (tretinoin)

Medicine Details:

vieulcine Delans.				
BENZTROPINE MESYLATE (Suspected	d)	Reason:		
	0.0			
Batch:	Started:		Stopped:	
ZYPREXA (Suspected)		Reason:		
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 16/01/1998		Stopped:	
SERTRALINE HYDROCHLORIDE (Sus	pected)	Reason:		
	50.0 Milligram	Daily		
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124850 Seq: 1 Gender: F

Reported: 10/02/1998 Weight: 60.00 Hospitalisation: Age: 18

Onset Date: 31/01/1998 **DOB**: 10/11/1979

Outcome: Unknown Causality: Causality possible

Reaction Details:

Couction Botano.									
Preferred Term	Severity	Report Description	Treatment						
Syncope		Fainting spell							
Convulsion		Seizure							
Orthostatic hypotension									

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 17/12/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient has been taking zyprexa for approx. 1 month at 5mg/day. the dose was increased to 10mg/day and a few days later the patient experienced a seizure at the end of a fainting spell. the patients dose has been reduced to 5mg/day. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repor ospitalisati Onset D	ate: 31/01/199/ me: Recovered	8		Gender: F Weight: Age: DOB: Causality: Causality probable		
	eferred Term	Severity	Repo	t Description	Treatment	
ace oedem ruritus ash Irticaria	a				Zyprexa ceased	
ZYPREXA (S	uspected)		Reas		Oral	
	uspected) t	0.0 Started:			Oral	
Batc	uspected) t	Started:			Oral	

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	port	Detail	ls:
----	------	--------	-----

 Case Number:
 124854
 Seq: 1
 Gender:
 F

 Reported:
 10/02/1998
 Weight:

Hospitalisation: Age:

Onset Date: 31/01/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Somnolence		Sedation	
	Weight increased			

Medicine Details:

ZYPREXA (Suspected)			
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	S	topped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Pt experienced reactions after being treated for 2 months. treatment dose was gradually reduced to 7.5mg and then to 5 mg once daily. the patient is still feeling sedated. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124855 Seq: 1 Gender: M

Reported: 10/02/1998 Weight:

Hospitalisation: Age: 46Y
Onset Date: 31/01/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/09/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	2 - 7.5	14/09/1993	3.7	
	Neutrophils	2 - 7.5	12/01/1998	1.6	
	leucocytes	4 - 11	23/02/1998	6.3	
	leucocytes	4 - 11	12/01/1998	3.9	

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 124942 Seq: 1 Gender: M

 Reported:
 13/02/1998
 Weight:
 70.00

 Hospitalisation:
 Age:
 70Y

 Onset Date:
 25/10/1997
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting		Began 1 day after commencing olanzapine	

Medicine Details:

CLONAZEPAM (Other drug)	Reason:					
	2.0 Milligram	Daily				
Batch:	Started: 01/01/1995		Stopped:	CONTIN		
OLANZAPINE (Suspected)		Reason:	Unspecified schizophrenia			
	20.0 Milligram	Daily				
Batch:	Started: 24/10/1997		Stopped:	CONTIN		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 125089 Seq: 1 Gender: M
Reported: 18/02/1998 Weight:
Hospitalisation: Age: 17Y

Onset Date: 16/12/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Required Visit to Doctor		Zyprexa dose reduced to 30mg / day.
, , , , , , , , , , , , , , , , , , ,	Required Visit to Doctor		

Medicine Details:

CLONAZEPAM (Other drug)			Reason:	
	1.0	Milligram	As necessary	
Batch:	Started:		Stop	pped:
LARGACTIL (Other drug)			Reason:	
	100.0	Milligram	As necessary	
Batch:	Started:		Stop	pped:
LITHICARB (Other drug)			Reason:	
	1.2	Gram	Daily	
Batch:	Started:		Stop	pped: 16/12/1997
COGENTIN (Other drug)			Reason:	
	2.0	Milligram	Daily	
Batch:	Started:		Stop	pped: 17/12/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reaction Details	8/02/1998 6/12/1997 lot yet recovered	Seq: 1		Gender: Weight: Age: DOB: Causality:	
Medicine Detai	ls:				
ZYPREXA (Suspecte	d)	FO O Milliana	Reason:	Onal	
Tablet Batch:		50.0 Milligram Started: 16/11/1997	Daily	Oral	CONTIN
Balcii.		Started. 10/11/1997		Stopped:	CONTIN
Laboratory Inve	estigations:				
Additional Info	rmation:				

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Report Details:

Case Number: 125272

Reported: 24/02/1998

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: U

Weight:

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

lospitalisation:			Age:		
Onset Date: 14/02/1998			DOB:		
Outcome: Unknown			Causality: Causality probable		
eaction Details:					
Preferred Term	Se	everity	Repo	ort Description	Treatment
Chills		F	reezing episod	e felt as if going to die.	
ain	F		Pain all over body lasted two hours.		
lallucination		\	/isual hallucinat	ions	
)yskinesia					
leadache					
lyperhidrosis					
nsomnia					
Muscle twitching					
Medicine Details: PERGOLIDE (Other drug)			Rea	son:	
		0.0			
Batch:	s	tarted:		Stopped:	CONTIN
SELEGILINE HYDROCHLORID	E (Other drug)	0.0	Rea	son:	
Batch:	s	tarted:		Stopped:	CONTIN
SINEMET (Other drug)			Rea	son:	
ν, σ,		0.0			
Batch:	s	Started:		Stopped:	CONTIN
CARDIZEM (Other drug)			Rea	son:	
		0.0			
Batch:	s	Started:		Stopped:	
abaratan Investigat	iono				
aboratory Investigations: Date Type Range		Date Tested Result		Details	
Additional Informatio	n:				
ort Run: 04/06/2007 04:27PN	Л Database: pt	usime02	Д	DRS004	Page 144 of 526



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 125272 Reported: 24/02/1998 Hospitalisation: Onset Date: 14/02/1998 Outcome: Unknown Reaction Details:	Seq: 1	Gender: U Weight: Age: DOB: Causality: Causality probable
Medicine Details:		
ZYPREXA (Suspected)		Reason: Depression
Tablet Batch:	5.0 Milligram Started: 14/02/1998	Daily Oral
Batcii.	Starteu. 14/02/1990	Stopped: 16/02/1998
Laboratory Investigation	s:	
Additional Information:		

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Gender: F Case Number: 125351 Seq: 1

Reported: 27/02/1998 Weight: 44.00 **Hospitalisation:** Age: 40Y

Onset Date: 05/01/1998 DOB: Causality: Causality possible

Outcome: Not yet recovered

Reaction Details:

•	todotion Botans.				
	Preferred Term	Severity	Report Description	Treatment	
	Urinary retention				

Medicine Details:

Medicine Details.				
PAROXETINE HYDROCHLORIDE (Ot	her drug)	Reason:		
Tablet	40.0 Milligram	Daily	Oral	
Batch:	Started: 01/04/1997	St	opped:	
OLANZAPINE (Suspected)		Reason: Unspe	ecified psychosis	
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started: 04/01/1998	St	opped:	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:						
Case Number: 125538	Seq: 1	Gender: M				
Reported: 05/03/1998		Weight:				

Hospitalisation: Age:
Onset Date: 31/01/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

dotion botano.						
Preferred Term	Severity	Report Description	Treatment			
Paraesthesia		Electric shock feeling				
Extrapyramidal disorder		Masked face				
Hypoaesthesia		Numbness from elbow down				

Medicine Details:

Micalcinic Details.			
EPILIM (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stoppe	d:
LITHIUM CARBONATE (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stoppe	d:
LORAZEPAM (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stoppe	d:
ZYPREXA (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stoppe	d:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 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: 125540 Seq: 1 Gender: U

Reported: 05/03/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
	Tinnitus			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Oral Batch: Started: Stopped:

Laboratory Investigations:

iaboratory invocagationor					
Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 125542 Seq: 1 Gender: M

Reported: 05/03/1998 Weight:

Hospitalisation: Age: 16Y
Onset Date: 31/12/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased			Zyprexa ceased, risperidone commenced

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 15.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 125543 Seq: 1 Gender: U

Reported: 05/03/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/01/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure	

Medicine Details:

modiomo Botano.				
ZYPREXA (Suspected)		Reason:		
Tablet	0.0	Oral		
Batch:	Started:	Stopped:		
RISPERIDONE (Suspected)		Reason:		
	0.0			
Batch:	Started:	Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Report Details:

Case Number: 125545

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 05/03/1998			weight				
ospitalisation:		Age:					
Onset Date:		DOB:					
Outcome: Unknown			Causality	: Causality possible			
eaction Details:							
Preferred Term	Severity	Report Desc	ription	Treatment			
ardive dyskinesia		Beginnings of tardive dys	kinesia				
Somnolence		Excessive drowsiness					
leadache		Head pains					
Productive cough		Rising phlegm					
Medicine Details:							
ZYPREXA (Suspected)		Reason:					
Tablet	0.0		Oral				
Batch:	Started:		Stopped:				
aboratory Investigatio		1 1					
Date Type	Range Date Test	ted Result	Deta	ails			
		I					
Additional Information:							
oort Run: 04/06/2007 04:27PM	Database: pusime02	ADRS004		Page 151 of 526			



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 125546 Seq: 1 Gender: M

Reported: 05/03/1998 **Weight:** 110.00

Hospitalisation: Age:
Onset Date: 31/12/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 125547 Seq: 1 Gender: F

Reported: 05/03/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Gained 5 kg in 23 days of treatment	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/01/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 125548 Seq: 1 Gender: U

Reported: 05/03/1998 Weight: Hospitalisation: Age:

Onset Date: 31/12/1998 **DOB:**

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Weight increased		Gained 12 kg	
Increased appetite		Inc appetite with uncontrollable sugar cravings	

Medicine Details:

Medicine Details.				
VENLAFAXINE HYDROCHLORIDE	(Other drug)	Reason:	Depression	
Tablet	75.0 Milligram	Daily	Oral	
Batch:	Started: 08/05/1997		Stopped:	CONTIN
ZYPREXA (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 12/08/1997		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Report Details:

Case Number: 125549

Reported: 05/03/1998

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight:

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

ospitalisation:				Age : 62Y	
Onset Date:		DOB:			
Outcome: Unknown				Causality: Causality possible	
eaction Details:	1	T			
Preferred Term	Severity	Rep	ort Descriptio		
Somnolence		Drowsiness on a	awakening	Zyprexa reduced from 10_mg to 5 mg on pharmacists recommendation. reactions severity improved slightly.	
izziness					
ledicine Details:					
ZYPREXA (Suspected)	10.0		son:		
Tablet Batch:	10.0 Started: 10	Milligram	Daily	Oral oped:	
aboratory Investigation	ns: Range Date Tes	ted Result		Details	
76.					
dditional Information:					



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 125552 Seq: 1 Gender: U

Reported: 05/03/1998 Weight: Hospitalisation: Age:

Onset Date: 31/12/1998 DOB:

Outcome: Unknown

Causality	:	Causality	possible
Causality	/:	Causality	possible

F	Reaction Details:			
	Preferred Term	Severity	Report Description	Treatment
	Oedema peripheral			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 125554 Seq: 1 Gender: M

Reported: 05/03/1998 **Weight:**

Hospitalisation: Age: 34Y
Onset Date: 31/01/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nail disorder		Thickening of nail	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: 01/11/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report De	etaiis:				
Case Num	ber: 125555	Seq: 1		Gene	der: F
Repor	ted: 05/03/1998			Weig	ght:
lospitalisat	ion:			A	ge:
Onset D	ate: 31/12/1998			D	OB:
Outcome: Unknown				Causa	lity: Causality possible
eaction D	etails:				
Pre	eferred Term	Severity	Repo	t Description	Treatment
Constipation					
Increased a	opetite				
Dedema					
<i>l</i> ledicine	Details:				
Medicine ZYPREXA (S			Reas	on:	
	uspected)	(Reas 0.0	on: Oral	
ZYPREXA (S	uspected) et	(Started:	0.0		
Table	uspected) et		0.0	Oral	
ZYPREXA (S Table Bato	uspected) et	Started:	0.0	Oral Stopped:	Details

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 125557 Seq: 1 Gender: M
Reported: 05/03/1998 Weight:
Hospitalisation: Age:

pitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Splenomegaly		Hypersplenism	All medication ceased
Hepatic function abnormal		Increased liver function test	
Leukopenia		Neutrophil count decreased	

Medicine Details:

VALPRO (Suspected)		Reason:	
Tablet	0.0		Oral
Batch:	Started:	Stopped:	28/02/1998
HALOPERIDOL (Suspected)		Reason:	
Tablet	0.0		Oral
Batch:	Started:	Stopped:	28/02/1998
ZYPREXA (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	28/02/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has experinced prior alcohol abuse and is hepatitis b positive the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

_	4. DE/03/4000	_	. 1		Weight:			
spitalisatio	d: 05/03/1998				=	ge:		
Spitalisation Onset Dat						ge. OB:		
	e: Unknown					ity: Causality possible		
action Det						ity: Gaadanty poolisio		
	erred Term	Se	everity	Repo	ort Description	Treatment		
nenorrhoea								
edicine De YPREXA (Sus Tablet			0.0	Reas	son: Oral			
Batch:		s	started:		Stopped:			
ARBIMAZOLE	(Suspected)			Reas				
Tablet			0.0		Oral			
Batch:		Started:		Stopped:				
aboratory Date	Investigatio	Ons: Range	Date Tested	Result		Details		
——————————————————————————————————————				_				

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

 Case Number:
 125560
 Seq: 1
 Gender: M

 Reported:
 05/03/1998
 Weight:

Hospitalisation: Age: 21Y
Onset Date: 20/02/1998
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

<u>tcaction Betails.</u>			
Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Appeared day after other reactions	
Hyperhidrosis		Cold and clamy	
Face oedema		Swollen forehead	Zyprexa ceased
Pallor		Very pale	
Dizziness			
Purpura			
Pyrexia			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: **Started**: 19/02/1998 **Stopped**: 20/02/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

Case Number: 125562

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

spitalisation:	8				Weight:	
spitalisation.		Age:				
Onset Date:					DOB:	
Outcome: Unknown					Causality:	Causality possible
action Details:					.	
Preferred Term	Se	verity		ort Descript	ion	Treatment
mnolence			Extreme somno	lence		
edicine Details:						
YPREXA (Suspected)			Rea	ason:		
Tablet		5.0	Milligram	Daily	Oral	
Batch:	St	arted:	o .		opped:	
ARBAMAZEPINE (Suspected)			Rea	ason:	••	
Tablet		200.0	Milligram	Daily	Oral	
Batch:	St	arted:		St	opped:	
aboratory Investigati	ONS:	Date Teste	ed Result		Detail	s



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 125636
 Seq: 1
 Gender: F

 Reported:
 10/03/1998
 Weight:

Hospitalisation:
Onset Date: 06/02/1998
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Disturbance liver function increased.	Ceased olanzapine
Nausea			

Medicine Details:

DI-GESIC (Other drug)		Reason:	Lumbalgia
	0.0	As r	necessary
Batch:	Started:		Stopped:
OMEPRAZOLE (Other drug)		Reason:	
	20.0 Mi	lligram Dail	у
Batch:	Started:	L TERM	Stopped:
CALCITRIOL (Other drug)		Reason:	
	0.5 Mi	crogram Dail	у
Batch:	Started:	L TERM	Stopped:
THIORIDAZINE HYDROCHLORIDE (Other drug)	Reason:	
	30.0 Mi	lligram Dail	у
Batch:	Started: 01/11/	1997	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		06/02/1998	111	
	AST = SGOT		06/02/1998	62	
	GGT = SGGT =		06/02/1998	420	
	GGT = SGGT =		27/02/1998	135	
	SAP = ALP		06/02/1998	317	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	nΛ	rt	D۵	tail	le.
1/6	μυ	ıι	$rac{1}{2}$	lai	IJ.

 Case Number:
 125636
 Seq: 1
 Gender:
 F

 Reported:
 10/03/1998
 Weight:

Hospitalisation:
Onset Date: 06/02/1998
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

Medicine Details.			
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started: 20/11/1997	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 03/12/1997	Stopped : 08/02/1998	

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 125695 Seq: 1 Gender: F

Reported: 10/03/1998 Weight:
Hospitalisation: Age: 18Y

Onset Date: 25/09/1997 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Increased appetite		Obsessive eating	Zyprexa ceased
	Weight increased		Weight gain of 2 - 3 stone	

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified psychosisTablet10.0 MilligramDailyOral

Batch: Started: 01/07/1997 **Stopped:** 25/09/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Rej	port l	Detai	ls:
-----	--------	-------	-----

Case Number: 125696 Seq: 1 Gender: F

Reported: 10/03/1998 Weight:
Hospitalisation: Age: 15Y

Onset Date: 20/09/1997 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	<u> </u>			1
	Preferred Term	Severity	Report Description	Treatment
	Face oedema		Swelling of left side of face	Zyprexa ceased
	Tongue oedema			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

Tablet 5.0 Milligram Daily Oral

Batch: Started: 08/08/1997 **Stopped:** 25/09/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 125947
 Seq: 1
 Gender:
 F

 Reported:
 19/03/1998
 Weight:

Hospitalisation: Age: 67

Onset Date: 27/11/1997 **DOB**: 08/11/1930

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Olanzapine ceased

Medicine Details:

FERRO-GRADUMET (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
HALDOL DECANOATE (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started: 18/11/1997	Stopped: 30/11/1997	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	12.5 Milligram	Daily Oral	
Batch:	Started:	Stopped: 07/12/1997	

Laboratory Investigations:

	. <u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		05/11/1997	2.8	
	Neutrophils		03/12/1997	1.4	
	White blood cells		05/11/1997	4.2	
	White blood cells		03/12/1997	2.52	

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repor spitalisat Onset D	oate: 23/03/199 me: Unknown	98	: 1				С	Gender: Weight: Age: DOB: ausality:	0.00 A2	ble
	eferred Term	S	everity		Repo	rt De	scription		Treatmen	t
ania										
edicine										
OLOFT (Inte	eraction)		150.0	Milligram	Reas	son: Daily	Depression	Oral		
Bato	:h:	5	Started:	wiiiigraiii		Daily	Stopped:	Olai		
YPREXA (In					Reas	son:	Unspecified so	hizophrenia	3	
Table	et		20.0	Milligram		Daily		Oral		
Bato	:h:	5	Started:		L TERM		Stopped:			
	'y Investigat ^{Type}	t ions: Range	Date Tes	ted R	esult			Deta	ils	
Date										

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 126468 Seq: 1 Gender: M

Reported: 07/04/1998 Weight:
Hospitalisation: Age: 28Y

Onset Date: 31/03/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction betails.			
Preferred Term	Severity	Report Description	Treatment
Weight increased		5 kg weight gain	
Dry mouth			

Medicine Details:

ZYPREXA (Suspected)

Reason:

10.0 Milligram Daily

Batch: Started: 01/03/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 126580 Reported: 07/04/19 ospitalisation:	•			_	: M : 85.00 : 65Y
Onset Date:				DOE	
Outcome: Unknow	'n		c	_	: Causality certain
eaction Details:					
Preferred Term	Severity	Repo	ort Description		Treatment
lalaise	•	Felt very unwell	·		
ain		Pain all over boo	ly		
xtrapyramidal disorder					
lallucination					
leadache					
lyperhidrosis					
Medicine Details:					
OMEPRAZOLE (Other drug)		Rea	son:		
OMEPRAZOLE (Other drug)	0.0	Rea	son:		
OMEPRAZOLE (Other drug) Batch:	0.0 Started :	Rea	son: Stopped:		
	Started:				
Batch: LASIX (Other drug)	Started:		Stopped:		
Batch: LASIX (Other drug) Batch:	Started:	Rea	Stopped: son: Stopped:		
Batch: LASIX (Other drug)	Started: 0.0 Started:	Rea	Stopped:		
Batch: LASIX (Other drug) Batch: BI-QUINATE (Other drug)	Started: 0.0 Started: 0.0	Rea	Stopped: Stopped:		
Batch: LASIX (Other drug) Batch: BI-QUINATE (Other drug) Batch:	Started: 0.0 Started:	Rea Rea	Stopped: son: Stopped:		
Batch: LASIX (Other drug) Batch: BI-QUINATE (Other drug)	Started: 0.0 Started: 0.0	Rea Rea	Stopped: Stopped: Stopped: Stopped:		
Batch: LASIX (Other drug) Batch: BI-QUINATE (Other drug) Batch:	Started: 0.0 Started: 0.0 Started:	Rea Rea	Stopped: Stopped: Stopped: Stopped:		
Batch: LASIX (Other drug) Batch: BI-QUINATE (Other drug) Batch: VALIUM (Other drug) Batch:	Started: 0.0 Started: 0.0 Started:	Rea Rea	Stopped: Stopped: Stopped: Stopped: Stopped:		
Batch: LASIX (Other drug) Batch: BI-QUINATE (Other drug) Batch: VALIUM (Other drug)	Started: 0.0 Started: 0.0 Started:	Rea Rea Rea	Stopped: Stopped: Stopped: Stopped: Stopped:		ails

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	07/04/1998 Unknown	Seq: 1			Gender: Weight: Age: DOB: Causality:	85.00 65Y
Medicine Deta	ails:					
ZYPREXA (Suspec	ted)			Reason:		
Tablet			Milligram	2 times	Oral	
Batch:		Started:			Stopped:	
Laboratory In	vestigations:					
Additional Inf Patient took just 1/2						

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 126698 Seq: 1 Gender: M

Reported: 11/05/1998 Weight:
Hospitalisation: Age: 21Y

Onset Date: 24/02/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperbilirubinaemia			
Hypertension			
Jaundice			

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified psychosisTablet10.0 MilligramDailyOral

Batch: **Started**: 19/02/1998 **Stopped**: 20/02/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin		17/02/1998	32	Bilirubin total and bilirubin direct.
	Bilirubin		24/02/1998	49	Bilirubin total and bilirubin direct.
	Bilirubin		25/02/1998	53	Bilirubin total and bilirubin direct.
	Bilirubin		26/02/1998	54	Bilirubin total and bilirubin direct.
	Bilirubin		27/02/1998	49	Bilirubin total and bilirubin direct.
	Bilirubin		02/03/1998	22	Bilirubin total and bilirubin direct.
	Bilirubin		25/02/1998	9	Bilirubin total and bilirubin direct.

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Detail	ls:
--------	--------	-----

 Case Number:
 126698
 Seq: 1
 Gender: M

 Reported:
 11/05/1998
 Weight:

Hospitalisation: Age: 21Y
Onset Date: 24/02/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

 ZYPREXA (Suspected)
 Reason:
 Unspecified psychosis

 Tablet
 10.0 Milligram
 Daily
 Oral

 Batch:
 Started: 19/02/1998
 Stopped: 20/02/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin		26/02/1998	8	Bilirubin total and bilirubin direct.
	Bilirubin		27/02/1998	10	Bilirubin total and bilirubin direct.
	Bilirubin		02/03/1998	6	Bilirubin total and bilirubin direct.

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 126758 Gender: M Seq: 1 Reported: 17/04/1998 Weight:

Hospitalisation: Age: 89

Onset Date: 14/02/1998 **DOB:** 28/12/1908

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caction betails.								
Preferred Term	Severity	Report Description	Treatment					
Thinking abnormal		Increasing cognitive deficits						
Delusion								
Hallucination								

<u>Medicine Details:</u>					
SINEMET (Other drug)					
	6.0	Dose Unspeci	fied Daily		
Batch:	Started:	L TE	ERM	Stopped:	
OLANZAPINE (Suspected)			Reason:		
	2.5	Milligram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt sufferes from advanced parkinsons disease.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 126819
 Seq: 1
 Gender: M

 Reported:
 20/04/1998
 Weight:

Hospitalisation: Age: 69

Onset Date: 22/03/1998 **DOB**: 28/06/1928

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Neural stiffness/muscle rigidity/increase in tone.	
Tachycardia		Peak 110/min.	
Hypertension		Peak 163/90.	
Blood creatine phosphokinase incr			
Coordination abnormal			
Delirium			
Dysarthria			
Neuroleptic malignant syndrome			Zyprexa ceased, intravenous fluid replacement commenced.
Opisthotonus			

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason: Unspe	ecified schizophrenia	
Tablet	1.0 Gram	Daily	Oral	
Batch:	Started:	St	opped:	CONTIN
DIAZEPAM (Other drug)		Reason: Unspe	ecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started:	St	opped:	CONTIN
LITHIUM CARBONATE (Other drug)		Reason: Unspe	ecified schizophrenia	
Tablet	1.0 Gram	Daily	Oral	
Batch:	Started:	St	opped:	CONTIN
ZYPREXA (Suspected)		Reason: Unspe	ecified schizophrenia	
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started: 20/03/1998	St	opped: 22/03/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		22/03/1999	4150	

Additional Information:

History of neuroleptic malignant syndrome on risperidone. case report published (johnson v, bruxner g. neuroleptic malignant syndrome associated with olanzapine. aust nz j psych 1998; 32: 884-6). another reaction was consciousness fluctuating.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 126819
 Seq: 1
 Gender: M

 Reported:
 20/04/1998
 Weight:

Hospitalisation: Age: 69

Onset Date: 22/03/1998 DOB: 28/06/1928

Outcome: Recovered Causality: Causality probable

Reaction Details:

caction betails:									
Preferred Term	Severity	Report Description	Treatment						
Pyrexia									
Thinking abnormal									
Urinary incontinence									

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason: Unspecified schizophrenia	а
Tablet	1.0 Gram	Daily Oral	
Batch:	Started:	Stopped:	CONTIN
DIAZEPAM (Other drug)		Reason: Unspecified schizophrenia	a
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	CONTIN
LITHIUM CARBONATE (Other drug)		Reason: Unspecified schizophrenia	а
Tablet	1.0 Gram	Daily Oral	
Batch:	Started:	Stopped:	CONTIN
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	a
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started: 20/03/1998	Stopped: 22/03/199	8

Laboratory Investigations:

Additional Information:

History of neuroleptic malignant syndrome on risperidone. case report published (johnson v, bruxner g. neuroleptic malignant syndrome associated with olanzapine. aust nz j psych 1998; 32: 884-6). another reaction was consciousness fluctuating.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

D	4 1	D - 4 -	
Repo	ort i	Jeta	IIS:

Case Number: 126921 Seq: 1 Gender: F
Reported: 24/04/1998 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

١,	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Dyskinesia		Involuntary jaw movements	
	Dyspnoea			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Zyprexa dose was decreased from 10mg to 7.5mg to 5mg and patient still experienced events

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Details:
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Case Number: 126934 Seq: 1 Gender: F

Reported: 24/04/1998 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			

Medicine Details:

ZYPREXA (Suspected) Reason:

20.0 Milligram Daily

Batch: Started: 01/12/1997 Stopped: 4M

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred when dose was 20mg. dose was reduced to 10mg but event persisted. dose was then reduced to 5mg and event abated. dose was increased back to 10mg and reaction returned. patient is now on 7.5mg the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 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:
 126936
 Seq: 1
 Gender:
 F

 Reported:
 24/04/1998
 Weight:

Hospitalisation: Age: 51

Onset Date: 13/03/1998 **DOB:** 26/12/1946

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Urticaria		Hives on legs, arms, hands, ears & head	
Pruritus		Itchy head	
Rash		Rash on legs, arms, hands, ears & head	

Medicine Details:

Medicine Details.			
MONOPRIL (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 16/02/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 126938
 Seq: 1
 Gender:
 F

 Reported:
 24/04/1998
 Weight:

Hospitalisation: Age:
Onset Date: 31/03/1998 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Rash		Facial rash	Zyprexa ceased
Photosensitivity reaction		Facial rash appeared to be photosensitive	
Face oedema		Swollen lips, eyelids, head and face	

Medicine Details:

CHLORPROMAZINE HYDROCHL	Reason:			
Tablet	700.0 Milligra	m Daily		Oral
Batch:	Started:		Stopped:	
ZYPREXA (Suspected)		Reason:		
Tablet	15.0 Milligra	m Daily		Oral
Batch:	Started: 01/02/1998	1	Stopped:	13/03/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 126940
 Seq: 1
 Gender: M

 Reported:
 24/04/1998
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mania			

Medicine Details:

Medicine Details.			
MELLERIL (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	0.0	Daily Oral	
Batch:	Started: 01/09/1997	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 126941 Seq: 1 Gender: F

Reported: 24/04/1998 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema		Swelling both ankles	

Medicine Details:

OLANZAPINE (Suspected) Reason:

Tablet 25.0 Milligram Daily Oral

Batch: Started: 01/02/1998 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 126942
 Seq: 1
 Gender: M

 Reported:
 24/04/1998
 Weight:

Hospitalisation: Hospitalisation prolonged
Onset Date: 31/03/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Dystonia		Movement disorder/ shrugging of shoulders	
Speech disorder		Mute	
Schizophreniform disorder		Negative symptoms	
Nightmare		Nightmares/ abnormal dreams	
Mania			
Priapism			

Medicine Details:

Medicine Details.			
ZOLOFT (Other drug)		Reason: Depression	
Tablet	150.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily Oral	
	· ·	- ,	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 126944	Seq: 1		Gende	r: M	
Reported: 24/04/1998	}		Weigh	t:	
ospitalisation:			Age		
Onset Date:			DO		
Outcome: Unknown			Causalit	y: Causality possible	
eaction Details:					
Preferred Term	Severity	Report Desc	cription	Treatment	
Electrocardiogram abnormal					
Hypotension					
Medicine Details: ZYPREXA (Suspected)		Reason:			
Tablet	0.0		Oral		
Batch:	Started:		Stopped:		
_aboratory Investigati					
Date Type	Range Date Tested	Result	De	tails	
Additional Information	ı:	•			
eport Run: 04/06/2007 04:27PM	Database: pusime02	ADRS004		Page 184 of 526	

Rep



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 126989 Seq: 1 Gender: F

 Reported: 29/04/1998
 Weight: 65.00

 Hospitalisation:
 Age: 42Y

Onset Date: 13/03/1998

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Zyprexa ceased

Medicine Details:

Medicine Details.				
FLUPENTHIXOL DECANOATE (Other	drug)	Reason: Unspe	cified schizophrenia	
Injection	40.0 Milligram	Weekly	Intramuscular	
Batch:	Started: 01/08/1997	Ste	opped:	
DIAMICRON (Other drug)		Reason: Diabet	es mellitus	
Tablet	240.0 Milligram	Daily	Oral	
Batch:	Started: 01/12/1997	Ste	opped:	
METFORMIN HYDROCHLORIDE (Oth	er drug)	Reason: Diabet	es mellitus	
Tablet	3.0 Gram	Daily	Oral	
Batch:	Started: 01/08/1997	Ste	opped: 20/04/1998	
IMDUR (Other drug)		Reason:		
Tablet	30.0 Milligram	Daily	Oral	
Batch:	Started: 28/03/1998	Sto	opped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	<51 U/L	13/03/1998	143	
	ALT = SGPT	<51 U/L	09/04/1998	84	
	AST = SGOT	<41 U/L	13/03/1998	59	
	AST = SGOT	<41 U/L	09/04/1998	41	
	Bilirubin	<21 UMOL/L	13/03/1998	13	
	Bilirubin	<21 UMOL/L	09/04/1998	15	
	GGT = SGGT =	<33 U/L	13/03/1998	243	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 126989 Seq: 1 Gender: F

Reported: 29/04/1998 Weight: 65.00
Hospitalisation: Age: 42Y

Onset Date: 13/03/1998

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.				
ASPIRIN (Other drug)		Reason:		
Oral application	150.0 Milligram	Daily	Oral	
Batch:	Started: 28/03/1998	Stoppe	ed:	
ZYPREXA (Suspected)		Reason: Unspecifie	d schizophrenia	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 18/11/1997	Stoppe	ed: 23/03/1998	

Laboratory Investigations:

 	. <u>,</u>	• • .			
Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =	<33 U/L	09/04/1998	116	
	SAP = ALP	<121 U/L	13/03/1998	215	
	SAP = ALP	<121 U/L	09/04/1998	126	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 127208 Seq: 1 Gender: M

Reported: 06/05/1998 Weight: 123.00 Hospitalisation: Age: 31Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Genital ulceration		Penile meatus	
Hypertonia		Spasm in left leg and arm.	
Rash			

Medicine Details:

OLANZAPINE (Suspected)Reason:Unspecified schizophreniaTablet20.0 MilligramDailyOralBatch:Started: 24/04/1998Stopped: 25/04/1998

RISPERIDONE (Suspected)

Reason: Unspecified schizophrenia

2.0 Milligram Daily

Batch: Started: 01/01/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report D	etaiis:				
Case Num	ber: 127237	Seq: 1		G	Gender: M
Repo	rted: 06/05/1998			W	Veight:
ospitalisa	tion:				Age:
Onset I	Date:				DOB:
Outco	me: Unknown		Causality: Causality possib		
eaction E					
Pr	eferred Term	Severity	Report	Description	Treatment
remor			Arm tremor		
Convulsion			Night seizures		
			Posses		
ZYPREXA (S	Suspected)	0	Reason		neal .
ZYPREXA (S	Suspected) et	0. Started:		C)ral
Medicine ZYPREXA (S Tabl Bat	Suspected) et	0. Started:			Oral
ZYPREXA (\$ Table Bate	Suspected) et ch:	Started:		C	Oral
ZYPREXA (\$ Table Bate	Suspected) et	Started:	0	C	Details

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 127240 Seq: 1 Gender: M

Reported: 06/05/1998 Weight: 0.00 Hospitalisation: Age: 23Y

Onset Date: 24/03/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Breast mass		Pea sized lump under left nipple which was enlarged	

Medicine Details:

ZYPREXA (Suspected) Reason:

20.0 Milligram Daily Oral

Batch: Started: 01/12/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 127241
 Seq: 1
 Gender: M

 Reported:
 06/05/1998
 Weight:

Hospitalisation:
Onset Date: 31/12/1997
Age: 25Y

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		3-4 times a day	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/01/1997 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 127242 Seq: 1 Gender: F

Reported: 06/05/1998 Weight:
Hospitalisation: Age: 16Y

Onset Date: 31/12/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Treated with anticholinergic medications

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 127244
 Seq: 1
 Gender: M

 Reported:
 06/05/1998
 Weight:

Hospitalisation: Age: 45Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

touction Dotailor			
Preferred Term	Severity	Report Description	Treatment
Weight increased		6kg weight gain	
Testicular disorder		Three fold increase in size of testicles.	Zyprexa ceased
Oedema			

Medicine Details:

neulcine Delans.			
MOCLOBEMIDE (Other drug)		Reason:	
	600.0 Milligram	Daily	
Batch:	Started:	Stopped:	
CLONAZEPAM (Other drug)		Reason: Anxiety neurosis	
Tablet	15.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 01/02/1998	Stopped: 28/03/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: 06/05/199 lospitalisation: Onset Date: Outcome: Unknown	18		Gender:	•
Onset Date:			Weight:	
			Age:	70Y
Outcome: Unknown			DOB:	
			Causality:	Causality possible
action Details:				
Preferred Term	Severity	Report De	scription	Treatment
lood alkaline phosphatase		Increase in alp levels.		
lanine aminotransferase in	ncrease	Increase in alt levels		
lepatic function abnormal		Increase in liver enzyn	nes	
Madiaina Dataila				
Medicine Details: CARBAMAZEPINE (Suspected))	Reason:		
	0.0			
Batch:	Started:		Stopped:	
LITHIUM CARBONATE (Suspec	cted)	Reason:		
	0.0			
Batch:	Started:	_	Stopped:	
CLONAZEPAM (Suspected)		Reason:		
D 4.1	0.0			
Batch:	Started:	Danasa	Stopped:	
ZYPREXA (Suspected)	7.5	Reason:	Manic-depression psycho,	manic
Tablet		Milligram Daily	Oral	
Batch:	Started:		Stopped:	
aboratory Investigat	ions:			
_ , _	Range Date Tes		Detai	s
Date Type GGT = SGGT =		699.		

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Case Number: 127249

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 06/05	5/1998			Weigh	t:		
lospitalisation:			Age : 13Y				
Onset Date:				DO	В:		
Outcome: Unkn	own			Causalit	y: Causality possible		
eaction Details:	<u>, </u>						
Preferred Ter	m S	everity	Report Descri	ption	Treatment		
Bradycardia			7 beats per minutes				
Syncope		В	lacked out				
Tachycardia							
Medicine Details:							
ZYPREXA (Suspected)			Reason:				
		0.0					
Batch:	(Started:		Stopped:			
Laboratory Invest	igations:						
Date Type	Range	Date Tested	Result	De	tails		
Additional Informa	-4i a.u.						
Additional informa	ation:						
eport Run: 04/06/2007 04	:27PM Database: p	ousime02	ADRS004		Page 194 of 526		



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisati Onset Da	ed: 06/05/199 on: ate: ne: Unknown		1		Wei , E	nder: F ght: Age: DOB: ality: Causality possible
	ferred Term	Se	everity	Repo	ort Description	Treatment
Oedema				•	•	
Medicine I	Details:					
ZYPREXA (Su				Rea	son:	
Table			0.0		Oral	
Batch			tarted:		Stopped:	
FLUVOXAMIN	E MALEATE (Su	spected)		Rea	son:	
Datal		0	0.0		Otamua di	
Batch	l :	5	tarted:		Stopped:	
Laborator Date	/ Investigat Type	:ions: Range	Date Tested	Result		Details
				<u> </u>		
Additional	Informatio	n:				

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 127251
 Seq: 1
 Gender:
 F

 Reported:
 06/05/1998
 Weight:

Hospitalisation: Hospitalisation prolonged **Onset Date**: 02/02/1998 **ODB**: 02/09/1975

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperbilirubinaemia		Increased bilirubin levels	
Hepatic function abnormal		Increased liver function tests	Medication ceased
Cholecystitis			
Jaundice			
Nausea			
Vomiting			

Medicine Details:

	Reason: Unspecified ps	sychosis
5.0 Milligram	Daily	Oral
Started: 29/01/1998	Stopped:	01/02/1998
	Reason:	
150.0 Milligram	Daily	Oral
Started: 21/01/1998	Stopped:	
•	5.0 Milligram Started: 29/01/1998 150.0 Milligram	Started: 29/01/1998 Stopped: Reason: 150.0 Milligram Daily

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		02/02/1998	783	
	ALT = SGPT		04/02/1998	350	
	ALT = SGPT		10/02/1998	160	
	AST = SGOT		02/02/1998	289	
	AST = SGOT		04/02/1998	131	
	AST = SGOT		10/02/1998	32	
	Bilirubin		02/02/1998	99	

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 127251
 Seq: 1
 Gender:
 F

 Reported:
 06/05/1998
 Weight:

Hospitalisation: Hospitalisation prolonged Age: 22

Onset Date: 02/02/1998 **DOB**: 02/09/1975

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

MEGICINE DELANS.			
ZYPREXA (Suspected)		Reason: Unspecified pa	sychosis
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 29/01/1998	Stopped:	01/02/1998
SODIUM VALPROATE (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 21/01/1998	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin		04/02/1998	30	
	Bilirubin		10/02/1998	17	
	GGT = SGGT =		02/02/1998	246	
	GGT = SGGT =		04/02/1998	242	
	GGT = SGGT =		10/02/1998	149	
	SAP = ALP		02/02/1998	417	
	SAP = ALP		10/02/1998	205	

Additional Information:

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Case Number: 127263

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 07/05/199	8					Weig	ht:	
ospitalisation:						Ą	ge:	
Onset Date:		DOB:						
Outcome: Recovered	t					Causali	ty: Causality pos	sible
eaction Details:							1	
Preferred Term	Sev	erity/		Report	Description	n	Treatme	nt
Neuroleptic malignant syndr	ome						Zyprexa and halope ceased	eridol
Medicine Details:								
ZYPREXA (Suspected)				Reason	1:			
Tablet		10.0	Milligram	Da	aily	Oral		
Batch:	Sta	arted:			Sto	pped:		
HALOPERIDOL (Suspected)				Reason	1:			
		20.0	Milligram	Da	aily			
Batch:	Sta	arted:			Sto	pped:		
Laboratory Investigati	ions:							
Date Type		Date Tes	ted Re	esult		D	etails	
Additional Information	ո։							
eport Run: 04/06/2007 04:28PM	Database: pus	sime02		ADR	S004		Page 198	of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 127343 Seq: 1 Gender: F

 Reported:
 12/05/1998
 Weight:
 65.00

 Hospitalisation:
 Age:
 19Y

 Onset Date:
 07/05/1998
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

toaction Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Weight increased		Marked weight gain over 3 month period-13kg	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 26/02/1998 Stopped: 07/05/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

?sequelae - self harming due to poor self esteem and alteration of self image.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 127480
 Seq: 1
 Gender: M

 Reported:
 18/05/1998
 Weight: 89.00

Hospitalisation: Age: 29Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Olanzapine reduced to 5mg on 01/05/98.

Medicine Details:

OLANZAPINE (Suspected)

Reason: Unspecified neurosis

10.0 Milligram Daily

Batch: Started: 01/05/1997 Stopped: CONTIN

ALPRICA MACO

ALPRAZOLAM (Suspected) Reason: Anxiety neurosis

1.0 Milligram Daily

Batch: Started: 01/01/1995 Stopped:

PAROXETINE HYDROCHLORIDE (Suspected) Reason: Anxiety neurosis

20.0 Milligram Daily

Batch: Started: 01/10/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 1	27501	Seq:	1				Gender	: M	
Reported: 1		•					Weight		
ospitalisation:							Age	:	
Onset Date:							DOB	3:	
Outcome: U	nknown					C	ausality	: Causality poss	ible
eaction Details									
Preferred	Term	Se	everity		Report D	escription		Treatmer	nt
leurosis									
Medicine Detai									
ZYPREXA (Suspecte	d)		0.0		Reason:	Unspecified s		ia	
Tablet		04	0.0			O4	Oral		
Batch:		St	tarted:			Stopped:			
ZOLOFT (Suspected))		400 0 M	:::::::::::::::::::::::::::::::::::::::	Reason:	Depression	01		
Tablet		01	100.0 Mi	lligram	Dail		Oral		
Batch:			tarted:			Stopped:			
aboratory Inve									
Date Ty	/pe	Range	Date Tested	Resu	ılt		Deta	ails	
Additional Info	rmation	•							
Additional inio	rmatioi	1.							
oort Run: 04/06/2007	04:28PM	Database: pu	ısime02		ADRS	004		Page 201	of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 127585 Seq: 1 Gender: F

Reported: 15/05/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1998 DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash			Zyprexa ceased

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: Stopped: 31/01/1998

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Symptoms improved when zyprexa was discontinued and returned when drug was resumed. - the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:			
Case Number: 127586	Seq: 1	Gende	ar: M
Reported: 15/05/1998		Weigh	
Hospitalisation:)	_	e: 14
Onset Date:		_	B: 09/05/1984
Outcome: Unknown			ty: Causality possible
Reaction Details:		Gudani	y. Cadodity possible
Preferred Term	Severity	Report Description	Treatment
Disturbance in attention	i i	Inability to concentrate (thinking abnormal)	
		, ,	
Weight increased		Weight gain-4kg	
Increased appetite			
Somnolence			
Medicine Details:		December 11 and 15 and	_
ZYPREXA (Suspected) Tablet	F 0	Reason: Unspecified psychosis	
Batch:	Started: 12/0	Milligram Daily Oral 02/1998 Stopped: 20/02/1	000
I aboratory Investigati	one:		
Laboratory Investigation		ed Result Do	etails
	ONS: Range Date Teste	ed Result Do	etails

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	etails:				
Repor Hospitalisat Onset D	ber: 127660 rted: 22/05/1998 rion: Treated in outpoate: rme: Not yet recove	Seq: 1 patient department on red	ıly.	Gender: Weight: Age: DOB: Causality:	17Y
	eferred Term	Severity	Report Descri	ption	Treatment
Muscle twito	-			Co	ontinue treatment; more quent reviews.
Medicine OLANZAPIN	Details: E (Suspected)	10.0 Milli		specified schizophrenia	1
Bato	ch:	Started: 27/03/19		Stopped:	CONTIN
Laborato	ry Investigations	s:			
Laborato Date		S: Range Date Tested	Result	Deta	ils

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 127682 Seq: 1 Gender: M

Reported: 19/05/1998 Weight:

Hospitalisation: Age: 15Y
Onset Date: 20/03/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Visible muscle twitching	Reduce dose to 7.5mg

Medicine Details:

EPILIM (Other drug) Reason: Convulsions

1.0 Gram Daily

Batch: Started: L TERM Stopped:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: Started: 01/03/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 127803 Seq: 1 Gender: F

Reported: 26/05/1998 Weight: 41.00 Hospitalisation: Age: 26Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Face oedema		Swelling of face	
Oedema peripheral		Swelling of fingers and toes	
Tongue oedema		Swelling of tongue	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 01/01/1998 **Stopped:** 28/02/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Prior allergies to keflex, augmentin, caffeine, msg. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 127884
 Seq: 1
 Gender: M

 Reported:
 28/05/1998
 Weight:

Hospitalisation: Admitted to hospital Age: 64

Onset Date: 14/02/1998

Outcome: Recovered

DOB: 11/03/1933

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Freezing episodes	
Myalgia		Pain and aches	
Hallucination		Visual hallucinations	
Extrapyramidal disorder			Zyprexa ceased, rechallenged and ceased again.
Headache			
Hyperhidrosis			
Hypokinesia			
Insomnia			

Medicine Details:

3.0 Started:		Reason: Daily	Paralysis agitans
	Milligram	Daily	
Started:			
			Stopped:
drug)		Reason:	Paralysis agitans
10.0	Milligram	Daily	
Started:			Stopped:
		Reason:	Paralysis agitans
6.0	Dose Unspecif	fied Daily	
Started:			Stopped:
		Reason:	
300.0	Milligram	Daily	
Started:			Stopped:
	10.0 Started: 6.0 Started: 300.0	drug) 10.0 Milligram Started: 6.0 Dose Unspeci Started: 300.0 Milligram	drug) Reason: 10.0 Milligram Daily Started: Reason: 6.0 Dose Unspecified Daily Started: Reason: 300.0 Milligram Daily

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The events abated after stopping olanzapine and reappeared when olanzapine was given again.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 127884
 Seq: 1
 Gender: M

 Reported:
 28/05/1998
 Weight:

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

Onset Date: 14/02/1998 DOB: 11/03/1933

Outcome: Recovered Causality: Causality certain

Reaction Details:

Medicine Details:

OMEPRAZOLE (Other drug)	Reason:			
	20.0 Milligram	Daily		
Batch:	Started:	Stopped:		
CARDIZEM (Other drug)		Reason:		
	180.0 Milligram	Daily		
Batch:	Started:	Stopped:		
LASIX (Other drug)		Reason:		
	20.0 Milligram	Daily		
Batch:	Started:	Stopped:		
ZYPREXA (Suspected)		Reason: Depression		
Tablet	5.0 Milligram	Daily Oral		
Batch:	Started: 14/02/1998	Stopped: 16/02/1998		

Laboratory Investigations:

Additional Information:

The events abated after stopping olanzapine and reappeared when olanzapine was given again.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 128003 Seq: 1 Gender: F

Reported: 01/06/1998 Weight:
Hospitalisation: Age: 54Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Generalised peripheral oedema	

Medicine Details:

Medicine Details.			
LUVOX (Other drug)		Reason: Depression	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 01/11/1997	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schi	izophrenia
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 03/02/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 128004
 Seq: 1
 Gender: M

 Reported:
 01/06/1998
 Weight:

Hospitalisation: Age: 30Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			

Medicine Details:

CHLORPROMAZINE HYDROCHLOR	RIDE (Other drug)		Reason:		
Tablet	200.0	Milligram	As necessar	y Oral	
Batch:	Started:		St	opped:	
DIAZEPAM (Other drug)			Reason:		
Tablet	10.0	Milligram	Daily	Oral	
Batch:	Started:		St	opped:	
OLANZAPINE (Suspected)			Reason:		
Tablet	30.0	Milligram	Daily	Oral	
Batch:	Started: 01/0	03/1998	St	opped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Physician prescribed overdose the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: 01/06 Hospitalisation: Onset Date: 23/04 Outcome: Not y eaction Details:	4/1998	: 1			We	nder: M ight: Age: DOB: ality: Causality possible
Preferred Te	rm S	everity	Re	eport De	scription	Treatment
Mania Hypertension			Hypomanic Rise in blood			Quinapril increased and amlodipine given.
Agitation						
Medicine Details: CHLORPROMAZINE HYD Tablet	OROCHLORIDE (Othe	er drug)	F	Reason: Daily	Ora	
Batch:	\$	Started:		Dany	Stopped:	•
AMLODIPINE (Other drug	g)		R	Reason:	Essential benign hy	pertension
Tablet		5.0	Milligram	Daily	Ora	ıl
Batch:		Started:			Stopped:	
QUINAPRIL HYDROCHLO	ORIDE (Other drug)	45.0		Reason:	Essential benign hy	
Tablet	4		Milligram	Daily	Ora	ll .
Datah.	•	Started:			Stopped:	
Batch:				reason.		
Batch: ZYPREXA (Suspected) Tablet		10.0		Reason: Daily	Ora	ıl
ZYPREXA (Suspected)		10.0 Started: 23/0	Milligram	Daily		I CONTIN
ZYPREXA (Suspected) Tablet Batch:			Milligram		Ora Stopped:	
ZYPREXA (Suspected) Tablet			Milligram 04/1998			

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 128007 Seq: 1 Gender: M

Reported: 01/06/1998 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic steatosis			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Daily Oral

Batch: Started: 01/12/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient consumes approx two beers per day. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: 01/06/1998 pitalisation: Onset Date: Outcome: Recovered	Seq: 1		We	ender: F eight: Age: 49 DOB: 28/10/1948 sality: Causality probable
nction Details: Preferred Term	Severity	Report D	escription	Treatment
zziness		· '	,	Melleril ceased
edicine Details: ELLERIL (Other drug)		Reason:	Depression	
Tablet	100.0 N			al
Batch:	Started:		Stopped: 27	/03/1998
PREXA (Suspected)		Reason:	Manic depressive	psycho, depre
Tablet	10.0 N	Milligram Dail	y Or	al
Batch:	Started: 06/03	3/1998	Stopped:	CONTIN
aboratory Investigation	ıs:		Stopped:	
Date Type	Range Date Tester	d Result		Details
	<u> </u>			

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 128011 Seq: 1 Gender: M

Reported: 01/06/1998 Weight:
Hospitalisation: Age: 30

Onset Date: DOB: 10/10/1967

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Elevated liver function tests	

Medicine Details:

Medicine Details.			
ZACTIN (Other drug)		Reason: Depression	
Tablet	40.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1998	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started: 04/03/1998	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		06/03/1998	91	
	ALT = SGPT		27/03/1998	245	
	ALT = SGPT		03/04/1998	177	
	AST = SGOT		06/03/1998	39	
	AST = SGOT		27/03/1998	103	
	AST = SGOT		03/04/1998	80	

Additional Information:

Patient has history of illicit drug use the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 128329
 Seq: 1
 Gender:
 F

 Reported:
 12/06/1998
 Weight:

Hospitalisation: Age: 56

Onset Date: 15/05/1998 **DOB**: 10/06/1941

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Rash	Required Specialist Consultation	Allergic wildly spread papular rash - mild	Ceased trimethoprim

Medicine Details:

TRIMETHOPRIM (Suspected)		Reason:	Othr diseases	of urinary tract	
Tablet	300.0 Milligram	Daily		Oral	
Batch:	Started: 05/05/1998		Stopped:	16/05/1998	
OLANZAPINE (Suspected)		Reason:			
	30.0 Milligram	Daily			
Batch:	Started: 01/05/1998		Stopped:		CONTIN
CLONAZEPAM (Suspected)		Reason:			
	1.0 Milligram	Daily			
Batch:	Started: 03/05/1998		Stopped:		CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Previous history of skin reactions to many antibiotics. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Case Number: 128358

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 15/06/1998		weight:				
lospitalisation:		Age: 51Y				
Onset Date: 03/06/1998				OB:		
Outcome: Unknown				ity: Causality possible		
eaction Details:				ity: Gaddanty possible		
Preferred Term	Severity	Report D	Description	Treatment		
Rash	- Coronny	Rash mostly on arms				
taon .		trunk.	o arra rogo, rima orr			
Pruritus				Periactin 4mg tds, aurorix and zyprexa ceased.		
Medicine Details: ZYPREXA (Suspected)		Reason:				
(Guopoolou)	0.0					
Batch:	Started:		Stopped:			
AURORIX (Suspected)		Reason:				
, ,	0.0					
Batch:	Started:		Stopped:			
aboratory Investigation		atad Danit		N-4-11-		
Date Type	Range Date Te	sted Result	L	Details		
Additional Information						
	-					
port Run: 04/06/2007 04:28PM	Database: pusime02	ADRS	5004	Page 216 of 526		



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 128426 Seq: 1 Gender: M

Reported: 17/06/1998 Weight:

Hospitalisation: Age: 20Y
Onset Date: 12/05/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary retention			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: 10/05/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred when dose of zyprexa was increased from 10mg -->15mg--> than to 20mg.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 128429 Seq: 1 Gender: M

Reported: 17/06/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Elevated liver function tests	
Gynaecomastia			
Leukocytosis			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Daily Oral

Batch: Started: 01/01/1997 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Rep	ort	Deta	ils:
-----	-----	------	------

Case Number: 128430 Seq: 1 Gender: M
Reported: 17/06/1998 Weight:
Hospitalisation: Age: 32Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Dyspnoea Oedema peripheral			Dyspnoea treated with salbutamol

Medicine Details:

Medicine Details.			
TEMAZEPAM (Other drug)		Reason:	
Tablet	0.0	Daily Or	al
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily Or	al
Batch:	Started: 01/04/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has history of asthma. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 128432
 Seq: 1
 Gender: M

 Reported:
 17/06/1998
 Weight:

Hospitalisation: Age:

Onset Date: 31/12/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral			Zyprexa dose reduced to 7.5mg/d.

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was initiated onto 5mg/d of zyprexa. the dose was increased to 20mg/d and reaction developed. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 128434 Seq: 1 Gender: F
Reported: 17/06/1998 Weight:
Hospitalisation: Age:

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		, , , , , , , , , , , , , , , , , , , ,	Patients medication was increased to 15mg/d with unknown result.
Agitation			
Anxiety			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/01/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

D 1 D	. 1 - 11 -								
Report Details:									
Case Number: 128515 Seq: 1						Gend	der: M		
Reported: 18/06/1998					Weight:				
Hospitalisat			hospital			_	ge:		
Onset D			•				OB:		
	me: Dea	ath mavh	ne drug				lity: Causality possible		
		z,	o alag				inty: Guadanty podencie		
Reaction Details: Preferred Term			Sé	everity	Ren	ort Description	Treatment		
Cardiac arre		CIIII	- 00	eventy	Кер	ort Description	Treatment		
Confusional									
Ventricular f									
Medicine ZYPREXA (S		<u>:</u>			Rea	son:			
	,			0.0					
Bato	ch:		S	Started:		Stopped:			
						оторрош.			
Laborato	ry Inves	tigatio	ns:						
Date	Турє		Range	Date Tested	Result		Details		
A 1 1141		4.							
Additiona			o takina sa	o unknesse					
Any other me	euications	pauent wa	is taking are	e unknown					

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 128608 Seq: 1 Gender: M

Reported: 23/06/1998 Weight: 70.00
Hospitalisation: Age: 22Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	todotion botano:			1
	Preferred Term	Severity	Report Description	Treatment
	Gynaecomastia		Unilateral gynaecomastia	
	Galactorrhoea			

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/02/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 128612 Seq: 1 Gender: M

Reported: 23/06/1998 **Weight:**

Hospitalisation: Age: 46Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis			Excessive sweating	

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Tablet 10.0 Milligram Daily Oral

Batch: Started: 10/06/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt had olanzapine in the past and had similiar problem (excessive sweating).

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 128632 Seq: 1 Gender: F

 Reported: 24/06/1998
 Weight: 51.00

 Hospitalisation:
 Age: 76Y

 Onset Date: 22/05/1998
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Droforrod Torm Soverity		Treatment
Rash			Prednisone

Medicine Details:

COGENTIN (Other drug)

2.0 Milligram Daily

Batch: Started: L TERM Stopped: 05/06/1998

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

7.5 Milligram Daily

Batch: Started: 06/05/1998 Stopped: 05/06/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 128712 Seq: 1 Gender: M

Reported: 26/06/1998 Weight: 85.00
Hospitalisation: Age: 38Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

caction betails:								
Preferred Term	Severity	Report Description	Treatment					
Anxiety								
Tremor								
Vomiting								

Medicine Details:

MEGICINE Details.						
LITHIUM CARBONATE (Other drug)	Re	eason:	Schizophrenia			
Tablet	1.0 Dose Unspecifie	d Daily		Oral		
Batch:	Started: 01/01/1991		Stopped:			
ZYPREXA (Suspected)	Ro	eason:	Schizophrenia			
Tablet	10.0 Milligram	Daily		Oral		
Batch:	Started: 01/04/1998		Stopped:		CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced sudden onset of symptoms after 2 weeks on zyprexa, symptoms lasted about 2 days then resolved. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 128765 Seq: 1 Gender: F
Reported: 29/06/1998 Weight:

Hospitalisation: Admitted to hospital Age:
Onset Date:
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

'	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Blood creatine phosphokinase incr			
	Neuroleptic malignant syndrome			

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 01/05/1998	Stopped:	28/06/1998 1M
LUVOX (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 128775 Seq: 1 Gender: M

Reported: 29/06/1998 Weight:
Hospitalisation: Age: 22Y

Onset Date: 31/12/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Hypertonia		Muscle spasm	
Paraesthesia		Tingling in feet and legs.	
Muscle twitching			

Medicine Details:

Mcdicilic Details.					
ZYPREXA (Suspected)			Reason:		
Tablet	10.0	Milligram	Daily	Oral	
Batch:	Started:		St	opped:	CONTIN
CLOZARIL (Suspected)			Reason:		
Tablet	200.0	Milligram	Daily	Oral	
Batch:	Started:		St	opped:	

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient initially received zyprexa 5mg/d but was increased to 10mg/d. the patient was tapering off clozaril 425mg/d. patient commenced on zyprexa 5mg/d and over a four week period clozaril was decreased to 200mg/d, at this stage zyprexa was increased to 10mg/d. following the increase dose of zyprexa, the patient experienced symptoms. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 128780
 Seq: 1
 Gender: M

 Reported:
 29/06/1998
 Weight:

Hospitalisation: Age: 35

Onset Date: 24/02/1998 **DOB**: 19/07/1962

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

•	<u> </u>			1
	Preferred Term	Severity	Report Description	Treatment
	Hallucination		Auditory hallucination	
	Suicide attempt			

Medicine Details:

BENZTROPINE MESYLATE (Other drug)	Rea	son:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1991	Stopped:	24/02/1998
ALPHA-TOCOPHEROL (Other drug)	Rea	son: Disturbance of	coordination
Oral application	500.0 International Unit	Alternate days	Oral
Batch:	Started: 01/04/1995	Stopped:	22/02/1998
MODECATE (Suspected)	Rea	son: Schizophrenia	
Injection	18.7 Milligram	Fortnightly	Intramuscular
Batch:	Started: 01/01/1991	Stopped:	24/02/1998
ZYPREXA (Suspected)	Rea	son: Schizophrenia	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 10/02/1998	Stopped:	24/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient's dose of modecate was reduced and patient was improving. on 10/2/98 patient agreed to try zyprexa in a cross taper with the modecate, which at this stage was given 18.75mg every fortnight. after 13 days 24/2/98 patient committed suicide. doctor feels event could possibly be related to zyprexa. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 128785 Seq: 1 Gender: F

 Reported:
 29/06/1998
 Weight:

 Hospitalisation:
 Age:
 28Y

 Onset Date:
 22/05/1998
 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	<u> </u>			1
	Preferred Term	Severity	Report Description	Treatment
	Leukopenia		Decreased white blood cell count.	
	Neutropenia			

Medicine Details:

Medicine Details.			
CARBAMAZEPINE (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	30.0 Milligram	Daily Oral	
Batch:	Started: 16/05/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		04/05/1998	1.5	
	Neutrophils		09/05/1998	.8	
	Neutrophils		11/05/1998	2.3	
	Neutrophils		22/05/1998	1.6	
	Neutrophils		15/05/1998	2.5	
	White blood cells		04/05/1998	4.4	
	White blood cells		09/05/1998	4.1	

Additional Information:

Patient was started on zyprexa on 16/5/98 at 10mg/d this dose was increased to 20mg/d and on the 21/5/98 the dose was increased to 30mg daily.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 128785
 Seq: 1
 Gender:
 F

 Reported:
 29/06/1998
 Weight:

Hospitalisation:
Onset Date: 22/05/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.			
CARBAMAZEPINE (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	30.0 Milligram	Daily Oral	
Batch:	Started: 16/05/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells		11/05/1998	5.1	
	White blood cells		15/05/1998	5.3	
	White blood cells		22/05/1998	3.7	

Additional Information:

Patient was started on zyprexa on 16/5/98 at 10mg/d this dose was increased to 20mg/d and on the 21/5/98 the dose was increased to 30mg daily.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number Reported Iospitalisation	l: 29/06/199	Seq 8	: 1			Gende Weigh Ad	
Onset Date						DC	
Outcome	: Not yet re	covered					ty: Causality possible
eaction Deta	ails:						
	red Term	S	everity	Rep	ort Descri	ption	Treatment
Fatigue Orthostatic hyp	otension						
Medicine De		cted)	0.0	Rea	son:		
Batch:		9	0.0 Started:			Stopped:	
LARGACTIL (Su	spected)		Juli tou.	Rea	son:	оторрош.	
(,		0.0				
Batch:		5	Started:			Stopped:	
ZYPREXA (Susp	ected)			Rea	son:		
Tablet			5.0 Millio	gram	Daily	Oral	
Batch:		5	Started:			Stopped:	CONTIN
Laboratory	nvestigat	ions: Range	Date Tested	Result		Di	etails

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Within five days after beginning zyprexa patient experienced symptoms medications were continued and patient is still experiencing symptoms. patient is also on an antihypertensive (unspecified) drug.



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 128819 Seq: 1 Gender: F Reported: 01/07/1998 Weight: Age: 33Y Onset Date: 27/06/1998 DOB: OB: Causality: Causality: <td< th=""><th></th><th></th><th></th><th></th><th></th><th></th><th>ls:</th><th>Report Detail</th></td<>							ls:	Report Detail
Onset Date: 27/06/1998 Outcome: Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Report Description Tile Dystonia Severe Reson: Schizophrenia Reason: Schizophrenia Reaso		/eight:	Weig		: 1	-	128819 : 01/07/1998	Case Number: Reported:
Outcome: Recovered eaction Details: Preferred Term Severity Report Description Ti Dystonia Severe Benztropine Opisthotonus Medicine Details: OLANZAPINE (Suspected) Reason: Schizophrenia Tablet 10.0 Milligram Daily Oral Batch: Started: 06/06/1998 Stopped:		=				28		-
Preferred Term Severity Report Description Ti Dystonia Severe Benztropine Copisthotonus Medicine Details: OLANZAPINE (Suspected) Reason: Schizophrenia Tablet 10.0 Milligram Daily Oral Batch: Started: 06/06/1998 Stopped:	ity nossible							
Preferred Term Severity Report Description Ti Dystonia Severe Benztropine Opisthotonus Medicine Details: OLANZAPINE (Suspected) Reason: Schizophrenia Tablet 10.0 Milligram Daily Oral Batch: Started: 06/06/1998 Stopped:	ity poddibio	July: Guadanty poods	Juan			, u		
Dystonia Severe Benztropine 2mg iv. Medicine Details: OLANZAPINE (Suspected) Reason: Schizophrenia Tablet 10.0 Milligram Daily Oral Batch: Started: 06/06/1998 Stopped:	 reatment	Treatment	ort Description	Repo	everity	Se		
Medicine Details: OLANZAPINE (Suspected) Tablet 10.0 Milligram Batch: Started: 06/06/1998 Stopped: Laboratory Investigations:	2mg orally, then	Benztropine 2mg oral 2mg iv.	·	·				ystonia
Tablet 10.0 Milligram Daily Oral Batch: Started: 06/06/1998 Stopped: Laboratory Investigations:								pisthotonus
Tablet 10.0 Milligram Daily Oral Batch: Started: 06/06/1998 Stopped: Laboratory Investigations:								
Tablet 10.0 Milligram Daily Oral Batch: Started: 06/06/1998 Stopped: Laboratory Investigations:								
Tablet 10.0 Milligram Daily Oral Batch: Started: 06/06/1998 Stopped: Laboratory Investigations:			son: Schizophrenia	Pos				
Batch: Started: 06/06/1998 Stopped: Laboratory Investigations:		ıral			10.0 Mill		ispected)	
Laboratory Investigations:		ıaı	•			s		
Date Type Range Date Tested Result Details						tions:	nvestiga <u>ti</u>	aboratory Ir
		Details		Result	Date Tested			
Additional Information:						n:	formation	dditional In

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Date Range: 1 Jan 1960 To 31 Dec 1999 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: 129179 Seq: 1 Gender: M
Reported: 13/07/1998 Weight:

Age:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting	Severe		

Medicine Details:

ZYPREXA (Suspected) Reason:

 Tablet
 0.0
 Oral

 Batch:
 Started: 01/04/1998
 Stopped:

Laboratory Investigations:

<u> Luboi atoi</u>	y ilivostiga				
Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 129180 Seq: 1 Gender: M

Reported: 13/07/1998 Weight:
Hospitalisation: Age: 42

Onset Date: 03/03/1998 **DOB:** 16/03/1955

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	teaction Betails.			
	Preferred Term	Severity	Report Description	Treatment
	Hallucination		Auditory hallucinations	
	Schizophreniform disorder		Exacerbation of positive symptoms	Ceased zyprexa.

Medicine Details:

MODECATE (Other drug)			Reason:	Schizophrenia		
Injection	50.0	Milligram	Mont	hly	Intramuscular	
Batch:	Started:		L TERM	Stopped:		CONTIN
THIORIDAZINE HYDROCHLORIDE (Other	drug)		Reason:	Schizophrenia		
Tablet	50.0	Milligram	Daily		Oral	
Batch:	Started:		L TERM	Stopped:		CONTIN
BENZHEXOL HYDROCHLORIDE (Other di	ug)		Reason:			
Tablet	2.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		CONTIN
ZYPREXA (Suspected)			Reason:	Schizophrenia		
Capsule	5.0	Milligram	Daily		Oral	
Batch:	Started: 03	/03/1998		Stopped:	20/03/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 129181 Gender: M Seq: 1

Reported: 13/07/1998 Weight: **Hospitalisation:** Age:

Onset Date: 31/12/1998 DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness			

Medicine Details:

Medicine Details.					
ZYPREXA (Suspected)		Reaso	1:		
Capsule	20.0 Mil	lligram D	aily	Oral	
Batch:	Started:		Stopped:		CONTIN
HALOPERIDOL (Suspected)		Reaso	ո։		
Tablet	75.0 Mil	lligram D	aily	Oral	
Batch:	Started:		Stopped:		CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 129184 Seq: 1 Gender: F

Reported: 13/07/1998 Weight:
Hospitalisation: Age: 70Y

Onset Date: 31/05/1998 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			Zyprexa ceased

Medicine Details:

ZYPREXA (Suspected) Reason:

Capsule 0.0 Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 129270 Seq: 1 Gender: F
Reported: 17/07/1998 Weight:
Hospitalisation: Admitted to hospital Age: 63Y

Onset Date: 15/04/1998 **DOB:**

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touotioii Dotuiioi		-	
Preferred Term	Severity	Report Description	Treatment
	Required Visit to Doctor	Altered mental state.	Ceased olanzapine
	Required Visit to Doctor	Generalised muscle rigidity	
Blood creatine phosphokinase incr	Required Visit to Doctor		
Convulsion			
, ,,	Required Visit to Doctor		

Medicine Details:

Medicine Details.					
TEMAZEPAM (Other drug)	Reason:				
	20.0 Milligram	As necessary			
Batch:	Started:	Stopped:			
OLANZAPINE (Suspected)		Reason: Unspecified psychosis			
Tablet	12.5 Milligram	Daily Oral			
Batch:	Started: 07/04/1998	Stopped: 15/04/1998			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatinine		15/04/1998	249	

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 129277 Seq: 1 Gender: M

Reported: 17/07/1998 Weight: 63.00 Hospitalisation: Age: 20Y

Onset Date: 03/06/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

'	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	l
	Hypertonia		Cogwheeling rigidity of arms.		ĺ
	Convulsion	Severe	Jerks of neck.		ĺ
	Dystonia	Severe		2mg benztropine im.	l

Medicine Details:

AMOXYCILLIN SODIUM (Other drug) Reason: Chronic gingivitis

1.5 Gram Daily

Batch: Started: 02/06/1998 Stopped:

ZYPREXA (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 25/05/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 129304 Seq: 1 Gender: M

Reported: 20/07/1998 Weight:
Hospitalisation: Age: 18Y

Onset Date: 31/12/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Flushing		Flushing of hands, face, feet, after	
		exercise.	

Medicine Details:

OLANZAPINE (Suspected)Reason:Schizophrenia

Tablet 15.0 Milligram Daily Oral

Batch: Started: 01/08/1997 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	port	Detail	ls:
----	------	--------	-----

 Case Number:
 129609
 Seq: 1
 Gender:
 F

 Reported:
 27/07/1998
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/06/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE, ZYPREXA, Zyprexa IM, Zyprexa Zydis

Report Details:

Reported: 27/07/1998

Gender: F Case Number: 129610 Seq: 1

Weight: Hospitalisation: Age: 17Y

Onset Date: 31/05/1998 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Osteoarthritis		Severe oedema effecting knee joints.	
Oedema peripheral	Severe		Zyprexa ceased and placed on risperidone.

Medicine Details:

ZYPREXA (Suspected) Reason: Tablet 1.0 Milligram Daily Oral

Batch: Started: 01/04/1998 Stopped: 28/05/1998 1M

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month, the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month, the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 129611
 Seq: 1
 Gender:
 F

 Reported:
 27/07/1998
 Weight:

Hospitalisation: Hospitalisation prolonged Age: 37

Onset Date: DOB: 24/01/1961

Outcome: Unknown Causality: Causality possible

Reaction Details:

caction Details.			
Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			
Pre-eclampsia			

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified neurosisTablet5.0 MilligramDailyOral

Batch: Started: 01/07/1997 Stopped:

Laboratory Investigations:

<u> </u>	y mirodugudonor							
Date	Туре	Range	Date Tested	Result	Details			

Additional Information:

The pt began taking 5mg zyprexa in the first trimester of pregnancy. the pt also took zyprexa in the last trimester. the pt experienced amenorrhoea when she first started to take zyprexa. it was later realised that the pt was pregnant - though the pt had been amenorrhoeic. zyprexa was ceased. it is not known if the pt took any other medications during pregnancy. however, the menustration date was jul97 and the due date of the baby was 18 june 98. baby was born on 7 june 98. see report number 129612. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 129612
 Seq: 1
 Gender:
 F

 Reported:
 27/07/1998
 Weight:

Hospitalisation: Hospitalisation prolonged **Age:** 37

Onset Date: 12/06/1998 **DOB**: 24/01/1961

Outcome: Unknown Causality: Causality possible

Reaction Details:

TOUGHT D'OLUMO			
Preferred Term	Severity	Report Description	Treatment
Somnolence neonatal		Sleepy	
Cardiac murmur			
Cardiomegaly	Required Specialist Consultation		
Jaundice neonatal			

Medicine Details:

ZYPREXA (Suspected) Reason:

Oral application 5.0 Milligram Daily Breast milk transfer

Batch: Started: 01/07/1997 **Stopped:** 15/06/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Mother breast fed the baby (whilst taking zyprexa) until 13 june 98. on 12 june 98 the baby was jaudiced and appeared sleepy. an examination of the baby revealed a heart murmur and mild cardiomegaly, the baby was bottle fed until 15 june 98 when the mother discontinued zyprexa and commenced trifluperazine. breast feeding had also begun again on 15 june 98. the mothers condition had deteriorated whilst on trifluperazine and the baby is still experiencing jaundice and sedation. alot of babies are born with mild cardiac problems and it may take a few days until the heart valve closes (dr states). see mothers report 129611. the mother had experienced an elevated blood pressure (pre eclampsia) and the delivery was induced by gel on the cervix and also complicated

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 129613
 Seq: 1
 Gender:
 F

 Reported:
 27/07/1998
 Weight:

Hospitalisation: Age: 56Y
Onset Date: 06/03/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term Severity		Report Description	Treatment	
Hypertension		160/100 and peaked on 01/05/98 to 205/105	Zyprexa reduced to 22.5mg daily pt treated with atenolol 50mg bd	

Medicine Details:

ALPRAZOLAM (Other drug)		Rea	son:	Specific disord	lers of sleep	
Oral application	1.0	Dose Unspecified	As ne	cessary	Oral	
Batch:	Started:			Stopped:		CONTIN
ZYPREXA (Suspected)		Rea	son:			
Tablet	30.0	Milligram	Daily		Oral	
Batch:	Started: 01/0	02/1998		Stopped:		CONTIN
NULAX FRUIT LAXATIVE (Suspected)		Rea	son:	Constipation		
Tablet	0.5	Dose Unspecified	Daily		Oral	
Batch:	Started:			Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt is of a healthy weight for her height and has no family history of high blood pressure. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 129807
 Seq: 1
 Gender:
 F

 Reported:
 31/07/1998
 Weight:

Hospitalisation:
Onset Date: 06/07/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia	Required Specialist Consultation		
Eosinophilia	Required Specialist Consultation		
Leukocytosis			
Thrombocythaemia	Required Visit to Doctor		

Medicine Details:

Miculcine Details.				
ZYPREXA (Suspected)	ı	Reason:		
	10.0 Milligram	Daily		
Batch:	Started: 25/06/1998		Stopped:	
LITHICARB (Suspected)	ı	Reason:		
	1.0 Gram	Daily		
Batch:	Started: 01/07/1998		Stopped:	
EPILIM (Suspected)	ı	Reason:		
	1.0 Gram	Daily		
Batch:	Started: 23/06/1998		Stopped: 06/07/1998	
CLONAZEPAM (Suspected)		Reason:		
	500.0 Microgram	Daily		
Batch:	Started: 23/06/1998		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Eosinophils	(0.0-0.5)	06/07/1998	0.7	
	Eosinophils	(0.0-0.5)	15/07/1998	1.1	
	Eosinophils	(0.0-0.5)	17/07/1998	1.8	
	Eosinophils	(0.0-0.5)	23/07/1998	1.3	
	Haemoglobin	(11.5-16.5)	06/07/1998	10.1	
	Haemoglobin	(11.5-16.5)	15/07/1998	9.8	
	Haemoglobin	(11.5-16.5)	17/07/1998	10.0	

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 129807 Seq: 1 Gender: F

 Reported: 31/07/1998
 Weight:

 Hospitalisation:
 Age: 30Y

 Onset Date: 06/07/1998
 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)

Reason:

10.0 Milligram Daily

Batch: Started: 25/06/1998 Stopped:

LITHICARB (Suspected) Reason:

1.0 Gram Daily

Batch: Started: 01/07/1998 Stopped:

EPILIM (Suspected) Reason:

1.0 Gram Daily

Batch: Started: 23/06/1998 Stopped: 06/07/1998

CLONAZEPAM (Suspected) Reason:

500.0 Microgram Daily

Batch: Started: 23/06/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin	(11.5-16.5)	23/07/1998	9.7	
	Other data				Poikilocytosis, anisocytosis.
	Platelets	(150-16.5)	06/07/1998	397	
	Platelets	(150-16.5)	15/07/1998	866	
	Platelets	(150-16.5)	17/07/1998	866	
	Platelets	(150-16.5)	23/07/1998	594	

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 130012 Seq: 1 Gender: M
Reported: 07/08/1998 Weight:
Hospitalisation: Age:

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Muscle twitching		Twitching of the leg at night	
	Insomnia			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/04/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 130013 Seq: 1 Gender: F

Reported: 07/08/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/03/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

٠,	todotion Botanoi			
	Preferred Term	Severity	Report Description	Treatment
	Tardive dyskinesia			Olanzapine was discontinued and patient recommenced trifluperazine.

Medicine Details:

<u>Medicine Details:</u>			
ZOLOFT (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1998	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 130249 Seq: 1 Gender: F

Reported: 17/08/1998 Weight: 85.00
Hospitalisation: Age: 44Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle spasms		Cramps on a daily basis in both calves	Zyprexa ceased.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

15.0 Milligram Daily

Batch: Started: 01/01/1998 **Stopped:** 10/08/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 130283 Seq: 1 Gender: M

Reported: 18/08/1998 Weight: 65.00 Hospitalisation: Age: 37Y

Onset Date: 08/08/1998 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Choreoathetosis		Chorea movements of shoulders, muscles.	Haloperidol substituted for zyprexa.

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:			
Tablet	1.2 Gram	Daily		Oral	
Batch:	Started: 01/01/1994		Stopped:		CONTIN
ZYPREXA (Suspected)		Reason:	Schizophrenia		
Tablet	10.0 Milligram	Daily		Oral	
Batch:	Started: 31/07/1998		Stopped:	10/08/1998	
LUVOX (Suspected)		Reason:	Depression		
Tablet	100.0 Milligram	Daily		Oral	
Batch:	Started: 31/07/1998		Stopped:		CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 130288
 Seq: 1
 Gender:
 F

 Reported:
 18/08/1998
 Weight:

Hospitalisation: Age: 37Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botano.					
Preferred Term	Severity	Report Description	Treatment		
Hypothermia		Oral temperature fell to 34 celsius degrees.	Steroid replacement and treatment of infection. olanzapine ceased		
Infection					

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

0.0

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Hypothermia induced by risperidone and olanzapine in a patient with prader- willi syndrome. mja vol 169 17/8/98.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 130373 Seq: 1 Gender: M

Reported: 21/08/1998 Weight:
Hospitalisation: Age: 25Y

Onset Date: 15/07/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash			Zyprexa ceased

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/06/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 130375
 Seq: 1
 Gender:
 F

 Reported:
 21/08/1998
 Weight:

Hospitalisation: Age:

Onset Date: 31/07/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Conjunctivitis		Itchy eyes	
	Pruritus			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/07/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 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:
 130466
 Seq: 1
 Gender: M

 Reported:
 24/08/1998
 Weight:

Hospitalisation: Age: 27

Onset Date: 11/08/1998 DOB: 17/07/1971
Outcome: Death Causality: Causality possible

Reaction Details:

i Leactioi i	Details.			
	Preferred Term	Severity	Report Description	Treatment
Sudden d	eath		Found dead at home	
Myocardit	is			
Suicide at	tempt			

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
, ,	0.0		
Batch:	Started:	Stopped:	
DIAZEPAM (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	200.0 Milligram	Daily Oral	
Batch:	Started: 27/07/1998	Stopped: 11/08/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Histology				Autopsy revealed mycarditis was the direct condition directly leading to death at necropsy, the lungs were congested, with evidence of frank pulmonary oedema examination of the heart showed acute mycarditis with an eosinophilic infiltrate. coronary arteries were patent. there was no inflammation of other organs on microscopy or signs of vasculitis

Additional Information:

Patient died 11/8/98. patient was not on olanzapine at the time of death.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 130757 Seq: 1 Gender: M

Reported: 04/09/1998 Weight: 130.00 Hospitalisation: Age: 53Y

Onset Date: 12/08/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		2x seizure	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Sequelae: dislocated I shoulder. p/h: seizure.on dilantin which was stopped 12 months ago due to abn lft.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 130765 Seq: 1 Gender: F

Reported: 03/09/1998 Weight: 70.00
Hospitalisation: Age: 43Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

 VENLAFAXINE HYDROCHLORIDE (Other drug)
 Reason:
 Schizophrenia

375.0 Milligram Daily

Batch: Started: 01/01/1997 Stopped: CONTIN

OLANZAPINE (Suspected) Reason: Schizophrenia

 Tablet
 20.0 Milligram
 Daily
 Oral

 Batch:
 Started: 01/07/1998
 Stopped: 25/08/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 130834 Seq: 1 Gender: F

Reported: 07/09/1998 Weight: 55.00 Hospitalisation: Age: 23Y

Onset Date: 25/08/1998 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
Ī	Photosensitivity reaction		Photosensitivity rash to face and hands	

Medicine Details:

EPILIM (Other drug)		Reason:	Other&unspecifie	ed epilepsy
	1.4 Gram	Daily		
Batch:	Started:	L TERM	Stopped:	
AROPAX (Other drug)		Reason:	Depression	
Tablet	20.0 Milligram	Daily	C	Oral
Batch:	Started:		Stopped:	
MONOFEME 28 (Other drug)		Reason:	Contraception	
Tablet	1.0 Dose Uns	specified Daily	C	Oral
Batch:	Started: 01/01/1997		Stopped:	
OLANZAPINE (Suspected)		Reason:		
	5.0 Milligram	Daily		
Batch:	Started: 17/08/1998		Stopped: 2	7/08/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 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: 130845 Seq: 1 Gender: M

Reported: 07/09/1998 Weight:

Hospitalisation: Age: 69Y
Onset Date: 17/03/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		•	Pt wants to change back to modecate.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 05/03/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 130846 Seq: 1 Gender: F

Reported: 07/09/1998 Weight:
Hospitalisation: Age: 72Y

Onset Date: 22/04/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Recall of past emeories	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/04/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 130848 Seq: 1 Gender: F

 Reported: 07/09/1998
 Weight:

 Hospitalisation:
 Age: 45Y

 Onset Date: 31/07/1998
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Convulsion			Zyprexia ceased and anafranil reduced to 7 tablets a day and then ceased.
Drug level increased			

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)		Reason: Depression	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/06/1998	Stopped:	28/08/1998
ANAFRANIL (Suspected)		Reason: Depression	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 01/07/1998	Stopped:	28/08/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Serum drug level				The blood levels of clompramine were 980ng/ml which was well above the usual therapeutic range of 200-300ng/ml.

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:	Re	po	rt	De	tai	ls:
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 Case Number:
 130911
 Seq: 1
 Gender: M

 Reported:
 07/09/1998
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 09/07/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		General tonic clonic seizures	Zyprexia ceased

Medicine Details:

PREDNISOLONE (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
NEORAL (Other drug)		Reason:	
Capsule	250.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
AROPAX (Other drug)		Reason: Depression	
Tablet	40.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
PEPCIDINE (Other drug)		Reason:	
Tablet	40.0 Milligram	Daily Oral	
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 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

_	07/09/1998 Admitted to hospit 09/07/1998 Unknown	Seq: 1	DOB	: 68Y
Medicine Deta				_
ZYPREXA (Suspec	eted)	E.O. Müllinger	Reason: Unspecified psychosis	
Batch:		5.0 Milligram Started: 11/06/1998	Alternate days Stopped: 09/07/199	10
Laboratory In	vestigations:			
Additional Inf	ormation:			

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Case Number: 130947

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Repor	ted: 07/09/199	3 8					Weig	ht:		
ospitalisat	ion:			Age: A3						
Onset D	ate:			DOB:						
Outco	me: Unknown					ity: Causality	possib	le		
eaction D	etails:									
Pro	eferred Term	Se	everity		Report De	escription		Trea	tment	
Psychotic di	sorder		١	Worsenin	g of psychos	sis		Zoloft dose red	luced to	50mg/d
Orug ineffec	tive									
Medicine										
ZYPREXA (S					Reason:					
Table			0.0			<u>.</u>	Oral			
Bato		S	tarted:		Decem	Stopped	:			
ZOLOFT (Sus			100 0 N	Ailliaram	Reason:	Depression .	Oral			
Table Bat o		6	100.0 M	viiiigram	Daily	Stopped	Oral			
	y Investigat									
Date	Туре	Range	Date Teste	d Res	sult)etails		
Additiona	l Informatio	n:								
port Run: 04/	06/2007 04:28PM	M Database: pi	usime02		ADRSO	004		Page	264 (of 526



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported	r: 13130	4 S	Seq: 1				Gende	er: F
	l: 18/09/	1998					Weigh	t: 90.00
spitalisation	ı:						Ag	e: 35Y
Onset Date) :						DO	B:
Outcome	: Not ye	t recovered					Causalit	y: Causality possible
action Deta	ails:							
Prefe	rred Tern	1	Severity		Repo	rt Desc	cription	Treatment
ash				Spo che	ots on face, pa eks	apules c	over nose &	
ledicine De					Reas	on:		
VELFEY (Sasbe	sieu)		0.0		Reas	oui.		
Batch:			Started:				Stopped:	
PILIM (Suspect	ted)				Reas	son:		
` .	·		1.0	Gran	n	Daily		
Batch:			Started:				Stopped:	
UVOX (Suspec	ted)				Reas	on:		
			300.0	Milliç	gram	Daily		
Batch:			Started:		L TERM		Stopped:	
DLANZAPINE (S	uspected)				Reas	son:		
			30.0	Millig	gram	Daily		
			Started:		L TERM		Stopped:	
Batch:							оторреа.	
	nvestic						оторреи.	
Batch: aboratory Date	Investiç Type	gations:	Date Tes	ted	Result			etails

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 131344
 Seq: 1
 Gender:
 F

 Reported:
 18/09/1998
 Weight:

Hospitalisation: Age: 22

Onset Date: 13/08/1998 **DOB**: 24/06/1976

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Face oedema		Pressure and swelling around the eye.	Zyprexa dose decreased back to 10mg. risperidone was ceased.
Conjunctivitis		Red conjunctiva	
Visual disturbance			

Medicine Details:

Medicine Details.			
RISPERIDONE (Other drug)		Reason: Unspecified schizoph	nrenia
Tablet	0.0	Oral	
Batch:	Started: 01/04/1997	Stopped: 20/07	7/1998
ZYPREXA (Suspected)		Reason: Unspecified schizoph	nrenia
Tablet	15.0 Milligram	Daily Oral	
Batch:	Started: 06/08/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 131346
 Seq: 1
 Gender:
 F

 Reported:
 18/09/1998
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 31/08/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Deep vein thrombosis			Zyprexa ceased

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/04/1998 **Stopped:** 13/08/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 131348 Seq: 1 Gender: F

Reported: 18/09/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema			Zyprexa ceased

Medicine Details:

 ZYPREXA (Suspected)
 Reason:
 Unspecified schizophrenia

 Tablet
 0.0
 Daily
 Oral

 Batch:
 Started: 01/01/1998
 Stopped: 31/01/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 131692
 Seq: 1
 Gender: M

 Reported:
 28/09/1998
 Weight:

Hospitalisation: Admitted to hospital Age: 89

Onset Date: DOB: 28/12/1908

Outcome: Unknown Causality: Causality possible

Reaction Details:

reaction Details.	action betails.							
Preferred Term	Severity	Report Description	Treatment					
Delirium		Acute delirium						
Hallucination								
Orthostatic hypotension								

Medicine Details:

OLANZAPINE (Suspected) Reason:

2.5 Milligram Daily

Batch: Started: 01/02/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 131795
 Seq: 1
 Gender:
 F

 Reported:
 06/10/1998
 Weight:

Hospitalisation: Age: 45

Onset Date: 31/07/1998 **DOB:** 11/07/1953

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	todotion Botano.						
Preferred Term Severity		Severity	Report Description	Treatment			
	Oedema peripheral		Swelling hands and wrists				
	Gravitational oedema			Treated with frusemide and midamor.			

Medicine Details:

wealtine Details:			
FLUVOXAMINE MALEATE (Other drug)		Reason: Depression	
	0.0		
Batch:	Started:	Stopped:	
XANAX (Other drug)		Reason: Specific disorders of sleep	
Tablet	2.0 Milligram	As necessary Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Anxiety neurosis	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 01/07/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 131798
 Seq: 1
 Gender: M

 Reported:
 06/10/1998
 Weight:

Hospitalisation: Age: 30

Onset Date: 23/01/1998 **DOB:** 16/05/1967

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Dotano.			
Preferred Term	Severity	Report Description	Treatment
Agitation			
Gynaecomastia			Benztropine. zyprexa was ceased
Psychotic disorder			
Somnolence			
Tremor			

Medicine Details:

ZYPREXA (Suspected)		Reason: Schi	zophrenia	
Tablet	12.5 Milligram	Daily	Oral	
Batch:	Started:	S	stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Zyprexa was increased to 12.5mg from 10mg symptoms were noted. zyprexa was decreased to 10mg patient suffered other symptoms. dose was decreased to 7.5mg and diazepam was added, taken as required. on 18/3/98 pt experiened symptoms and zyprexa was decreased to 5mg. pt condition was worsening so zyprexa was increased to 7.5mg. in june 98 and july 98 showed ongoing symptoms, zyprexa was increased to 10mg. on 25/8/98 pt complained of symptoms so zyprexa was decreased to 2.5mg/daily until ceased.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repor Hospitalisati Onset D		Seq: 1		Gender: F Weight: Age: 36Y DOB: Causality: Causality possible		
eaction D						
	eferred Term	Severity	Repo	ort Description	Treatment	
Personality of	disorder		nappropriate be	haviour		
Medicine	Details:					
ZYPREXA (S			Reas	son: Unspecified schizoph	renia	
Table	et	10.0 M	Milligram	Daily Oral		
Batc	h:	Started:		Stopped:		
I aborator	ry Investigati	ons:				
Date	Туре	Range Date Teste	d Result]	Details	
Additiona	I Information	· · · · · · · · · · · · · · · · · · ·				
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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 131800 Reported: 06/10/1998 ospitalisation: Onset Date: Outcome: Unknown	Seq: 1		Gender: Weight: Age: DOB: Causality:	
eaction Details:	0	Daniel Daniel		Totalogical
Preferred Term ersonality disorder	Severity	Report Descrip appropriate behaviour	otion	Treatment
ledicine Details: ZYPREXA (Suspected)		Reason: Uns	pecified schizophrenia	
Tablet	20.0 Milli		Oral	
Batch:	Started:		Stopped:	
aboratory Investigațio				
Date Type	Range Date Tested	Result	Details	8
Additional Information:	•	<u>, </u>		
oort Run : 04/06/2007	Datahasa: nusima02	ADRS004		Page 273 of 526

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repoi Hospitalisat Onset D		Seq: 1		Gender: M Weight: Age: 49Y DOB: Causality: Causality possible		
eaction E						
	eferred Term	Severity		ort Description	Treatment	
Personality	disorder		Inappropriate be	haviour		
Medicine						
ZYPREXA (S		40.0	Reas	·	a	
Tabl Bat e		10.0 Started:	Milligram	Daily Oral Stopped:		
Laborato Date	ry Investigati Type	ONS: Range Date Teste	ed Result	Deta	ils	
	, , , , , , , , , , , , , , , , , , ,					
Additiona	al Information	1:				
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Date Range: 1 Jan 1960 To 31 Dec 1999 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: 131802 Seq: 1 Gender: F

Reported: 06/10/1998 Weight:
Hospitalisation: Age: 52Y

Onset Date: 31/08/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Hands swelling	

Medicine Details:

neulcine Details.				
CARBAMAZEPINE (Other drug)		Reason:		
Oral application	0.0		Oral	
Batch:	Started:	Sto		
GABAPENTIN (Other drug)		Reason:		
	0.0			
Batch:	Started:	Sto	pped:	CONTIN
YPREXA (Suspected)		Reason: Unspe	cified psychosis	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started:	Sto	pped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt also on antihypertensives - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 131804 Seq: 1 Gender: F

Reported: 06/10/1998 Weight:
Hospitalisation: Age: 32Y

Onset Date: 31/12/1998 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vaginal infection		Vaginal dryness	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 20.0 Milligram Daily Oral

Batch: Started: 01/01/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Zyprexa ceased. pt's health deteriorated and she started risperidone. risperidone ceased and pt placed back onto zyprexa 20mg daily and the reaction returned. pt still taking zyprexa. - the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 132267
 Seq: 1
 Gender:
 F

 Reported:
 19/10/1998
 Weight:

Hospitalisation: Age: 20Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Generalised oedema			
Increased appetite			Patient is being transferred from zyprexa to risperidone.
Weight increased			

Medicine Details:

 ZYPREXA (Suspected)
 Reason:
 Schizophrenia

 Tablet
 10.0
 Milligram
 Daily
 Oral

 Batch:
 Started: 23/06/1998
 Stopped: 28/09/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	132269	Seq: 1		Ge	nder: ⊦
Reported:	19/10/1998			We	eight:
spitalisation:					Age:
Onset Date:					DOB:
Outcome:	Recovered			Caus	ality: Causality probable
ction Detai	ls:		_		
Preferre	ed Term	Severity	Rep	ort Description	Treatment
edema periphe	ral		Peripheral oede	ma of hands and feet.	Ceased zyprexa
edicine Deta		0.0		nson: Ora	
Tablet Batch:		0.0 Started:		ll	
aboratory In	vestigation	Ons: Range Date Tes	sted Result	T	Details
Date	Туре	range Date res	sted Result		Details
Additional Inf	ormation	:			
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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	132271	Seq:	1			Gender:	F	
Reported:	19/10/199	_				Weight:		
spitalisation:						Age:		
Onset Date:						DOB:		
Outcome:	Recovered	t				Causality:	Causality proba	able
ection Detai								
	ed Term	Se	verity	-	ort Description		Treatmer	nt
dema periphe	ral		Oe	edema periphe	eral of hands and	l feet. Ce	ased zyprexa	
edicine Deta YPREXA (Suspec				Rea	son:			
Tablet Batch:			0.0 tarted:		Stoppe	Oral		
boratory In	vestigat	ons:	Data Tarata	I Downth		Datai		
Date	Туре	Range	Date Tested	Result		Detai	IS .	
dditional Inf	ormatio	1 :						
rt Run: 04/06/200	07 04:29PM	Database: pu	ısime02	A	DRS004		Page 279	of 526



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

ase Number:	132272	Seq: 1		Ge	ender: F
	19/10/1998	-			eight:
spitalisation:					Age:
Onset Date:					DOB:
Outcome:	Recovered			Cau	sality: Causality probable
ction Detai					
	ed Term	Severity		ort Description	Treatment
dema periphe	ral		Oedema periphe	eral of hands and feet.	Ceased zyprexa
edicine Deta	ted)		Rea	son:	
Oral applica	ation	0.0		Or	ral
Batch:		Started:		Stopped:	
aboratory In	vestigatio	ns:			
Date	Туре	Range Date Tes	sted Result		Details
dditional Inf	ormation:				
ort Run: 04/06/200	7 04:29PM	Database: pusime02		ADRS004	Page 280 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 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:
 132402
 Seq: 1
 Gender: M

 Reported:
 26/10/1998
 Weight:
 75.00

Hospitalisation:
Onset Date: 11/10/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			Started propranolol.

Medicine Details:

Medicine Details.			
LARGACTIL (Other drug)		Reason: Manic-depression psycho,manic	
	100.0 Milligram	As necessary	
Batch:	Started:	Stopped:	
EPILIM (Other drug)		Reason: Manic-depression psycho,manic	
Tablet	2.0 Gram	Daily Oral	
Batch:	Started: 02/10/1998	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
	5.0 Milligram	Daily	
Batch:	Started: 16/09/1998	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 132524
 Seq: 1
 Gender:
 F

 Reported:
 30/10/1998
 Weight:
 70.00

 Hospitalisation:
 Age: 55Y

Onset Date: 14/10/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

STELAZINE (Other drug)		Rea	son: Unspecifie	ed schizophrenia		
Tablet	8.0	Milligram	As necessary	Oral		
Batch:	Started:	L TERM	Stopp	ed:		
THIORIDAZINE HYDROCHLORIDE	(Other drug)	Rea	son: Unspecifie	ed schizophrenia		
Tablet	200.0	Milligram	Daily	Oral		
Batch:	Started:	L TERM	Stopp	ed: 09/09/1998		
FLUOXETINE HYDROCHLORIDE (Other drug)	Rea	son:			
	40.0	Milligram	Daily			
Batch:	Started:	L TERM	Stopp	ed:	CONTIN	
COGENTIN (Other drug)		Rea	son:			
	1.0	Milligram	Daily			
Batch:	Started:	L TERM	Stopp	ed:	CONTIN	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		22/07/1998	30	
	ALT = SGPT		14/10/1998	561	
	AST = SGOT		22/07/1998	28	
	AST = SGOT		14/10/1998	371	
	GGT = SGGT =		22/07/1998	58	
	GGT = SGGT =		14/10/1998	513	
	LDH		22/07/1998	194	

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 132524
 Seq: 1
 Gender:
 F

 Reported:
 30/10/1998
 Weight:
 70.00

 Reported: 30/10/1998
 Weight: 70.00

 Hospitalisation:
 Age: 55Y

 Onset Date: 14/10/1998
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)		Reason: Unspecified schizophrenia
Tablet	5.0 Milligram	Daily Oral
Batch:	Started: 02/09/1998	Stopped: 07/10/1998
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia
Tablet	7.5 Milligram	Daily Oral
Batch:	Started: 07/10/1998	Stopped: 12/10/1998
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia
Tablet	5.0 Milligram	Daily Oral
Batch:	Started: 12/10/1998	Stopped: 16/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	LDH		14/10/1998	511	
	SAP = ALP		22/07/1998	94	
	SAP = ALP		14/10/1998	252	

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 132579 Seq: 1 Gender: M

Reported: 30/10/1998 Weight:

Hospitalisation: Age: 70Y
Onset Date: 21/08/1998
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia	Required Specialist Consultation	Mild akathisia	
Extrapyramidal disorder	Severe	Moderate severe parkinsomism	Olanzapine ceased

Medicine Details:

SODIUM VALPROATE (Other drug) Reason: Manic-depression psycho,manic

800.0 Milligram Daily

Batch: Started: 10/08/1998 Stopped:

 OLANZAPINE (Suspected)
 Reason:
 Manic-depression psycho,manic

10.0 Milligram

Daily

Batch: Started: 11/08/1998 Stopped: 04/09/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt on 5mg olanzapine between 29/07/98 - 11/08/98

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 132587	Seq: 1		Gender	: IVI
Reported: 30/10/199	98		Weight:	
spitalisation:			Age:	58Y
Onset Date:			DOB	:
Outcome: Not yet re	covered		Causality	: Causality possible
ction Details:				
Preferred Term	Severity	Report [Description	Treatment
edema peripheral		Pitting to knees.	G	radually reduce and ceased
			Ol	anazpine.
reased appetite				
eight increased				
edicine Details: LANZAPINE (Suspected)		Reason	Schizophrenia	
	15.0	Milligram Da	ily	
Batch:	Started: 06	/08/1998	Stopped: 03/11/199	8
aboratory Investigat	tions: Range Date Tes	sted Result	Deta	ils
	<u>l</u>			
dditional Informatio	n:			
rt Run · 04/06/2007 - 04·29PN	M Database: pusime02	ADRS	S004	Page 285 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 132716 Seq: 1 Gender: F

Reported: 02/11/1998 Weight:
Hospitalisation: Age: 32Y

Onset Date: 31/10/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	Nouvelon Botano.								
	Preferred Term	Severity	Report Description	Treatment					
	Oesophageal atresia								
	Tracheo-oesophageal fistula								

Medicine Details:

ZYPREXA (Suspected) Reason:

0.0

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Mother received zyprexa for an unknown indication during all three trimesters of her pregnancy. on 25/10/98 mother gave birth to a female baby at 29 weeks gestation. the baby's birth weight was 1.44kg. the baby had congenital abnormalities consisting of an oesophageal atresia and a tracheo-oesophageal fistula. the baby has been transferred for surgery. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 132722	Seq: 1		Gende	r: M			
Reported: 02/11/1998			Weight:				
ospitalisation:			Age:				
Onset Date:			DO				
Outcome: Not yet reco	overed		Causalit	y: Causality possible			
eaction Details:							
Preferred Term	Severity	Report Des		Treatment			
Neight increased	Pt	t gained 10kg in weigh	t.				
Medicine Details: ZYPREXA (Suspected) Tablet	0.0	Reason:					
Batch:	0.0 Started:		Oral Stopped:				
							
Laboratory Investigation	DNS: Range Date Tested	Result	De	tails			
Date Type	Range Date resteu	result		talis			
Additional Information	:						
eport Run: 04/06/2007 04:29PM	Database: pusime02	ADRS004	•	Page 287 of 526			

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	Del. 132723	Seq. 1			Gender.	IVI	
_	ted: 02/11/1998				Weight:	A F	
ospitalisati					Age: / DOB:	CP	
Onset D						Carraglita anaba	- h l o
	me: Recovered				Causanty:	Causality proba	abie
action D	etalis: eferred Term	Severity	T Po	port Descrip	otion	Treatmen	.+
onvulsion	elelled Tellii	Seventy	Epileptic fit.	port Descrip		rexa ceased	ı
		I	1-606		—) P	<u> </u>	
ledicine							
ZYPREXA (S		F. /		eason:	0		
Table Batc		5.0 Started:) Milligram	Daily	Oral Stopped:		
	***	<u> </u>			эторроц.		
.aborator	ry Investigatio	ons: Range Date Te	ested Result	T	Details		
Date	Туре	Range Date 16	Result		Details		
dditiona	I Information	<u>.</u>					
aaitiona		•					
ort Run : 04/0	06/2007 04:29PM	Database: pusime02		ADRS004		Page 288	of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

 Case Number:
 132724
 Seq: 1
 Gender:
 F

 Reported:
 02/11/1998
 Weight:

Hospitalisation: Age: 24Y
Onset Date: 26/09/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			Dr may decrease the dose of zyprexa of 10mg to 7.5mg.

Medicine Details:

MEGICINE DETAILS.			
SODIUM VALPROATE (Other drug)		Reason:	
Oral application	1.2 Gram	Daily Oral	
Batch:	Started:	Stopped:	CONTIN
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 15/09/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	no	rt	De	tail	ls:
176	μυ		\mathbf{r}	tai	.

Case Number: 132794 Seq: 1 Gender: F

Reported: 04/11/1998 Weight: 70.00 Hospitalisation: Age: 23Y

Onset Date: 26/08/1998 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	toaction Botaile.				
	Preferred Term	Severity	Report Description	Treatment	
	Dizziness				
	Somnolence				

Medicine Details:

modifie Botalio.			
ZYPREXA (Suspected)		Reason: Schizophrenia	a
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 25/08/1998	Stopped:	26/08/1998
TEMAZEPAM (Suspected)		Reason:	
Oral application	20.0 Milligram	Daily	Oral
Batch:	Started: 25/08/1998	Stopped:	26/08/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 132795 Seq: 1 Gender: F

Reported: 04/11/1998 Weight: 70.00 Hospitalisation: Age: 23Y

Onset Date: 02/09/1998 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Bp 95/75	

Medicine Details:

RISPERIDONE (Other drug)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 22/08/1998	Stopped:	
THIAMINE (Other drug)		Reason: Alcoholic addi	ction
Oral application	100.0 Milligram	Daily	Oral
Batch:	Started: 22/08/1998	Stopped:	10/09/1998
TEMAZEPAM (Suspected)		Reason:	
	10.0 Milligram	As necessary	
Batch:	Started: 26/08/1998	Stopped:	03/09/1998
ZYPREXA (Suspected)		Reason: Schizophrenia	ı
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started: 26/08/1998	Stopped:	03/09/1998

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 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detail	04/11/1998 02/09/1998 Recovered s:	Seq: 1				Gender: Weight: Age: DOB: ausality:	70.00 23Y	
Medicine Deta								
Tablet	ROCHLORIDE (Suspe		Milligram	Reason:	Depression	Oral		
Batch:		Started:) Milligram	Daily	Stonned:	03/09/1998		
Laboratory Inv	vestigations:							
Additional Info	ormation:							

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 133225
 Seq: 1
 Gender: M

 Reported:
 13/11/1998
 Weight:

Hospitalisation: Age: 44Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Dermatitis bullous		Vesiculobullous rash on trunk, wrists, arms.	

Medicine Details:

ZYPREXA (Suspected) Reason: Schizophrenia

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/08/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 133226
 Seq: 1
 Gender:
 F

 Reported:
 13/11/1998
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	toaction Botailei			
	Preferred Term	Severity	Report Description	Treatment
	Weight increased		Gained 3.25kg	
	Somnolence		Sedation	

Medicine Details:

ZYPREXA (Suspected) Reason: Schizophrenia

10.0 Milligram Daily

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Previous weight gain reported with other psychotropic medications.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 133227		Seq	Seq: 1			Gender: M		
Reported: 13/11/1998		_			Weight:			
ospitalisation	:					Ag	e:	
Onset Date:					DOB:			
Outcome	: Unknow	n				Causalit	y: Causality possible	
action Deta						ı		
	red Term	Se	everity	Repo	ort Descriptio	n	Treatment	
rectile dysfund	ction							
ledicine De				De-	son:			
Tablet	ecteu)		0.0	Rea	SOII:	Oral		
Batch:		ç	Started:		Stor	oped:	CONTIN	
aboratory l	nvestiga	ations:						
Date	Туре	Range	Date Tested	Result		De	etails	
dditional lı	nformati	on:						
ort Run: 04/06/2	007 04·20I	PM Database: p	usime02	^	DRS004		Dogo 205 -f	EOG
//Linuin. 04/00/2	001 04.291	ivi Dalabase. p	usilli c uz	P	ND13004		Page 295 of	ე∠ხ



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 133228
 Seq: 1
 Gender: M

 Reported:
 13/11/1998
 Weight:

Hospitalisation: Admitted to hospital **Age:** 47

Onset Date: 04/10/1998

Outcome: Unknown

DOB: 30/11/1950

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		90bpm to 120bpm.	
Hypertension		From 130/70 to 170/90.	
Blood creatine phosphokinase incr			
Catatonia			
Extrapyramidal disorder			
Hyperkinesia			
Hypertonia			
Leukocytosis			
Nausea			
Somnolence			
Syncope			Stemetil. ceased zyprexa

Medicine Details:

modifie Botano.		
ZYPREXA (Suspected)		Reason: Schizophrenia
Tablet	20.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 28/10/1998 4M
STEMETIL (Suspected)		Reason: Nausea and vomiting
Tablet	0.0	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
Ī		Creatine	U/LITER	04/10/1998	13820	
		Creatine	U/LITER	05/10/1998	6358	
		Creatine	U/LITER	07/10/1995	7889	
		Creatine	U/LITER	09/10/1998	5409	
		Creatine	U/LITER	20/10/1998	109	

Additional Information:

The patient was restarted on olazapine again on 10 oct 98 at a dose of 5mg which was increased to 10mg/day on 20 oct 98. the patient experiences severe drowisness. other reactions were weakness and delirium. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 133228
 Seq: 1
 Gender: M

 Reported:
 13/11/1998
 Weight:

Hospitalisation: Admitted to hospital **Age:** 47

Onset Date: 04/10/1998

Outcome: Unknown

DOB: 30/11/1950

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			

Medicine Details:

modifie Botano.		
ZYPREXA (Suspected)		Reason: Schizophrenia
Tablet	20.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 28/10/1998 4M
STEMETIL (Suspected)		Reason: Nausea and vomiting
Tablet	0.0	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

The patient was restarted on olazapine again on 10 oct 98 at a dose of 5mg which was increased to 10mg/day on 20 oct 98. the patient experiences severe drowisness. other reactions were weakness and delirium. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Case Number: 133229

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 13/11/1998	Weight:						
ospitalisation:		Age : 70Y					
Onset Date:		DOB:					
Outcome: Recovered			Causa	ality: Causality probable			
action Details:	T T			T			
Preferred Term	Severity	Report De	escription	Treatment			
ypothermia		emp 33 c degrees.		Zyprexa was discontinued fo two weeks and was commenced on clopixol.			
edicine Details:		Reason:					
	0.0						
Batch:	Started:		Stopped:	CONTIN			
YPREXA (Suspected)		Reason:					
Tablet	7.5 N	lilligram Daily					
Batch:	Started:		Stopped:				
aboratory Investigation	S: Range Date Tested	d Result		Details			
		1					
dditional Information:							



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 133233
 Seq: 1
 Gender: M

 Reported:
 16/11/1998
 Weight:

Hospitalisation: Age: 31

Onset Date: DOB: 16/05/1967

Outcome: Unknown Causality: Causality possible

Reaction Details:

tokonon bottanon						
	Preferred Term	Severity	Report Description	Treatment		
	Headache					

Medicine Details:

ZYPREXA (Suspected) Reason: Schizophrenia

10.0 Milligram Daily

Batch: Started: 12/09/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was commenced on zyprexa in sept 97 at 5mg, 12/9/97 dose was increased to 10mg which resulted in patient suferring symptoms, so dose was decreased to 7.5mg.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 133573	Seq: 1		Gend		
Reported: 23/11/1998			Weigl		
ospitalisation:				je: 16Y	
Onset Date:			DOB:		
Outcome: Unknown			Causaii	ty: Causality possible	
action Details: Preferred Term	Severity	Report De	ecription	Treatment	
herapeutic response decreased		Тероп Бе	SCIPTION	Heatinent	
/eight increased				Olanzapine discontinued.	
ledicine Details: DLANZAPINE (Suspected)		Reason:			
Tablet	0.0		Oral		
Batch:	Started:		Stopped:		
.aboratory Investigations Date Type Ra	: ange Date Tested	Result	D	etails	
Additional Information:					
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Case Number: 133747

Reported: 27/11/1998

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight:

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Hospitalisation:		Age : 38Y				
Onset Date:				OB: lity: Causality possible		
Outcome: Recove	red		Causanty:			
eaction Details:		T				
Preferred Term	Severity		Description	Treatment		
Weight increased		Patient has experiengain.	nced a 10kg weight			
Hyperkinesia	Required Specialist Consultation					
Nausea						
Nervousness						
Vomiting						
Medicine Details: OGEN (Other drug)		Reason	:			
Tablet	0.0	Da	nily Oral			
Batch:	Started:		Stopped:	CONTIN		
ZYPREXA (Suspected)		Reason	: Unspecified schizoph	nrenia		
Tablet	10.0	Milligram Da	-			
Batch:	Started:		Stopped:	CONTIN		
PROZAC (Suspected)		Reason	·			
Oral application		Milligram Da	nily Oral			
Batch:	Started:		Stopped:	CONTIN		
Laboratory Investig Date Type	ations: Range Date Tes	sted Result		Details		
Additional Informati	ion:					
eport Run : 04/06/2007 - 04:29	PM Database: nusime02	ΔDR	S004	Page 301 of 526		

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 133748
 Seq: 1
 Gender: M

 Reported:
 27/11/1998
 Weight:

Hospitalisation: Age: A8

Onset Date: 19/10/1998 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Pat collapsed while standing, bp 70/50.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of parkinson's disease.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 133749 Seq: 1 Gender: M

Reported: 27/11/1998 Weight:
Hospitalisation: Age: 83Y

Onset Date: 31/10/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Epileptic seizure.	Zyprexa dicontinued.

Medicine Details:

Medicine Details.			
ARICEPT (Other drug)			
	0.0		
Batch:	Started:	Stopped:	
CARDIZEM (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 15/10/1998	Stopped:	15/10/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of lewy body dementia and epilepsy. the patient had not experienced an epileptic seizure for appox. 5 years. reaction occured 6 hours after taking zyprexa. patient's dementia has appeared to have worsened as a result of the typical grand mal seizure. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 133753
 Seq: 1
 Gender: M

 Reported:
 27/11/1998
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
I	Dyskinesia		Dyskinetic movement of the mouth.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/01/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of organic mood disorder. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 133756 Seq: 1 Gender: F
Reported: 27/11/1998 Weight:
Hospitalisation: Age: AE

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced myoclonic twitches.	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other	AROXETINE HYDROCHLORIDE (Other drug)				
Tablet	40.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN
CARBAMAZEPINE (Other drug)			Reason:		
Tablet	400.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN
ZYPREXA (Suspected)			Reason:		
Tablet	10.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Olanzapine (zyprexa) was given at 2.5mg/day which was then increased to 10mg/day.

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Case Number: 133759

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 27/11/199		Weight:						
ospitalisation:		Age: 17Y						
Onset Date:				DO	B:			
Outcome: Not yet re	ecovered				Causalit	y: Causality poss	ible	
eaction Details:	<u>, </u>	1						
Preferred Term	Se	everity	Rep	ort Descrip	otion	Treatmer	nt	
Somnolence								
Weight increased								
Medicine Details:								
ZYPREXA (Suspected)				son:				
Tablet		15.0 Milli	gram	Daily	Oral			
Batch:	St	tarted:		;	Stopped:			
Laboratory Investigat	ions:							
Date Type	Range	Date Tested	Result		De	etails		
Additional Informatio	n:							
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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 133760
 Seq: 1
 Gender:
 F

 Reported:
 27/11/1998
 Weight:

Hospitalisation: Age: 25Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neurosis		Obsessive compulsive disorder.	Zyprexa ceased.

Medicine Details:

Medicine Details.					
MELLERIL (Other drug)			Reason:	Unspecified schizophrenia	
Tablet	50.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
ZYPREXA (Suspected)			Reason:	Unspecified schizophrenia	
Tablet	20.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Family history of obsessive compulsive disorder. after approx. 6 months, thioridazine was decreased to 50mg. at this dose, reactions first began, these worsened in severity as thioridazine was decreased to 25mg/d, olanzepine was then ceased and the patient began to improve. the thioridazine has also been ceased and patient continues to improve.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 133761	Seq: 1				G	ender: F			
Reported: 27/11/19		·			Weight:				
ospitalisation:						Age:			
Onset Date:						DOB:			
Outcome: Unknown	า				Cai	usality: Ca	ausality poss	ible	
action Details:									
Preferred Term	Severi			ort Desc			Treatmer	nt	
gitation		Pati	ent experien	ced pan	ic attacks.				
ledicine Details:									
YPREXA (Suspected)					Inspecified schi				
Tablet		5.0 Millio	gram	Daily		ral			
Batch:	Started	d:			Stopped:				
oborotory Investiga	tions:								
aboratory Investiga Date Type		e Tested	Result			Details			
7.									
dditional Informatio	on:								
	MA Datab	00		DDCcc :					
ort Run: 04/06/2007 04:29P	PM Database: pusime	:∪∠	P	DRS004			Page 308	ot 526	



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 13376 Reported: 27/11/	•		Gender: M Weight:				
ospitalisation:			Ag				
Onset Date:			DO				
Outcome: Unkno	wn		Causalit	y: Causality possible			
eaction Details:							
Preferred Tern	n Severity	Report Des	scription	Treatment			
Frectile dysfunction							
/ledicine Details:							
ZYPREXA (Suspected)	0.0	Reason:	0.751				
Tablet Batch:	0.0 Started:	Daily	Oral Stopped:				
				J			
_aboratory Investig							
Date Type	Range Date Test	ted Result	De	etails			
Additional Informa	tion:						
port Run: 04/06/2007 04:2	9PM Database: pusime02	ADRS00	4	Page 309 of 526			



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 133764	Seq: 1			Gender:	F	
Reported: 27/11/199	8			Weight:		
ospitalisation:				Age:	35Y	
Onset Date:				DOB:		
Outcome: Unknown				Causality:	Causality possib	ole
action Details:				1		
Preferred Term	Severity	-	rt Description	on	Treatment	
enstrual disorder		Menstral disturba	inces.			
edicine Details:						
YPREXA (Suspected) Tablet	0.0	Reas		Oral		
Batch:	Started:		Daily	opped:		
Batch.	Otartea.			рреи.		
aboratory Investigat	ions:					
Date Type	Range Date Tested	d Result		Detail	s	
dditional Informatio	n:					
ort Run: 04/06/2007 04:29PM	1 Database: pusime02	Δ	DRS004		Page 310	of 526
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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 133765
 Seq: 1
 Gender: M

 Reported:
 27/11/1998
 Weight:

Hospitalisation: Admitted to hospital Age: 44Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Psychotic disorder		Extrapyramidal syndrome. Pat. experienced a relapse of psychotic features.	Patient recommenced zyprexa treatment at 20mg/day. while hospitalised, the patient received diazepam and chlorpromazine to reduce the patient's distress.
Alopecia			

Medicine Details:

ZYPREXA (Suspected)		Reason:	Unspecified psychosis	
Tablet	20.0 Milligram	Daily	Oral	
Batch:	Started: 01/02/1998		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient originally began zyprexa treatment at 10mg/day in feb 98 but became non-compliant due to alopecia and had a relapse of psychotic features and was hospitalised. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 134222 Seq: 1 Gender: M

Reported: 11/12/1998 Weight: Hospitalisation: Age:

spitalisation: Age: 35Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Face oedema		Swelling of lips and mouth area.	Zyprexa discontinued.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of schizophrenia. patient commenced zyprexa after discontinuing resperidone.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 134223
 Seq: 1
 Gender: M

 Reported:
 11/12/1998
 Weight:

Hospitalisation: Admitted to hospital Age: 52Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia		· · · · · · · · · · · · · · · · · · ·	
Hypothermia			Zyprexa discontinued and recommenced at 1.25mg every second day.
Orthostatic hypotension			

Medicine Details:

 ZYPREXA (Suspected)
 Reason:
 Unspecified psychosis

 Tablet
 10.0 Milligram
 Daily
 Oral

 Batch:
 Started:
 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of psychosis, klinefelter's syndrome, epilepsy, alcohol abuse and sensitivity to anti-psychotics. the patient was previously treated with risperidone but discontinued treatment due to intolerance.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 134224 Seq: 1 Gender: F
Reported: 11/12/1998 Weight:

Hospitalisation: Hospitalisation prolonged Age: 56

Onset Date: DOB: 02/10/1942

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Pancreatitis			All medications ceased.	

Medicine Details:

ZYPREXA (Suspected)		Reason: Unspec	ified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 01/10/1998	Stop	oped: 28/11/1998	
SODIUM VALPROATE (Suspected)		Reason: Unspec	ified schizophrenia	
Tablet	0.0	Daily	Oral	
Batch:	Started:	Stop	oped: 28/11/1998	
LITHIUM CARBONATE (Suspected)		Reason: Unspec	ified schizophrenia	
Tablet	0.0	Daily	Oral	
Batch:	Started:	Stop	oped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

In early november the patient became suddenly ill overnight. she was transferred from the psychiatric unit to the intensive care unit. the doctor could not be certain that the pancreatitis was caused by olanzapine as there has been some association between valproate and pancreatitis in the literature, however, the patient had been maintained on valporate for greater than six months. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: 21/12/1998 ospitalisation: Onset Date: 11/12/1998 Outcome: Not yet recoveraction Details: Preferred Term leutropenia	vered Severity		,	Weight: 37 Age: 57 DOB:	
Onset Date: 11/12/1998 Outcome: Not yet recovaction Details: Preferred Term	ı				Υ
Outcome: Not yet recovaction Details: Preferred Term	ı			DOD.	
action Details: Preferred Term	ı		(
Preferred Term	Severity		'	Causality: Ca	ausality possible
	Severity				
eutropenia		Re	port Description		Treatment
edicine Details:					
OGENTIN (Other drug)	ſ	.0	eason:		
Batch:	Started:	0	Stopped		
/PREXA (Suspected)	Starteu.	R.		chizophrenia	
Oral application	F	.0 Milligram	Oral		
Batch:		5.0 Milligram Daily Started: 02/11/1998 Stopped:			
aboratory Investigation Date Type		ested Result		Details	
.,,,,,,	- iange				

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 134642
 Seq: 1
 Gender: M

 Reported:
 24/12/1998
 Weight:

Hospitalisation: Age: 70

Onset Date: DOB: 28/05/1928

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Zyprexa ceased

Medicine Details:

Medicine Details.				
SODIUM VALPROATE (Other drug)		Reason: Unspecified p	sychosis	
Tablet	800.0 Milligram	Daily	Oral	
Batch:	Started: 07/08/1998	Stopped:		CONTIN
ZYPREXA (Suspected)		Reason: Unspecified p	sychosis	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 04/08/1998	Stopped	04/09/1998	5W

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of mania, organic psychosis, mood disorder, myocardial infarction and a head injury sustained during infancy.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 134649
 Seq: 1
 Gender: M

 Reported:
 24/12/1998
 Weight:

Hospitalisation: Age: 50Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema		Severe pitted oedema of ankles.	Dr will reduce dose of zyprexa.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/11/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of schizophrenia. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	Jei. 134032	Seq. 1			Gender.	Г
_	ted: 24/12/1998				Weight:	AD
spitalisati					Age:	AD
Onset Da					DOB:	Oarraalita aarab abda
	ne: Recovered				Causality:	Causality probable
action De		Coverity	T Don	art Dagarini	tion	Tractment
arrhoea	eferred Term	Severity	Кер	ort Descript		Treatment orexa ceased.
edicine I			Por	son:		
Tablet		0.0		Son: Daily	Oral	
Batch		Started:	,		topped:	
borator	v Investigatio	one:				
Date			ested Result		Detail	S .
	,,					
Date	y Investigation	Range Date Te	ested Result		Detail	S
ort Run · 04/0	6/2007 04:29PM	Database: pusime02	,	ADRS004		Page 318 of 52

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 134654 Gender: F Seq: 1 Weight: Reported: 24/12/1998

Hospitalisation: Age: A2 **Onset Date:** DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence			

Medicine Details:				
LITHIUM CARBONATE (Other drug)		Reason:		
	0.0			
Batch:	Started:		Stopped:	CONTIN
ZYPREXA (Suspected)		Reason: L	Inspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/1997		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of schizo-affective disorder. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 134660 Seq: 1 Gender: M

Reported: 24/12/1998 Weight:
Hospitalisation: Age: AD

Onset Date: 15/11/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Low neutrophil count.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 12/06/1998 Stopped: CONTIN

Laboratory Investigations:

<u>Laborato</u>	i y ilittootiga				
Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		05/06/1998	2.1	
	Neutrophils		15/11/1998	1.7	

Additional Information:

Patient history: previous low neutrophil counts, no recent illness.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 134867 Seq: 1 Gender: M

Reported: 06/01/1999 Weight: 96.00 Hospitalisation: Age: 17Y

Onset Date: 11/12/1998 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

teaction Details.				
Preferred Term	Severity	Report Description	Treatment	
Tremor		Shaking of hands and arms		
Somnolence		Somnolent		
Fatigue		Very tired		
Agitation				

Medicine Details:

ZOLOFT (Other drug)			Reason:	Other atyp forms schizophrenia	
	100.0	Milligram	Daily		
Batch:	Started:	LT	ERM	Stopped:	
CLARATYNE (Other drug)	Reason:				
	1.0	Dose Unspec	ified Daily		
Batch:	Started:			Stopped:	
ZYPREXA (Suspected)		Reason:			
	10.0	Milligram	Daily		
Batch:	Started: 11	/12/1998		Stopped: 16/12/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

When risperdal recommenced on 20/12/98 shaking stopped.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 134992
 Seq: 1
 Gender:
 F

 Reported:
 08/01/1999
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Urticaria		Patient has experienced rash on arms and body.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/11/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The paitent had lesions approximately 2cm in diameter on her arms and body. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 134993
 Seq: 1
 Gender: M

 Reported:
 08/01/1999
 Weight:

Hospitalisation: Age: 15Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	todotion botanoi			
	Preferred Term	Severity	Report Description	Treatment
	Hepatic function abnormal		Elevated liver function.	
	Weight increased		Most weight gained in sep 98 went from 63 to 80kg.	
	Cushing's syndrome			

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified psychosisTablet5.0 MilligramDailyOral

Batch: Started: 01/08/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Associated with the weight gain the patient has numerous striae especially on his lower back and ingruinal region. the appearance of striae is making the patient anxious and reluctant to continue therapy. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 134994 Seq: 1 Gender: F

Reported: 08/01/1999 Weight:
Hospitalisation: Age: 40Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neurosis		Obsessional thoughts	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of unspecifed schizo-affective disorder. for the last three months, the patient has experienced obsessional thoughts. these thoughts include excess planning of her day and constant refining of her daily plan. the patient has no history or family history of obsessive compulsive disorder. pt stopped zyprexa and recovered. recommenced the drug again and same reaction occurred.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 134995
 Seq: 1
 Gender:
 F

 Reported:
 08/01/1999
 Weight:

Hospitalisation: Age: 52Y
Onset Date: 06/12/1998 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Both ankles, calves and hands.	

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Other drug)			Reason:	Unspecified schizophreni	a
	800.0	Milligram	Mont	hly	
Batch:	Started:			Stopped:	CONTIN
TEGRETOL (Other drug)			Reason:		
Tablet	300.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN
ZYPREXA (Suspected)			Reason:	Unspecified schizophreni	a
Tablet	10.0	Milligram	Daily	Oral	
Batch:	Started: 27	/11/1998		Stopped:	CONTIN
VENLAFAXINE HYDROCHLORIDE (Suspect	ted)		Reason:		
Tablet	150.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The doctor is going to continued the patient on olanzapine, hoping that the oedema will abate. the patient has not tolerated many antipsychotics in the past and the doctor stated that they are running out of treatment options.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 135344
 Seq: 1
 Gender: F

 Reported:
 22/01/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 55Y
Onset Date: 11/12/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Drug ineffective			
Neutropenia			Zyprexa ceased and the patient was transferred to haloperidol.

Medicine Details:

<u>Medicine Details:</u>			
BENZYDAMINE HYDROCHLORIDE	E (Other drug)	Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 01/12/1998	Stopped: 28/12/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		15/05/1998	3.47	
	Neutrophils		11/12/1998	1.08	
	Neutrophils		12/12/1998	1.7	
	White blood cells		15/05/1998	5.6	
	White blood cells		11/12/1998	2.7	
	White blood cells		12/12/1998	3.5	

Additional Information:

The patient's previous medication was fluphenazine. the patient was experiencing a relapse of her schizophrenia so it was decided to change the patient onto zyprexa starting at 5mg daily. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:		
Case Number: 135346	Seq: 1	Gender: F
Reported: 22/01/1999		Weight:

Hospitalisation: Age: 34

Onset Date: DOB: 28/01/1964
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Reaction Details:			
Preferred Term	Severity	Report Description	Treatment
Weight increased		Patient has gained 7-8kg.	
Oedema peripheral		Patient wrists, fingers.	
Asthenia		Tiredness.	
Dizziness			
Gravitational oedema			
Tremor			Patient is currently taking risperidone at 3mg/day.

Medicine Details:

ZYPREXA (Suspected)		Reason:	Unspecified psychosis
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started : 24/08/1998		Stopped: 17/11/1998

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 135352
 Seq: 1
 Gender: M

 Reported:
 22/01/1999
 Weight:

Hospitalisation: Age: 40Y

Onset Date: 30/03/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	todotion Details.			
	Preferred Term	Severity	Report Description	Treatment
	Oedema peripheral			
	Weight increased			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 15.0 Milligram Daily Oral

Batch: Started: 03/11/1997 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

After zyprexa treatment was reduced it was reported that the peripheral oedema was still mildly present and the patient's weight gain had plateaued.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 135357 Seq: 1 Gender: F

Reported: 22/01/1999 Weight:
Hospitalisation: Age: 38Y

Onset Date: 31/12/1998 **DOB:**

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botanor			
Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		Physician prescribed overdose.	Zyprexa has been ceased and the patient's psychosis is being treated with ect and risperidone.

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified schizophreniaTablet50.0 MilligramDailyOral

Batch: **Started**: 01/12/1998 **Stopped**: 28/12/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Electrocardiograph				Ecg showed a qtc prolongation.

Additional Information:

It is believed the qt interval prolongation was due to the high dose of zyprexa. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 135359 Seq: 1 Gender: F
Reported: 22/01/1999 Weight:
Hospitalisation: Age: AD

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	<u>toaotion Dotanoi</u>			
	Preferred Term	Severity	Report Description	Treatment
	Nervousness		Patient restless and began pacing the room.	
	Hyperkinesia			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

It is unknown if the patient was taking any other medication.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 135753
 Seq: 1
 Gender:
 F

 Reported:
 01/02/1999
 Weight:

Hospitalisation: Age: 22

Onset Date: 01/01/1999 **DOB**: 24/01/1976

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Confusional state	Life threatening		Cipramil and olanzapine discontinued
Coordination abnormal			
Fatigue			
Insomnia			
Nystagmus			
Salivary hypersecretion			

Medicine Details:

	Reason:	
40.0 Milligram	Daily Oral	
Started: 01/11/1998	Stopped: 31/12	2/1998
	Reason: Unspecified schizoph	nrenia
20.0 Milligram	Daily Oral	
Started: 01/09/1998	Stopped: 31/12	2/1998
	40.0 Milligram Started: 01/11/1998 20.0 Milligram	Started: 01/11/1998 Stopped: 31/12 Reason: Unspecified schizopl 20.0 Milligram Daily Oral

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

The patient had a bad car accident the day after ceasing medication. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 135782 Seq: 1 Gender: M

Reported: 03/02/1999

Hospitalisation:
Onset Date:

Weight: 85.00
Age: 45Y
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia		Not in male pattern- generalised scalp thinning.	

Medicine Details:

OLANZAPINE (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/02/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No other evident cause. needs to stay on it - brittle psychosis, best yet treatment. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Gender: F Case Number: 135851 Seq: 1 Weight: Reported: 05/02/1999

Hospitalisation: Age: Onset Date: 31/12/1998 DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
	Pulmonary embolism			
	Thinking abnormal			Ceased zyprexa

Medicine Details:						
PREDNISOLONE (Suspected)			Reason:			
	0.0					
Batch:	Started:			Stopped:		
ZYPREXA (Suspected)			Reason:			
Tablet	10.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:	17/12/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient died on approximately 26/12/98. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 135852 Seq: 1 Gender: F

Reported: 05/02/1999 Weight: Hospitalisation: Age: A3

Onset Date: 31/12/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Rash pustular		Rash on face	
Weight increased		Weight increase of 5 kilograms.	
Somnolence			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/12/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

For 48 hours after commencing zyprexa treatment patient experienced symptoms. approximately 1 week after commencing treatment with zyprexa experienced further symptoms. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

lospitalisatio Onset Da Outcon	ed: 05/02/1999 on: ate: ne: Not yet rec			Weig A De	ler: M ht: ge: A1 OB: ity: Causality possible
eaction De	etails: ferred Term	Severity	Report		Treatment
- - - - - - - - - - - - - - - - - - -			cess sweating	-	
Medicine [ZYPREXA (Su			Reason	:	
Tablet	:	0.0		Oral	
Batch	n:	Started:		Stopped:	CONTIN
_aboratory	y Investigati Type	ons: Range Date Tested	Result	[Details
	1,712		1100011		
Additional	Information	ı:			
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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 135890
 Seq: 1
 Gender:
 F

 Reported:
 08/02/1999
 Weight:

Hospitalisation: Age: 56Y
Onset Date: 11/12/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

vieuicine Details.		
LARGACTIL (Other drug)		Reason: Unspecified schizophrenia
	25.0 Milligram	1 time
Batch:	Started: 10/12/1998	Stopped : 10/12/1998
COGENTIN (Other drug)		Reason: Other&unspecif brain diseases
Oral application	2.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia
Oral application	5.0 Milligram	Daily Oral
Batch:	Started: 01/11/1998	Stopped: 28/12/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		05/05/1998	3.47	
	Neutrophils		11/12/1998	1.08	
	Neutrophils		12/12/1998	1.7	
	Neutrophils		14/12/1998	1.71	
	Neutrophils		22/12/1998	1.92	
	White blood cells		05/05/1998	5.6	
	White blood cells		11/12/1998	2.7	

Additional Information:

Patient recovering. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 135890
 Seq: 1
 Gender:
 F

 Reported:
 08/02/1999
 Weight:

Hospitalisation:
Onset Date: 11/12/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

vieuicine Details.			
LARGACTIL (Other drug)		Reason: Unspecified schizophrenia	
	25.0 Milligram	1 time	
Batch:	Started: 10/12/1998	Stopped: 10/12/1998	
COGENTIN (Other drug)		Reason: Other&unspecif brain diseases	
Oral application	2.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Oral application	5.0 Milligram	Daily Oral	
Batch:	Started: 01/11/1998	Stopped: 28/12/1998	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ		White blood cells		12/12/1998	3.5	
١		White blood cells		14/12/1998	3.8	
ı		White blood cells		22/12/1998	4.0	

Additional Information:

Patient recovering. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Panic attacks for 3 mo Panic attacks for 3 mo Reason: 5.0 Milligram Daily ted: 30/04/1998	from 5mg.
Panic attacks for 3 mo Reason: 5.0 Milligram Daily	Olanzapine reduced to 2.5mg from 5mg. Schizophrenia ily Oral
Panic attacks for 3 mo Reason: 5.0 Milligram Daily	Olanzapine reduced to 2.5mg from 5mg. Schizophrenia ily Oral
5.0 Milligram Daily	Schizophrenia ily Oral
5.0 Milligram Daily	ily Oral
teu. 30/04/1996	эторрей.
ate Tested Result	Details
) &	ate Tested Result

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 136415 Seq: 1 Gender: F

Reported: 19/02/1999 Weight:
Hospitalisation: Age: 64Y

Onset Date: 31/01/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vaginal haemorrhage		Vaginal bleeding lasting 4 days.	

Medicine Details:

ZYPREXA (Suspected) Reason: Schizophrenia

0.0

Batch: Started: Stopped:

ZOLOFT (Suspected) Reason: Depression

Tablet 50.0 Milligram Daily Oral

Batch: Started: 12/01/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Report Details:

Case Number: 136516

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 19/02/1999				Weight:		
ospitalisation:		Age:				
Onset Date:				DOB	:	
Outcome: Not yet recovered	ed		С	ausality	: Causality poss	ible
eaction Details:				T		
Preferred Term	Severity	Report	Description		Treatmer	
ausea				Do to di	ose of zyprexa wa 45mg from 50mg, d not resolve.	s reduced events
omiting						
ledicine Details:						
ZYPREXA (Suspected)		Reaso	n:			
Tablet	50.0 Mil	ligram D	aily	Oral		
Batch:	Started:		Stopped:		CONTIN	
_aboratory Investigations:						
	nge Date Tested	Result		Deta	ils	
dditional Information:						
uditional information:						
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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 136517
 Seq: 1
 Gender: M

 Reported:
 19/02/1999
 Weight:

Hospitalisation: Age: 38Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

touotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Delusion		Increased delusional ideation	
Neurosis		Violent behaviour (hostility).	Ceased zyprexa
Psychotic disorder			

Medicine Details:

BENZTROPINE MESYLATE (Other drug)		Reason:	
Oral application	1.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1995	Stopped:	CONTIN
CLONAZEPAM (Other drug)		Reason:	
Oral application	1.0 Milligram	Daily Oral	
Batch:	Started: 10/11/1997	Stopped:	CONTIN
HALDOL DECANOATE (Other drug)		Reason:	
Injection	175.0 Milligram	Alternate weeks Intram	uscular
Batch:	Started: 01/01/1999	Stopped:	CONTIN
ALCOHOL (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: Reported: Hospitalisation: Onset Date: Outcome:	19/02/1999	Seq: 1			Gender: Weight: Age: DOB: ausality:	38Y	
Reaction Detai	ls:						
Medicine Deta			Reason:	Schizophrenia			_
Tablet	itou)	20.0 Milligram	Daily	Comzopinema	Oral		
Batch:		Started: 12/01/1999		Stopped:	18/01/1999		
Laboratory In	vestigations:						
Additional Inf the dosage start da accurate but indica	ate is not accurate b	out indicates that start occurr red sometime during the yea	ed sometim r.	ne during the y	ear. the do	osage start date is not	

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 136603 Seq: 1 Gender: F

Reported: 24/02/1999 Weight:
Hospitalisation: Age: 18Y

Onset Date: 18/11/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 15/11/1998 Stopped: CONTIN

Laboratory Investigations:

	.,				
Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		30/10/1998	21	
	ALT = SGPT		18/11/1998	158	
	ALT = SGPT		20/11/1998	96	
	ALT = SGPT		26/11/1998	38	
	ALT = SGPT		03/12/1998	31	
	GGT = SGGT =		30/10/1998	21	
	GGT = SGGT =		18/11/1998	240	

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 136603 Seq: 1 Gender: F

Reported: 24/02/1999 Weight:
Hospitalisation: Age: 18Y

Onset Date: 18/11/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 15/11/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =		20/11/1998	200	
	GGT = SGGT =		26/11/1998	149	
	GGT = SGGT =		03/12/1998	118	
	SAP = ALP		30/10/1998	-	
	SAP = ALP		18/11/1998	-	
	SAP = ALP		20/11/1998	173	
	SAP = ALP		26/11/1998	148	

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Deta	24/02/199 18/11/199 Recovered	8	1		Weig Aç DC	ler: F ht: ge: 18Y DB: ity: Causality possible
Medicine Det						
ZYPREXA (Suspe	cted)				son: Unspecified psychosis	3
			10.0 Milli		Daily	
Batch:		S	tarted: 15/11/19	998	Stopped:	CONTIN
Laboratory Ir			1			
Date	Type = ALP	Range	Date Tested	Result		Details
Additional In		n:	03/12/1998	-		

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 136668	Seq: 1		Gender: M			
Reported: 26/02/1999		Weight:				
spitalisation:			Age:			
Onset Date:			DOB:			
Outcome: Unknown		Ca	usality: Causality possible			
action Details:						
Preferred Term	Severity	Report Description	Treatment			
espiratory depression						
omnolence						
edicine Details:						
DLANZAPINE (Suspected)		Reason:				
	0.0					
Batch:	Started:	Stopped:				
aboratory Investigatio	ns:					
Date Type	Range Date Tested	Result	Details			
dditional Information:						
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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 136917
 Seq: 1
 Gender:
 F

 Reported:
 04/03/1999
 Weight:

Hospitalisation:
Onset Date: 17/02/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Hemiparesis		Left sided weakness	Zyprexa ceased
Dysphagia			
Somnolence			

Medicine Details:

LOSEC (Other drug)		Reason:	Other diseases of esophage	jus
	20.0 Milligram	Daily		
Batch:	Started: 05/12/1998		Stopped:	CONTIN
ALPHA-TOCOPHEROL (Other drug)		Reason:		
	2.0 Gram	Daily		
Batch:	Started: 19/01/1999		Stopped:	CONTIN
ZYPREXA (Suspected)		Reason:	Unspecified psychosis	
	5.0 Milligram	Daily		
Batch:	Started: 16/02/1999		Stopped: 18/02/1999)

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt had a similar reaction to doxepin.



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 137153
 Seq: 1
 Gender:
 F

 Reported:
 10/03/1999
 Weight:

Hospitalisation:
Onset Date:
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nightmare			

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)	l	Reason: Unspecified psychosis	
Tablet	10.0 Milligram	As necessary Oral	
Batch:	Started:	Stopped:	CONTIN
OROXINE (Suspected)	ı	Reason: Thyroiditis	
Tablet	150.0 Microgram	As necessary Oral	
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No nightmares on 5mg zyprexa

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 137155
 Seq: 1
 Gender: M

 Reported:
 10/03/1999
 Weight:

Hospitalisation: Age: 27Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nightmare			

Medicine Details:

ALCOHOL (Other drug)	Reason:					
	6.0 Dose Uns					
Batch:	Started:	Stopped:				
ZYPREXA (Suspected)		Reason: Unspecified psychosis				
Tablet	7.5 Milligram	As necessary Oral				
Batch:	Started:	Stopped:	CONTIN			
CIPRAMIL (Suspected)		Reason: Unspecified psychosis				
Tablet	40.0 Milligram	Daily Oral				
Batch:	Started:	Stopped:	CONTIN			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

10-20 cigarettes daily and 6 stubbies a week. nightmares occuring on 5mg zyprexa worse when dose increased

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 137360 Seq: 1 Gender: M
Reported: 17/03/1999 Weight:
Hospitalisation: Age: 21Y

Onset Date: 05/02/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis			

Medicine Details:

SODIUM VALPROATE (Suspected) Reason: Convulsions

400.0 Milligram Daily

Batch: **Started**: 14/01/1999 **Stopped**: 05/02/1999

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

20.0 Milligram Daily

Batch: Started: 01/01/1998 Stopped: 05/02/1999

Laboratory Investigations:

<u> </u>	atory invoctigationer				
Date	Date Type R		ype Range Date Tested Resu		Details
	Liver biopsy				Liver biopsy: likely acute hepatitis secondary to sodium valproate.

Additional Information:

Comcommitant hepatitis c exposure/infection. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 137551
 Seq: 1
 Gender: M

 Reported:
 19/03/1999
 Weight:
 65.00

Hospitalisation: Hospitalisation prolonged Age: 75Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

reaction Details.				
Preferred Term	Severity	Report Description	Treatment	l
Aggression				l
Agitation			Ceased aricept, serenace prn	ĺ
Tremor				l

Medicine Details:

ARICEPT (Suspected)

Tablet

0.0

Batch:

Started: 01/02/1998

Reason:

Presenile dementia

Oral

Stopped: 11/02/1999

Reason:

Tablet 1.0 Dose Unspecified Daily Oral

Batch: Started: 13/02/1999 Stopped: 14/02/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Please see original report for details of other drugs - lipex,aspirin, euhypnos. patient has alzheimers with only moderate agitation. zyprexa was tried but symptoms worsened. patient has deteriorated to nursing home care. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Weight:

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Reported: 19/03/1999

Case Number: 137593 Seq: 1 Gender: F

Hospitalisation: Age: 53

Onset Date: 31/01/1999 **DOB**: 26/04/1945

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Convulsion		Numerous small petit mal seizure the past few days	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/12/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - phenytoin, carbamazepine and sodium valproate. the patient has a history of schizophrenia and controlled epliepsy. zyprexa is the only medication that has recently been changed. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

ase Number:	137594	Seq: 1					Gender: F	:	
Reported:		-					Weight:		
spitalisation:							Age:		
Onset Date:							DOB:		
Outcome:	Unknown					C	ausality: C	Causality poss	ible
<u>iction Detai</u>		ı	-						
	ed Term	Seve			ort Desc			Treatmer	nt
sh maculo-par	oular		Ra	sh after 2 day	s of taki	ng zyprexa.	Ceas	ed zyprexa	
edicine Deta					son:				
Tablet			5.0 Milli	igram	Daily		Oral		
Batch:		Start	ed:			Stopped:			
aboratory In	vestigați	ons:							
Date	Туре	Range Da	ate Tested	Result			Details		
dditional Inf	ormation	n:							
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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 137595 Seq: 1 Gender: M

Reported: 19/03/1999 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

,	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Muscle twitching		Muscle twitching.	
	Photosensitivity reaction			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 7.5 Milligram Daily Oral

Batch: Started: 01/03/1997 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient noticed that when he stayed out of the sun, his muscle twitching improved. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 137596 Seq: 1 Gender: F
Reported: 19/03/1999 Weight:
Hospitalisation: Age:

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			
Muscle twitching			
Tardive dyskinesia			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/08/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - trifluoperazine and clonazepam. zyprexa treatment was introduced at 5mg per day and was increased to 10mg per day. the patient experienced movement disorders such as tics and mouth movements. the dose was then reduced to 5mg per day and the movements resolved. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 137597 Seq: 1 Gender: F
Reported: 19/03/1999 Weight:
Hospitalisation: Age: 69Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion botano.			
Preferred Term	Severity	Report Description	Treatment
Rash		Swelling & skin peeling after sunning herself.	
Photosensitivity reaction			The patient was treated with betamethasone which alleviated the rash. ceased zyprexa

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified schizophreniaTablet10.0 MilligramDailyOralBatch:Started:Stopped:08/02/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - benzathopine & fluphenazine.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details	:	
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Case Number: 137598 Seq: 1 Gender: M
Reported: 19/03/1999 Weight:
Hospitalisation: Age: 52Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blepharitis			

Medicine Details:

ZYPREXA (Suspected)	Reason:				
Tablet	0.0	Daily	Oral		
Batch:	Started:	Stop	pped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient commenced zyprexa treatment approximately 6 months ago. for the entire treatment period the patient has experienced blepharitis.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 137599 Seq: 1 Gender: M
Reported: 19/03/1999 Weight:

Hospitalisation: Age: 19Y

Onset Date: 10/02/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u>reaction Details.</u>			
Preferred Term	Severity	Report Description	Treatment
Flushing			
Hyperkinesia			
Mydriasis			Zyprexa increased back to 20mg/day and diazepam was given for three days.
Vasodilatation			

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified psychosisTablet15.0 MilligramDailyOral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of drug induced psychosis.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 137600 Seq: 1 Gender: F

Reported: 19/03/1999 Weight:
Hospitalisation: Age: 51Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary retention			Ceased zyprexa

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 5.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - sinequin, largactil and valium.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 137601
 Seq: 1
 Gender: M

 Reported:
 19/03/1999
 Weight:

Hospitalisation: Age: 14Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	<u> </u>				
	Preferred Term	Severity Report Description		Treatment	
			Pat experienced 2 epileptic seizures within 24 hrs	Ceased zyprexa	

Medicine Details:

ZYPREXA (Suspected) Reason: Behavior disorders of childhod

Tablet 2.5 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

See original report for other drug details - clonidine and zoloft. the patient has no history of epilepsy, but has mild mental retardation.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Onset Date: Outcome: Not yet recovered Iction Details: Preferred Term Sev Urosis Edicine Details: OGENTIN (Suspected) Batch: Sta ENADRYL (Suspected) Batch: Sta OGADON (Suspected) Batch: Sta	erity	Repor	Weig A D Causa rt Description	der: M ght: age: OB: lity: Causality possible Treatment
spitalisation: Onset Date: Outcome: Not yet recovered action Details: Preferred Term Seveurosis edicine Details: COGENTIN (Suspected) Batch: Sta MOGADON (Suspected) Batch: Sta			Causa	oge: OB: lity: Causality possible
Onset Date: Outcome: Not yet recovered action Details: Preferred Term Sev eurosis edicine Details: COGENTIN (Suspected) Batch: Sta BENADRYL (Suspected) Batch: Sta MOGADON (Suspected) Batch: Sta			rt Description	OB: lity: Causality possible
Preferred Term Seveurosis edicine Details: COGENTIN (Suspected)			rt Description	
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ZYPREXA (Suspected)		Reas	on:	
ZYPREXA (Suspected)	0.0			
	rted:		Stopped:	CONTIN
		Reas		nrenia
	10.0 Milligra	ram	Daily Oral	
Batch: Sta	rted: 01/11/1998		Stopped:	CONTIN
<u> </u>	1001 0 17 1 17 100		оторрош.	
aboratory Investigations:				
	Date Tested	Result		Details
7,				-

Additional Information:

Patient also taking benzodiazepine. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Report Details:

Case Number: 137603

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 19/03/1999		Weight:				
ospitalisation:		Age: 20Y				
Onset Date:		DOB:				
Outcome: Not yet recov	ered		Causality: Causality possible			
eaction Details:	Coverity	Danant Daa	- windian	Tractment		
Preferred Term	Severity	Report Des	cription	Treatment		
Bronchospasm Veight increased						
Medicine Details:						
ZYPREXA (Suspected)		Reason: (Otr spec symp psychor	pathol nec		
Tablet	2.5 Milligra	am Daily	Oral			
Batch:	Started:		Stopped:	CONTIN		
_aboratory Investigatior	ne:					
Date Type	Range Date Tested	Result	De	etails		
Additional Information:						



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 137726 Seq: 1 Gender: M

Reported: 25/03/1999

Hospitalisation:
Onset Date:

Weight: 95.00
Age: 45Y
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/02/1999 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Ct scan normal

Additional Information:

Loss of coordination in learned activities as bowling. drive a car. (merely a loss of proficiency). it's a minor problem - benefits certainly outweight disadvantages. see original report for details of lithium. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 137756 Seq: 1 Gender: M

Reported: 23/03/1999 Weight:

Hospitalisation: Age: 27Y
Onset Date: 26/02/1999
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Ceased olanzapine

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 5.0 Milligram Daily Oral

Batch: Started: 23/02/1999 **Stopped:** 27/02/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Please see original report for details of other drugs - enalapril.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 137792
 Seq: 1
 Gender: M

 Reported:
 26/03/1999
 Weight:

Hospitalisation: Age: 26Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Delusion		Grandiose delusions.	
Mania			Ceased olanzapine. instituted lithicarb (now 750mg bd).
Nervousness			

Medicine Details:

MELLERIL (Suspected)		Reason: Disturbance of sleep	
	100.0 Milligram	As necessary	
Batch:	Started: 29/01/1999	Stopped:	
DIAZEPAM (Suspected)		Reason: Disturbance of sleep	
	10.0 Milligram	As necessary	
Batch:	Started: 29/01/1999	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
	10.0 Milligram	Daily	
Batch:	Started: 27/01/1999	Stopped: 02/02/1999	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - clopixol depot.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 138160 Seq: 1 Gender: F

Reported: 07/04/1999

Hospitalisation:
Onset Date:

Weight: 85.00
Age: 27Y
DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash vesicular		Non-itchy vesicular rash on arms	Simple drying agents

Medicine Details:

ZYPREXA (Suspected)

Tablet

5.0 Milligram

Daily

Oral

Batch:

Started: 01/05/1998

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Zyprexa ceased for a short time - rash settled. came back when zyprexa restarted. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 138239
 Seq: 1
 Gender: M

 Reported:
 06/04/1999
 Weight:

Hospitalisation: Age: 27

Onset Date: 14/02/1999 **DOB**: 07/02/1972

Outcome: Recovered Causality: Causality possible

Reaction Details:

iteaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Agitation			
Hallucination			
Paranoia			

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)		Reason: Schizophrenia	
Tablet	30.0 Milligram	Daily Oral	
Batch:	Started: 01/02/1999	Stopped:	CONTIN
ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily Oral	
Batch:	Started: 08/02/1999	Stopped:	CONTIN

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient began zyprexa 10mg/day. on the 9/2/99 the dose was increased to 5mg mane and 20mg nocte. on 15/2/99 dose was further increased to 30mg given in one dose at night. zoloft was started on 8/2/99 at 50mg nocte. on 16/2/99 dose was increased to 50mg twice a day. the dose was later reduced to 50mg nocte.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 138240
 Seq: 1
 Gender:
 F

 Reported:
 06/04/1999
 Weight:

Hospitalisation: Age: 40

Onset Date: DOB: 15/11/1958

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			Dosage of zuclopenthixol was reduced from 100mg forthnightly to 50mg forthnighly. zyprexa was reduced to 7.5mg daily from 10mg daily, then ceased.
Hepatic function abnormal			

Medicine Details:

Medicine Details.				
ZUCLOPENTHIXOL DECANOATE (Sus	pected)	Reason: Schizoph	renia	
Oral application	100.0 Milligram	Fortnightly	Oral	
Batch:	Started: 12/01/1999	Stopp	oed:	
ZYPREXA (Suspected)		Reason: Schizoph	renia	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 06/01/1999	Stopp	oed:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		08/01/1999	13	
	ALT = SGPT		17/02/1999	131	
	Other data				Ultrasound showed mild fatty infiltration of the liver

Additional Information:

Hsitory of marijuana, Isd and alcohol abuse until 1984. patient started on zyprexa on 5mg/day and then increased to 10mg/day which caused severe symptoms.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 138241
 Seq: 1
 Gender:
 F

 Reported:
 06/04/1999
 Weight:

Reported: 06/04/1999

Hospitalisation:
Onset Date:

Weight:
Age: 41Y
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Rash on face, arms and trunk.	Ceased zyprexa.

Medicine Details:

ZYPREXA (Suspected)

Tablet

5.0 Milligram

Daily

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The rash persisted for a while but then worsened in severity.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 138422 Seq: 1 Gender: M

Reported: 14/04/1999 **Weight:** 100.00

Hospitalisation: Age: 82

Onset Date: DOB: 04/09/1916

Outcome: Recovered Causality: Causality possible

Reaction Details:

١,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Hepatic function abnormal		Abnormal lft's.	
	Coordination abnormal		Worsening mobility.	
	Pyrexia			Treated with iv ceftriaxone, gentamicin & metronidazole. olanzapine ceased.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: Started: 01/02/1999 **Stopped:** 23/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Ck was 251.
	Erythrocyte				Esr was elevated at 75.
	GGT = SGGT =				Ggt over 600.
	Haematology				Lft's were abnormal with a predominantly cholestatic picture. after 6 days of antibiotic therapy, his lft's worsened slightly. within 36 hours of ceasing olanzapine his lft's continued to worsen.

Additional Information:

See original report for other drug details - lasix, digoxin & ginemet m. previously on respiridone, changed because of poor mobility. the patient has underlying cholelithiasis, but i believe essentially this is asymptomatic. an ercp was performed on 1st april. the ducts did not look dilated and there was no eveidence of an intraductal stone, but a sphincterotomy was performed. following this, his lft's have started to improve. long history of paranoid schizophrenia. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 138422 Seq: 1 Gender: M

Reported: 14/04/1999 **Weight:** 100.00

Hospitalisation: Age: 82
Onset Date: DOB: 04/09/1916

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: **Started**: 01/02/1999 **Stopped**: 23/03/1999

Laboratory Investigations:

Laborato	oratory investigations.				
Date	Туре	Range	Date Tested	Result	Details
	Other data				An upper abdominal ultrasound performed on the day of admission in bendio showed multiple gall bladder stones with a contracted gall bladder.
	Protein				C-reactive protein was 179.
	SAP = ALP				Alkaline phosphatase over 400.
	White blood cells				White cell count was 8.0.

Additional Information:

See original report for other drug details - lasix, digoxin & ginemet m. previously on respiridone, changed because of poor mobility. the patient has underlying cholelithiasis, but i believe essentially this is asymptomatic. an ercp was performed on 1st april. the ducts did not look dilated and there was no eveidence of an intraductal stone, but a sphincterotomy was performed. following this, his lft's have started to improve. long history of paranoid schizophrenia. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 138507
 Seq: 1
 Gender: M

 Reported:
 19/04/1999
 Weight:

Hospitalisation: Age: 31Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome			
Hyperhidrosis			
Nausea			
Vertigo			
Visual disturbance			
Vomiting			

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified schizophreniaTablet10.0 MilligramDailyOral

Batch: Started: 01/10/1997 Stopped: CONTIN

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

The events ceased when the patient recommenced the zyprexa treatment. please see original report for details of other drugs - venlafaxine. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 139144
 Seq: 1
 Gender:
 F

 Reported:
 03/05/1999
 Weight:

Hospitalisation: Age: AD
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction		Photosensitivity rash	

Medicine Details:

ZYPREXA (Suspected) Reason: Othr&unspec metabolic diseases

Tablet 0.0 Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient discontinued zyprexa and symptoms resolved. the patient recommenced treatment as the patient needs the medication to control schizophrenia.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 139146 Seq: 1 Gender: F

 Reported:
 03/05/1999
 Weight:

 Hospitalisation:
 Age:

 Onset Date:
 15/02/1999
 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Leukopenia			Zyprexa and sodium valproate were ceased and recommenced on clonazepam and haloperidol.

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: 18/12/1998 **Stopped:** 05/03/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	(2-8)	07/07/1995	6.2	
	Neutrophils	(2-8)	17/10/1998	3.9	
	Neutrophils	(2-8)	15/02/1999	2.3	
	Neutrophils	(2-8)	06/02/1999	1.6	
	Neutrophils	(2-8)	05/03/1999	1.26	
	Neutrophils	(2-8)	07/03/1999	3.43	
	Neutrophils	(2-8)	06/03/1999	2.3	

Additional Information:

Please see original report for details of other drugs - valproate sodium.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 139146 Seq: 1 Gender: F

Reported: 03/05/1999 Weight:
Hospitalisation: Age:
Onset Date: 15/02/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: 18/12/1998 **Stopped:** 05/03/1999

Laboratory Investigations:

<u> </u>	.,				
Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	(2-8)	04/03/1999	1.75	
	Neutrophils	(2-8)	24/02/1999	2.8	
	White blood cells	(4-11 X 109/L)	07/07/1995	9.4	
	White blood cells	(4-11 X 109/L)	17/10/1998	7	
	White blood cells	(4-11 X 109/L)	06/02/1999	3.5	
	White blood cells	(4-11 X 109/L)	15/02/1999	4.9	
	White blood cells	(4-11 X 109/L)	24/02/1999	5.7	

Additional Information:

Please see original report for details of other drugs - valproate sodium.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 139146 Seq: 1 Gender: F

Reported: 03/05/1999 Weight:
Hospitalisation: Age:
Onset Date: 15/02/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: 18/12/1998 **Stopped:** 05/03/1999

Laboratory Investigations:

	,				
Date	Туре	Range	Date Tested	Result	Details
	White blood cells	(4-11 X 109/L)	04/03/1999	4.1	
	White blood cells	(4-11 X 109/L)	05/03/1999	3.2	
	White blood cells	(4-11 X 109/L)	06/03/1999	4.5	
	White blood cells	(4-11 X 109/L)	07/03/1999	5.9	

Additional Information:

Please see original report for details of other drugs - valproate sodium.

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Report Details:

Case Number: 139148

Reported: 03/05/1999

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight:

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

ospitalisatio	on:							Αg	je: A3
Onset Da			DOB:						
	ne: Not yet reco	overed					Ca	usali	ty: Causality possible
action De				_					
Pre	ferred Term	Se	verity		Repo	rt Desc	ription		Treatment
omnolence									Ceased lithium and decreased zyprexa to 5mg daily.
edicine [YPREXA (Su					Reas	on:			
Tablet			10.0	Milligram	11603	Daily		Oral	
Batch		Si	tarted:	wiiiigiaiii		Duny	Stopped:	O I GI	CONTIN
	BONATE (Suspect				Reas	on:			
Tablet		- · · ,	750.0	Milligram		Daily		Oral	
Batch	٠.	S	tarted:	J		,	Stopped:		
	y Investigatio								
Date	Туре	Range	Date Tes	ted Res	sult			D	etails
\dditional	Information	:		•	•				
oort Run : 04/0	6/2007 04:30PM	Database: pu	usime02		Al	DRS004			Page 377 of 526



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

lospitalisatio Onset Da Outcon	ed: 03/05/1999 on: ite: ne: Recovered		Gender: M Weight: Age: A3 DOB: Causality: Causality possible				
eaction De		Coverity	Dana	ut Decemention	Trantment		
Somnolence	ferred Term	Severity	Кероі	rt Description	Treatment Zyprexa reduced from 10mg daily to 2.5mg.		
Medicine E ZYPREXA (Su Tablet Batc h	spected)	10.0 N Started:	Reas Milligram	on: Unspecified schizo Daily Ora Stopped:			
	/ Investigatio		u I Down T		D. (-2)		
Date	Туре	Range Date Teste	ed Result		Details		
Additional	Information	:					
eport Run: 04/00	6/2007 04:30PM	Database: pusime02]A	DRS004	Page 378 of 526		



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 139150 Seq: 1 Gender: M

Reported: 03/05/1999 Weight:
Hospitalisation: Age:
Onset Date: 31/03/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Muscle spasms and rigidity	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 15.0 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Please see original report for details of other drugs - lithium. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 139151 Seq: 1 Gender: M

Reported: 03/05/1999 Weight:

Hospitalisation: Age: 22Y
Onset Date: 31/03/1999
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain from 76kg to 95kg	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/03/1999 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of asthma. please see original report for details of other drugs - atrovent, ventolin. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 139152 Seq: 1 Gender: F

Reported: 03/05/1999 Weight:
Hospitalisation: Age:

spitalisation: Age: 40Y
Onset Date: 31/12/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	todotion Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Immunoglobulins increased			
	Rash			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: 01/10/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Please see original report for details of other drugs - zoloft, valium. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 139538 Seq: 1 Gender: F

Reported: 14/05/1999 Weight:
Hospitalisation: Age: 62Y

Onset Date: 10/10/1998 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia			Ceased sodium valproate and commenced lithium.

Medicine Details:

Medicine Details.						
OLANZAPINE (Suspected)			Reason:	Unspecified so	chizophrenia	
Tablet	35.0	Milligram	As neo	cessary	Oral	
Batch:	Started:			Stopped:		CONTIN
SODIUM VALPROATE (Suspected)			Reason:			
Tablet	800.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:	10/10/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs: sertraline, citalopram, coloxyl with senna, metamucil and lithium. olanzapine dose originally implicated but later dose increased with no apparent adr.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 139542 Seq: 1 Gender: M

Reported: 14/05/1999 Weight: 82.00 Hospitalisation: Age: 77Y

Onset Date: 19/10/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
-	Oedema peripheral			Ceased olanzapine

Medicine Details:

OLANZAPINE (Suspected) Reason:

5.0 Milligram As necessary

Batch: Started: 05/10/1998 **Stopped:** 19/10/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs: aspirin, fosinopril, levodopa/carbidopa, ranitidine, allopurinol, amoxycillin, prune juice, coloxyl with senna, ural, aqueos cream, chlorothiazide and citalopram.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 139555 Seq: 1 Gender: M

Reported: 14/05/1999 Weight:

Hospitalisation: Age: 36Y
Onset Date: 31/01/1999
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

caction betains.			
Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			Surgery has been considered to remove the excess breast tissue.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/09/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drug. - lithium. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	oa	rt	De	tai	ls:
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Case Number: 139556 Seq: 1 Gender: F

Reported: 14/05/1999 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient commenced zyprexa treatment at 5mg/day dose by having a 10mg tablet.

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Report Details:

Case Number: 139557

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 14/05/1999	ted: 14/05/1999 Weight:							
lospitalisation:		Age: A2						
Onset Date:		DOB: Causality: Causality possible						
Outcome: Not yet red	covered							
eaction Details:								
Preferred Term	Severity	Rep	ort Description		Treatmen	ıt		
Gynaecomastia								
Hyperproteinaemia								
Medicine Details: ZYPREXA (Suspected)		Re	ason: Unspecified	schizophrenia				
Tablet	10.0	0 Milligram	Daily	Oral				
Batch:	Started:		Stopped	:				
Laboratory Investigati	one:							
Laboratory Investigati Date Type	Range Date Te	ested Result	T	Details				
.,,,,,	- I am ge							
Additional Information	1:							
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DOB:

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:							
Case Number:	139877	Seq: 1	Gender:	F			
Reported:	24/05/1999		Weight:				
Hospitalisation:			Age:	38Y			

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Onset Date:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Gained 40kg in weight	

Medicine Details:				
OLANZAPINE (Suspected)		Reason:		
	0.0			
Batch:	Started:	Stopp	ed:	
CLOZARIL (Suspected)		Reason:		
Tablet	62.2 Milligram	Daily	Oral	
Batch:	Started:	Stopp	ed:	

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient also had weight gain previously with olanzapine.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 140005
 Seq: 1
 Gender:
 F

 Reported:
 28/05/1999
 Weight:

Hospitalisation: Age: 40Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration		Rolling eyes	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

Tablet 20.0 Milligram Daily Oral

Batch: Started: 01/10/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 140006 Seq: 1 Gender: F

Reported: 28/05/1999 Weight:
Hospitalisation: Age: 40Y
Onset Date: 31/03/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction betains.							
Preferred Term Severity		Report Description	Treatment				
Hypertonia		Cogwheeling of upper limbs					
Muscle spasms		Cramps in right calf and thigh					
Pain	Dull pain in right leg.						
Dystonia		Dystonia of thumb					
Tremor		Tremor of upper limbs					

Medicine Details:

ZYPREXA (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drug therapy: sodium valproate. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Report Details:

Case Number: 140185

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 02/06/1	999				Weight	t:			
lospitalisation:		Age:							
Onset Date:					DOI				
Outcome: Unknow	/n				Causality	: Causality poss	ible		
Reaction Details:									
Preferred Term	Sc	everity	Repor	t Descript	ion	Treatmen	nt		
Convulsion		M	yoclonic jerking						
Drug level increased		Р	lasma level incre	ased					
Hyperkinesia									
Madiaina Dataila									
Medicine Details: OLANZAPINE (Interaction)			Reas	n.					
OLANZAFINE (Interaction)		0.0	Neast	,,,,					
Batch:	S	Started:		St	opped:				
CLOZARIL (Interaction)			Reas		ecified schizophrer	nia			
Tablet		700.0 Mi		Daily	Oral				
Batch:	8	Started:	· ·	-	opped:				
Laboratory Investig		I							
Date Type	Range	Date Tested	Result		De	tails			
Additional Informati	on:								
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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	port	Detai	ls:
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 Case Number:
 140190
 Seq: 1
 Gender: F

 Reported:
 02/06/1999
 Weight:

Hospitalisation: Age: 46Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	todotion Details.			
	Preferred Term	Severity	Report Description	Treatment
	Salivary hypersecretion			
	Tardive dyskinesia			

Medicine Details:

Medicine Details.						
OLANZAPINE (Suspected)			Reason:	Reason:		
	0.0					
Batch:	Started:			Stopped:		
CLOZARIL (Suspected)			Reason:	Unspecified schizophrenia		
Tablet	350.0	Milligram	Daily	Oral		
Batch:	Started:			Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Please see original report for details of other drugs - haloperidol, benzatropine.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 140404
 Seq: 1
 Gender:
 F

 Reported:
 10/06/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 27Y
Onset Date: 11/05/1999
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Depression		Became very depressed about extreme weight gain.	
Cushing's syndrome		Patient developed cushingoid syndrome on face.	
Purpura		Pink/purple striae on axillae & lower abdomen.	
Hypertension			
Obesity			

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1999	Stopped: 07/05/1999	
LARGACTIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	150.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1999	Stopped: 07/05/1999	
LUVOX (Suspected)		Reason: Unspecified schizophrenia	
Tablet	100.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1999	Stopped: 07/05/1999	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Fasting cortisol 370 (125-695)nmol/l.

Additional Information:

See original report for other drug details - coversyl. stopped all psychotropic tablets 4 days prior to admission. patient came in with significant paracetamol overdose. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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DOB:

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 140566 Seq: 1 Gender: F

Reported: 11/06/1999 Weight:
Hospitalisation: Age: 26Y

Outcome: Unknown Causality: Causality possible

Reaction Details:

Onset Date:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Increase in prolactin levels.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 2.5 Milligram Daily Oral

Batch: Started: 01/12/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 140567
 Seq: 1
 Gender: M

 Reported:
 11/06/1999
 Weight:

Hospitalisation: Age: 29

Onset Date: 31/01/1999 DOB: 21/03/1969

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
		Strange behaviours (such as head banging)	
Personality disorder			
Psychotic disorder			Ceased zyprexa
Sleep disorder			

Medicine Details:

 ZYPREXA (Suspected)
 Reason:
 Schizophrenia

 Tablet
 7.5 Milligram
 Daily
 Oral

 Batch:
 Started: 22/01/1999
 Stopped: 05/02/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug: risperidone. when zyprexa was started patient developed an acute worsening of his symptoms. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	140568	Seq:	1		Gender: M					
Reported	11/06/199	99				Weig	ht:			
lospitalisation:						A	ge:			
Onset Date:	: 01/05/199	99				D	OB:			
Outcome:	Recovere	:d	Causality: Causality possible							
eaction Deta	ils:									
Prefer	red Term	Sev	erity	Rep	ort Desc	ription	Treatmer	nt		
Neuroleptic mali	gnant synd	rome								
Medicine Det ZYPREXA (Suspe			20.0 Milli		i son: Daily	Oral				
Batch:		Sta	irted:	igrain	Daily	Stopped:				
l abayatan l		.:								
<u>_aboratory l</u> Date	Type	Range [Date Tested	Result		Γ	Details			
_ = 5.1.5	.) -	· · · · · · · · ·								
Additional In	formatio	n:								
eport Run: 04/06/20	007 04:30PM	M Database: pusi	ime02	,	ADRS004		Page 395	of 526		



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 140707 Seq: 1 Gender: F

Reported: 21/06/1999 Weight: 75.00 Hospitalisation: Age: 27Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

•					
	Preferred Term	eferred Term Severity Report Description			
	Weight increased		Excess weight gain - 10kg		
	Acne	Pimple-like reaction on forearms			

Medicine Details:

ZYPREXA (Suspected)Reason: Manic depressive psycho, depre

10.0 Milligram Daily

Batch: Started: 08/05/1998 **Stopped:** 26/04/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

When drug restarted, pimples came back. drug ceased for excess weight gain and pimples went again.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 140893 Seq: 1 Gender: F

Reported: 28/06/1999 Weight:
Hospitalisation: Age: 22Y

Onset Date: 28/05/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced generalised seizures.	
			ı

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

 Tablet
 10.0 Milligram
 Daily
 Oral

 Batch:
 Started: 26/05/1999
 Stopped: 28/05/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No clear prior history of seizures. alcohol abuse. investigations (fbc, uels, ca, bsl, cerebral ct all normal).

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 140936
 Seq: 1
 Gender: M

 Reported:
 28/06/1999
 Weight:

Reported: 28/06/1999 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Zyprexa dosage was reduced to 10mg/day.

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient commenced olanzapine treatment at 10mg/day and experienced no problems. the dosage was then increased to 20mg/day and then experienced the reaction.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 140937	Seq: 1		Gende	r: M
Reported: 28/06/1999			Weight	:
ospitalisation:			Age	
Onset Date:			DO	
Outcome: Not yet reco	vered		Causality	: Causality possible
action Details:			· T	
Preferred Term	Severity	Report De	scription	Treatment
Gait disturbance	Ur	nsteadiness on feet		
Medicine Details: ZYPREXA (Suspected)		Reason:		
Tablet	10.0 Mil	lligram Daily	Oral	
Batch:	Started:		Stopped:	
.aboratory Investigatio				
Date Type	Range Date Tested	Result	De	ails
Additional Information:				
oort Run : 04/06/2007 04:30PM	Database: pusime02	ADRS00)4	Page 399 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
	\sim		-	u	

Case Number: 140939 Seq: 1 Gender: M

Reported: 28/06/1999 Weight: Hospitalisation: Age: A1

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Elevated ast and alt enzymes	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient's medical history included an underlying viral infection.

Report Run: 04/06/2007 04:30PM Database: pusime02 ADRS004 Page 400 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 140940
 Seq: 1
 Gender:
 F

 Reported:
 28/06/1999
 Weight:

Hospitalisation: Age: 28Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Hypertension	Required Specialist Consultation	Mild hypertension (140/100)	
Tachycardia			

Medicine Details:

ZYPREXA (Suspected)	Reason:				
Tablet	15.0 Milligram	Daily	Oral		
Batch:	Started:	Sto	opped:	5W	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

For 3 weeks the patient was receiving 10mg/day. during the last 2 weeks the patient was receiving 15mg/day and then experienced reactions.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 140941 Seq: 1 Gender: F

Reported: 28/06/1999 Weight:
Hospitalisation: Age: 69Y

Onset Date: 29/04/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Antinuclear antibody positive	Required Specialist Consultation		Zyprexa discontinued. therapy changed to modecate.
Photosensitivity reaction		Photosensitivity reaction occurred in april 1999	

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified schizophreniaTablet15.0 MilligramDailyOral

Batch: **Started**: 01/01/1999 **Stopped**: 29/04/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 140942
 Seq: 1
 Gender:
 F

 Reported:
 28/06/1999
 Weight:

Hospitalisation: Age: 49

Onset Date: DOB: 12/07/1949

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Te	rm Severity	erred Term Severity Report Description	n Treatment
Eye disorder		Discolouration of the sclera - tu colour	urned grey Zyprexa has been reduced to 2.5mg/day.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

Tablet 15.0 Milligram Daily Oral

Batch: Started: 23/12/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drugs - lithium, diazepam, deptran.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Laboratory Inv						-	
	estigations:	ge Date Teste	rd Result	Details			
Tablet Batch:		0.0 Started:		Oral Stopped:			
Medicine Detai ZYPREXA (Suspecte			Reason:				
Acne		Severe	Moderately severe acne	shortly after			
eaction Details Preferred	Term	Severity	Report Desc		Treatment		
Onset Date: Outcome:				DOB:	Age: 16Y DOB: ausality: Causality possible		
()neat Data:							



Date Range: 1 Jan 1960 To 31 Dec 1999 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:
 140944
 Seq: 1
 Gender: M

 Reported:
 28/06/1999
 Weight:

Hospitalisation: Age: 30Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

, ,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
E	Bronchospasm			
I	Pneumonia			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 30.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

The patient has a history of asthma.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report I	Details:
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Case Number: 140945 Seq: 1 Gender: F

Reported: 28/06/1999 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Skin reaction on arms	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Oral Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Zyprexa was ceased and the reaction resolved. olanzapine was restarted and the skin reaction reoccurred.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 140946 Seq: 1 Gender: F

Reported: 28/06/1999 Weight:

Hospitalisation: Admitted to hospital Age: 60Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Perfuse sweating	
Dystonia		Spasm of facial muscles, grimacing	
Hypertonia		Spasm of upper limbs	
Pyrexia		Temperature of 40 degrees celcius	The patient underwent tests to determine her creatine phosphokinase (cpk) levels to investigate the possibility of neuroleptic malignant syndrome. the patient's cpk levels were found to be normal. zyprexa discontinued for an unspecified time.
Hypertonia		Upper limb muscle spasm	

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified schizophreniaTablet17.5 MilligramDailyOral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient commenced zyprexa treatment at 10mg/day but the patient's psychiatric symptoms were not under control at this dose. after 2.5 weeks, the dose of zyprexa was increased to 17.5mg/day. the patient then experienced the reactions. the zyprexa treatment was recommenced at 10mg/day. the patient experienced less facial spasms at the reduced dose. at the time of discharge the patient was still experiencing the facial spasms and episodes of increased temperature accompanied by perfuse sweating. the dose of zyprexa was reduced again to 7.5mg in an attempt to resolve the episodes of fever. the patient now experiences the episodes of fever once every 2 to 3 days and reaches temps of 40 degress celcius during these episodes. the

Report Run: 04/06/2007 04:30PM Database: pusime02 ADRS004 Page 407 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 140946 Seq: 1 Gender: F

Reported: 28/06/1999 Weight:

Hospitalisation: Admitted to hospital Age: 60Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight decreased		Weight loss of approximately 1 stone.	

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified schizophreniaTablet17.5 MilligramDailyOral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Additional Information:

The patient commenced zyprexa treatment at 10mg/day but the patient's psychiatric symptoms were not under control at this dose. after 2.5 weeks, the dose of zyprexa was increased to 17.5mg/day. the patient then experienced the reactions. the zyprexa treatment was recommenced at 10mg/day. the patient experienced less facial spasms at the reduced dose. at the time of discharge the patient was still experiencing the facial spasms and episodes of increased temperature accompanied by perfuse sweating. the dose of zyprexa was reduced again to 7.5mg in an attempt to resolve the episodes of fever. the patient now experiences the episodes of fever once every 2 to 3 days and reaches temps of 40 degress celcius during these episodes. the

Report Run: 04/06/2007 04:30PM Database: pusime02 ADRS004 Page 408 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 141003
 Seq: 1
 Gender:
 F

 Reported:
 30/06/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 0

Onset Date: 28/06/1999 **DOB**: 22/06/1999

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Three generalised tonic-clonic seizures.	

Medicine Details:

Medicine Details.				
ALCOHOL (Suspected)		Reason:		
	0.0			
Batch:	Started:	Stop	ped:	
ZYPREXA (Suspected)		Reason: Unspecif	fied schizophrenia	a
Tablet	0.0	Daily	Oral	
Batch:	Started: 26/05/1996	Stop	ped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient history includes: a two year history of psychotic symptoms (somatic, olfactory hallucinations) and delusions of persecution, polysubstance abuse including alcohol, amphetamines (but no for several months), hepatitis c with mildly abnormal transaminases. the patient has no definite prior history of seizures. treatment was recommenced on 15 june 99 at 5mg/day with no reoccurrence of the adverse event.

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Date Range: 1 Jan 1960 To 31 Dec 1999 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: 141011 Seq: 1 Gender: F

Reported: 30/06/1999 Weight:
Hospitalisation: Age: 60Y

Onset Date: 31/05/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal		Abnormal st wave interval.	

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
	0.0		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 141057 Seq: 1 Gender: F

 Reported:
 01/07/1999
 Weight:

 Hospitalisation:
 Age:
 76Y

 Onset Date:
 09/03/1999
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

touction bottom			
Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		, ,	Ceased epilim, prednisolone, zyprexa. platelets infusions.

Medicine Details:

ZYPREXA (Suspected)		Reason:
	15.0 Milligram	Daily
Batch:	Started: 01/01/1988	Stopped : 21/04/1999
EPILIM (Suspected)		Reason: Other&unspecified epilepsy
	200.0 Milligram	Daily
Batch:	Started:	Stopped : 15/03/1999
ALPRIM (Suspected)		Reason:
Tablet	300.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 15/03/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets		08/03/1999	59	
	Platelets		15/03/1999	45	
	Platelets		16/03/1999	40	
	Platelets		17/03/1999	41	
	Platelets		18/03/1999	36	
	Platelets		22/03/1999	28	
	Platelets		30/03/1999	25	

Additional Information:

See original report for other drugs details: temazeapm, zoloft, phenobarbitone cephalexin, phenytoin, risperdone. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 141057 Seq: 1 Gender: F

Reported: 01/07/1999 Weight:
Hospitalisation: Age: 76Y

Onset Date: 09/03/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)		Reason:
	15.0 Milligram	Daily
Batch:	Started: 01/01/1988	Stopped: 21/04/1999
EPILIM (Suspected)		Reason: Other&unspecified epilepsy
	200.0 Milligram	Daily
Batch:	Started:	Stopped: 15/03/1999
ALPRIM (Suspected)		Reason:
Tablet	300.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 15/03/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets		01/01/1999	23	
	Platelets		05/04/1999	56	
	Platelets		07/04/1999	69	
	Platelets		09/04/1999	45	
	Platelets		14/04/1999	37	
	Platelets		15/04/1999	161	
	Platelets		16/04/1999	55	

Additional Information:

See original report for other drugs details: temazeapm, zoloft, phenobarbitone cephalexin, phenytoin, risperdone. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Report Run: 04/06/2007 04:30PM Database: pusime02 ADRS004 Page 412 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 141057
 Seq: 1
 Gender:
 F

 Reported:
 01/07/1999
 Weight:

Reported: 01/07/1999 Weight:
Hospitalisation: Age: 76Y

Onset Date: 09/03/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

modific Botano.		
ZYPREXA (Suspected)		Reason:
	15.0 Milligram	Daily
Batch:	Started: 01/01/1988	Stopped: 21/04/1999
EPILIM (Suspected)		Reason: Other&unspecified epilepsy
	200.0 Milligram	Daily
Batch:	Started:	Stopped: 15/03/1999
ALPRIM (Suspected)		Reason:
Tablet	300.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 15/03/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets		17/04/1999	45	
	Platelets		18/04/1999	50	
	Platelets		20/04/1999	76	
	Platelets		21/04/1999	94	
	Platelets		23/04/1999	162	
	Platelets		26/04/1999	152	

Additional Information:

See original report for other drugs details: temazeapm, zoloft, phenobarbitone cephalexin, phenytoin, risperdone. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 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: 141193 Seq: 1 Gender: F

Reported: 05/07/1999 Weight:
Hospitalisation: Age: 70Y

Onset Date: 04/02/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Rash maculo-papular	Severe	Massive generalised macular rash	
	Face oedema			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 15.0 Milligram Daily Oral

Batch: Started: 14/12/1998 **Stopped:** 08/02/1999

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Report Run: 04/06/2007 04:30PM Database: pusime02 ADRS004 Page 414 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	port	Detail	ls:
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 Case Number:
 141325
 Seq: 1
 Gender: F

 Reported:
 09/07/1999
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Prolactin levels increased.	

Medicine Details:

ZYPREXA (Suspected)		Reason:				
Tablet	0.0	Daily	Oral			
Batch:	Started:	Stor	oped:	02W		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient's medical history includes treatment with risperidone. reaction occurred 1 week after commencing treatment with zyprexa.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reporte ospitalisatio Onset Dat	-L 00/07/1005	Seq:	1			Gende	
-	ed: 09/07/1999					Weigh	
Oliset Dat						Ago DO	e: 18Y
Outcom	e: Unknown						y: Causality possible
action De						Causant	y. Causality possible
	erred Term	Se	everity	Repo	ort Descr	iption	Treatment
Nopecia							
/ledicine D	etails:						
ZYPREXA (Sus				Rea	son:		
Tablet			0.0		Daily	Oral	
Batch:		S	tarted:			Stopped:	
-h4							
annrator.	Investigatio		т т				
Date Date	Type	Range	Date Tested	Result		De	tails



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 141327
 Seq: 1
 Gender: M

 Reported:
 09/07/1999
 Weight:

Hospitalisation: Age: 45Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Convulsion.	

Medicine Details:

OLANZAPINE (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of experiencing fitting at the ages of 17 and 25 but has not experienced a fit since. reaction occurred 6 months after taking olanzapine.

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Case Number: 141328

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 09/07/1999			Weight			
spitalisation:			Age			
Onset Date:		DOB:				
Outcome: Not yet recover	red	Causality: Causality possible				
action Details:			,			
Preferred Term	Severity	Report Descriptio	n	Treatment		
rthralgia		rthralgia-joint pain.				
1yalgia	M	Iyalgia-muscle pain.				
ledicine Details: OLANZAPINE (Suspected)		Reason:				
Tablet	0.0	Reason:	Oral			
Batch:	Started:	040.	oped:			
aboratory Investigations	s:					
	ange Date Tested	l Result	Deta	ails		
Additional Information:						
port Run: 04/06/2007 04:30PM Da	tabase: pusime02	ADRS004		Page 418 of 526		

Rep



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 141343 Seq: 1 Gender: M

Reported: 08/07/1999 Weight: 90.00 Hospitalisation: Age: 32Y

Onset Date: 01/07/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	touction Dotaile.			
	Preferred Term	Severity	Report Description	Treatment
	Blood creatine phosphokinase incr		Ck increased from 36 to 75	
	Pyrexia		Increased temperature 38.3	
	Leukocytosis		Increased wcc 13.4	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 5.0 Milligram Daily Oral

Batch: **Started**: 22/06/1999 **Stopped**: 29/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was being rechallenged with zyprexa. early signs of nms. see original report for details of other drug - lithicarb.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 141460
 Seq: 1
 Gender: M

 Reported:
 13/07/1999
 Weight:

Reported: 13/07/1999 Weight:
Hospitalisation: Age: 34Y

Onset Date: 31/05/1999 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash	Severe	Severe atopic dermatitis.	

Medicine Details:

Medicine Details.		
SODIUM VALPROATE (Suspected)		Reason: Unspecified schizophrenia
Tablet	800.0 Milligram	Daily Oral
Batch:	Started: 20/04/1999	Stopped: 29/06/1999
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia
Tablet	20.0 Milligram	Daily Oral
Batch:	Started: 06/04/1999	Stopped : 29/06/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Severe atopic dermatitis - expecially affecting face, upper torso but also scatterd elsewhere. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 141714 Seq: 1 Gender: F
Reported: 19/07/1999 Weight:
Hospitalisation: Admitted to hospital Age:

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Muscle spasms and leg jerking	
Blood creatine phosphokinase incr			
Hypertonia			
Neuroleptic malignant syndrome			
Pyrexia			
Tremor			

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 7.5 Milligram Daily Oral

Batch: Started: 01/03/1999 Stopped:

Laboratory Investigations:

<u> Luborator</u>	y ilivostiga				
Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 141757
 Seq: 1
 Gender:
 F

 Reported:
 19/07/1999
 Weight:

Hospitalisation: Age: 26

Onset Date: DOB: 03/08/1972

Outcome: Unknown Causality: Causality possible

Reaction Details:

caction betains.				
Preferred Term	Severity	Report Description	Treatment	ì
Neutropenia			Clozaril & olanzapine were discontinued	1

Medicine Details:

OLANZAPINE (Suspected) Reason:

10.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils				1.300.cu mm on 26 july 1999.

Additional Information:

Please see original report for details of other drugs - venlafaxine.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 142051
 Seq: 1
 Gender: M

 Reported:
 29/07/1999
 Weight:

Hospitalisation: Age: 18Y
Onset Date: 10/07/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination		Auditory hallucinations	
Hypertonia			Ceased neuroleptics. given hydration and treated with benztropine and clonazepam
Blood creatine phosphokinase incr Dehydration Neuroleptic malignant syndrome Pyrexia			

Medicine Details:

FLUANXOL (Suspected)		Reason: Unspecified psy	chosis
Injection	100.0 Milligram	Weekly I	ntramuscular
Batch:	Started: 31/05/1999	Stopped:	
COGENTIN (Suspected)		Reason:	
Tablet	1.0 Milligram	As necessary (Oral
Batch:	Started: 30/06/1999	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified psy	chosis
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 01/07/1999	Stopped:	12/07/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine kinase		12/07/1999	138.2	
	Creatine kinase		13/07/1999	-	
	Creatine kinase		23/07/1999	-	
	Creatine		12/07/1999	18689	
	Creatine		13/07/1999	9790	
	Creatine		23/07/1999	148	

Additional Information:

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Case Number: 142273

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Medicine Details: OLANZAPINE (Suspected) Tablet		Stopped breat		Causa	hrenia	ality possible Treatment
Outcome: Not yet recovered raction Details: Preferred Term S pnoea Predicine Details: OLANZAPINE (Suspected) Tablet	15.0	Stopped breat	thing.	iption	hrenia	
Preferred Term S pnoea Iedicine Details: DLANZAPINE (Suspected) Tablet	15.0	Stopped breat	thing.	ription	hrenia	
Preferred Term S conoea edicine Details: DLANZAPINE (Suspected) Tablet	15.0	Stopped breat	thing.	nspecified schizop	hrenia	Treatment
edicine Details: DLANZAPINE (Suspected) Tablet	15.0	Stopped breat	thing.	nspecified schizop	hrenia	Treatment
edicine Details: DLANZAPINE (Suspected) Tablet	15.0	R	deason: Un			
CLANZAPINE (Suspected) Tablet						
CLANZAPINE (Suspected) Tablet						
LANZAPINE (Suspected) Tablet						
LANZAPINE (Suspected) Tablet						
LANZAPINE (Suspected) Tablet						
LANZAPINE (Suspected) Tablet						
LANZAPINE (Suspected) Tablet						
LANZAPINE (Suspected) Tablet						
LANZAPINE (Suspected) Tablet						
Tablet						
		wiiiigram	Daily	Orai		
Batch:	Started:			Stopped:		
aboratory Investigations:						
Date Type Range	Date Teste	ed Result			Details	



Case Number: 142274

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 02/08/1999)	Weight:					
ospitalisation:			Age:				
Onset Date:			DOB:				
Outcome: Not yet rec	overed		Causali	ty: Causality possible			
eaction Details:	0	T 5	December	Tanadanant			
Preferred Term pnoea	Severity	Stopped breathing.	Description	Treatment			
		Terepped 2.com.ig.					
edicine Details:							
OLANZAPINE (Suspected)		Reason		enia			
Tablet	15.0 Started:) Milligram D	aily Oral				
Batch:			Stopped:				
aboratory Investigatio	ons:						
Date Type	Range Date Te	sted Result	De	etails			
dditional Information	:						
ort Run: 04/06/2007 04:30PM	Database: pusime02		RS004				



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 142275
 Seq: 1
 Gender: M

 Reported:
 02/08/1999
 Weight:

Hospitalisation: Age: 19

Onset Date: DOB: 20/12/1979

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		"flashlight shooting star" blue in colour.	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 5.0 Milligram Daily Oral

Batch: Started: 21/10/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred one to two times a week particularly if there was a delay in the patient taking his medication. the dose of olanzapine was reduced to 2.5mg/day. symptoms became less noticeable 2 weeks after reducing the olanzapine dose.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 142276
 Seq: 1
 Gender: M

 Reported:
 02/08/1999
 Weight:

Hospitalisation: Age: 19

Onset Date: 17/06/1999 **DOB**: 27/11/1979

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Two grand mal seizures.	
Depression			Patient commenced paroxetine treatment for post-psychotic depression.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 25/05/1999 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drug. - paroxetine. symptoms occurred 3 weeks after commencing therapy with olanzapine.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:142423Seq: 1Gender: FReported:05/08/1999Weight:Hospitalisation:Admitted to hospitalAge:

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

i todotion Botans.			
Preferred Term	Severity	Report Description	Treatment
Hallucination		Visual hallucinations	
Agitation			Briefly treated with risperidone and hospitalised. olanzapine ceased
Delirium			
Somnolence			

Medicine Details:

ZYPREXA (Suspected)		Reason: Unspecified psychosis	
	5.0 Milligram	Daily	
Batch:	Started : 26/07/1999	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
	15.0 Milligram	Daily	
Batch:	Started:	Stopped: 04/07/1999	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Zyprexa dose was increased from 5mg/daily to 10mg/d and then to 15mg/ daily. patient was also taking serzone.

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Case Number: 142516

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 09/08/1999		Weight: Age:					
lospitalisation:							
Onset Date:					DO	В:	
Outcome: Not yet recov		Causality: Causality possible					
eaction Details:		., 1				Т	-
Preferred Term	Sever	ity	Repor	t Des	scription		Treatment
Pyrexia Visual disturbance							Olanzapine ceased
Visual disturbance						ľ	Olarizapine ecaseu
Medicine Details: OLANZAPINE (Suspected)			Reaso	 on:	Depression		
Tablet		2.5 Milligr		Daily	•	Oral	
Batch:	Starte			•	Stopped:		
Laboratory Investigation Date Type		te Tested	Result			De	tails
1,700	Trango Bu	.o rootou	rtocuit				Namo
Additional Information:							
eport Run: 04/06/2007 04:30PM I	Database: pusime	∍02	AΓ)RS00)4		Page 429 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 142517 Seq: 1 Gender: M

Reported: 09/08/1999 Weight:
Hospitalisation: Age:
Onset Date: 31/07/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state		Acute brain syndrome	

Medicine Details:

OLANZAPINE (Suspected) Reason:

Tablet 2.5 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation Onset Da	ed: 09/08/199 on: ite: ne: Not yet re		: 1		Gender: F Weight: Age: DOB: Causality: Causality possible			
	ferred Term	Se	everity	Reno	ort Description	Treatment		
Weight increa			overity	ТОР	nt Bocomption	Treatment		
Madiaina F) oto:lo:							
Medicine I	Details: The Mesylate	(Other drug)		Rea	son:			
Brown or the	INC IIICOTEATE	(Other drug)	0.0	r.cu				
Batch	:	S	tarted:	Stopped:				
	SONE (Other dru			Rea				
	•	<i>.</i> ,	0.0					
Batch	:	S	tarted:	Stopped:				
OLANZAPINE	(Suspected)			Rea				
Tablet			0.0	Oral				
Batch	:	S	tarted:	Stopped:				
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 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 14 Reported: 09 Hospitalisation: Onset Date: Outcome: Ut	9/08/1999 nknown	Seq: 1	M Causality possible				
Preferred		Severity	Repo	ort Description	Treatment		
Rash							
Medicine Detail	s:						
ZYPREXA (Suspected	i)		Rea	son:			
		0.0					
Batch:		Started:		Stopped:			
Laboratory Inve		no Doto Tootod	Dogult	Data	ilo		
Date Type Range		ge Date Tested	Result	Deta	lio ell		
Additional Information:							

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 142575
 Seq: 1
 Gender: M

 Reported:
 11/08/1999
 Weight:

Hospitalisation: Age: 42Y
Onset Date: 31/05/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Caction Details.			
Preferred Term	Severity	Report Description	Treatment
Salivary gland enlargement			Clozaril ceased. a short trial of 2mg per day benztropine was given.
Headache Hyperhidrosis Leukopenia Nausea Salivary hypersecretion Tachycardia Thrombocytopenia			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other of	drug)		Reason:		
	100.0	Milligram	Daily		
Batch:	Started:			Stopped:	
CLOZARIL (Suspected)			Reason:	Unspecified schizophrenia	
Tablet	175.0	Milligram	Daily	Oral	
Batch:	Started: 01/0	05/1999		Stopped:	
OLANZAPINE (Suspected)			Reason:		
	5.0	Milligram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
Haematology			Platelets dropped to 129; lymphocytes dropped to 0.5. white cell dropped to 3.7 and neutrophils dropped to 2.8.			
		Immunology				Viral serology done earlier was consistent with a previous - but not recent - mumps infection.

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 142615 Seq: 1 Gender: F

Reported: 16/08/1999 Weight: 130.00 Hospitalisation: Age: 39Y

Onset Date: 31/07/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tongue oedema		Swollen tongue	Withdrawal of olanzapine

Medicine Details:

OLANZAPINE (Suspected) Reason: Otr spec symp psychopathol nec

 Tablet
 10.0 Milligram
 Daily
 Oral

 Batch:
 Started: 01/07/1998
 Stopped: 28/07/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 142677
 Seq: 1
 Gender:
 F

 Reported:
 16/08/1999
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 31/12/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
(Grand mal convulsion		Seizure.	Zyprexa discontinued.

Medicine Details:

Medicine Details.				
ZOLOFT (Suspected)		Reason: De	epression	
Tablet	200.0 Millig	ram Daily	Oral	
Batch:	Started:		Stopped:	
ZYPREXA (Suspected)		Reason:		
Tablet	2.5 Millig	ram Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Numbe	r: 142829	Seq:	1		Gender: M				
Reported	d: 20/08/19	99		Weight:					
ospitalisation						Age:			
Onset Dat	e:					DOB:			
Outcome	e: Recover	ed			С	ausality: Ca	ausality prob	able	
action Det	ails:								
Prefe	rred Term	Se	everity	Repo	ort Description		Treatmer	nt	
remor			Sha	aking in hand	s and feet.	Zyprex	ka therapy cea	ased.	
ledicine Do ZYPREXA (Sus _l Tablet			0.0	Rea	son: Unspecified so	hizophrenia Oral			
Batch:		St	tarted:		Stopped:				
aboratory	Investiga	tions:							
Date	Туре	Range	Date Tested	Result		Details			
dditional l	nformatio	on:							
ort Run: 04/06/	2007 04:30P	M Database: pu	usime02	Α	DRS004		Page 436	of 526	



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repor Hospitalisati Onset D Outco	ate: me: Not yet re		1		Gender Weight Age DOE Causality	: :
Reaction D	eferred Term	Se	verity	Reno	ort Description	Treatment
Depersonalis		- 00		ja vu.	nt Becomption	rrodunone
Medicine						
AROPAX (Ot	ner drug)		0.0	Reas	son:	
Batc	h·	St	arted:		Stopped:	
SERENACE (0.	arteu.	son:		
			0.0			
Batc	h:	St	arted:		Stopped:	
TRIQUILAR (Other drug)			Reas	son:	
			0.0			
Batc		St	arted:		Stopped:	
NORMISON (Other drug)			Reas	son:	
Batc	L .	64	0.0 arted:		Ctowned:	
Ватс	n:	31	arted:		Stopped:	
Laborator	y Investigat					
Date	Туре	Range	Date Tested	Result	Deta	ails
Additiona	l Informatio	n:				

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details	s:					
Hospitalisation: Onset Date:	142830 20/08/1999 Not yet recovered	Seq: 1			Gender: Weight: Age: DOB:	
Reaction Detai					Causanty.	Causality possible
Medicine Deta	aile:					
ZYPREXA (Suspec				Reason:		
Tablet		10.	0 Milligram	Daily	Oral	
Batch:		Started:			Stopped:	CONTIN
Laboratory In	vestigations:					
Additional Inf	ormation:					

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 142834
 Seq: 1
 Gender:
 F

 Reported:
 20/08/1999
 Weight:

Hospitalisation: Age: 48Y
Onset Date: 04/08/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

١,	Acaction Details.										
	Preferred Term	Severity	Report Description	Treatment							
	Dyspnoea										
	Flatulence										
	Gravitational oedema										
	Hypochromic anaemia										

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

Tablet 10.0 Milligram Daily Oral

Batch: Started: 20/07/1999 **Stopped:** 12/08/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details: valium.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 142919 Seq: 1 Gender: F
Reported: 23/08/1999 Weight:
Hospitalisation: Age: A6

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria		Urticarial rash trunk/ears/face/eyelids	Ceased zoloft and zyprexa.

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 50.0 Milligram
 Daily
 Oral

 Batch:
 Started: 05/08/1999
 Stopped: 17/08/1999

 ZYPREXA (Suspected)
 Reason:
 Depression

 2.5 Milligram
 Daily

Batch: Started: 05/08/1999 **Stopped:** 17/08/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Plans to rechallenge with zoloft after symptoms have abated.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 142959 Seq: 1 Gender: M

Reported: 25/08/1999 Weight: 125.00 Hospitalisation: Age: 40Y

Onset Date: 31/05/1998 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	toaction Botaile.			
	Preferred Term	Severity	Report Description	Treatment
	Dyspnoea			
	Pulmonary fibrosis			

Medicine Details:

LITHIUM CARBONATE (Suspected)		Reason:		
Tablet	1.5 Gram	Daily	Oral	
Batch:	Started: 01/01/1989 L	TERM	Stopped:	CONTIN
SODIUM VALPROATE (Suspected)		Reason:		
Tablet	1.0 Gram	Daily	Oral	
Batch:	Started: 01/01/1994 L	TERM	Stopped:	CONTIN
OLANZAPINE (Suspected)		Reason:		
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 01/09/1997		Stopped:	CONTIN
ATENOLOL (Suspected)		Reason:		
Tablet	50.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/1984 L	TERM	Stopped:	CONTIN

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
		Lung biopsy Other data				Transbronchial lung bx:july 99- c/w pulm. fibrosis mild interstitial fibrosis many multimoderate giant cells c/w drug induced lung disease no granulomas. Ct scan - diffuse interstitial fibrosis, esp lower zones both lungs.
Į						

Additional Information:

Progressive exertional dyspnoea. no other respiratory symptoms. initial progression over 6 - 9 minutes, appears to have stabilised march - aug 1999. seen first by gp march 99 - resp function: normal volumes, mildly restrictive fev/uc, dlco decreased 57% predicted. to date: persisting lung function and ct abnormalities. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

eport Details		0.5.5.4				0	N.4
ase Number:		Seq: 1				Gender:	
Reported:	25/08/1999					Weight:	
spitalisation:	04/05/4000					Age:	
Onset Date:						DOB:	
	Not yet recovered				C	ausality:	Causality possible
action Detai	ls:						
ledicine Deta	ails:						
ledicine Deta FELODIPINE (Susp				Reason	:		
			20.0 Milligram			Oral	
FELODIPINE (Susp		Start	20.0 Milligram te d: 01/01/1994	Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet		Start		Da		Oral	CONTIN
FELODIPINE (Susp Tablet		Start		Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet		Start		Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet		Start		Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet		Start		Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet		Start		Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet		Start		Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet		Start		Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet		Start		Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet		Start		Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet		Start		Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet Batch:	pected)	Start		Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet Batch:		Start		Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet Batch:	pected)	Start		Da	iily	Oral	CONTIN
FELODIPINE (Susp Tablet Batch:	pected)	Start		Da	iily	Oral	CONTIN

Additional Information:

Progressive exertional dyspnoea. no other respiratory symptoms. initial progression over 6 - 9 minutes, appears to have stabilised march - aug 1999. seen first by gp march 99 - resp function: normal volumes, mildly restrictive fev/uc, dlco decreased 57% predicted. to date: persisting lung function and ct abnormalities. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 142974 Seq: 1 Gender: M

Reported: 25/08/1999

Hospitalisation:
Onset Date:

Weight: 80.00
Age: 66Y
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Bone marrow failure			
Neutropenia			
Pneumonia			

Medicine Details:

ZYPREXA (Suspected)

S.0 Milligram

Daily

Batch: Started: 01/01/1997 Stopped:

Laboratory Investigations:

	<u>,</u>					
Date	Туре	Type Range Date Tested Result		Result	Details	
	Histology				Bone marrow aspirate shows maturation arrest of white cell line consistent with toxic suppression.	
	Neutrophils				Neutrophil count 0.8	

Additional Information:

See original report for more information of other drugs - valium, kemadrin, modecate, melleril. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 142989
 Seq: 1
 Gender: F

 Reported:
 25/08/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 63

Onset Date: DOB: 12/07/1936

Outcome: Recovered Causality: Causality probable

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Cerebrovascular disorder		Cerebrovascular accident	Ceased zyprexa
Dysarthria			

Medicine Details:

ZYPREXA (Suspected)Reason:SchizophreniaTablet10.0 MilligramDailyOral

Batch: Started: 05/07/1999 **Stopped:** 10/08/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for details on other drugs: lipitor, daonil, monopril, zantac.

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Case Number: 143114

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 27/08/1999		Weight:				
ospitalisation:			A	Age:		
Onset Date: 21/07/1999		DOB: Causality: Causality possible				
Outcome: Not yet recovered	b					
action Details:	T					
Preferred Term	Severity	Report De	escription	Treatment		
gitation somnia						
Soffilia	<u> </u>			1		
ledicine Details: THIORIDAZINE HYDROCHLORIDE (Sus		Reason:				
Potoby	0.0		Stonnod: 10/07/	1000		
Batch: SINEMET (Suspected)	Started:	Reason:	Stopped: 19/07/ Paralysis agitans	1999		
Tablet	3.0 Do	se Unspecified Daily				
Batch:	Started:	se onspecified Daily	Stopped:	CONTIN		
DLANZAPINE (Suspected)	Otartea.	Reason:	Unspecified schizophi			
Tablet	5.0 Mil					
Batch:	Started: 20/07/1		Stopped:	CONTIN		
_aboratory Investigations: Date Type Ran	ge Date Tested	Result	[Details		
Laboratory Investigations: Date Type Ran Additional Information:	ge Date Tested	Result		Details		
oort Run: 04/06/2007 04:31PM Datal	base: pusime02	ADRSO	004	Page 445 of 526		



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

ase Nulliber. 143		4. ·			ender. F
Reported: 30/0	8/1999				eight:
spitalisation:					Age: 14Y
Onset Date:					DOB:
Outcome: Unk	nown			Caus	sality: Causality possible
ction Details:					
Preferred Te		Severity	Report D	escription	Treatment
ectrocardiogram QT	prolonged				
edicine Details: LANZAPINE (Suspecte		0.0	Reason:		
Batch:	;	Started:		Stopped:	
aboratory Inves					
Date Type	Range	Date Tested	Result		Details
dditional Inform	nation:				
ort Run : 04/06/2007 0	4:31PM Database:	pusime02	ADRS	004	Page 446 of 526

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 143255 Seq: 1 Gender: F

Reported: 31/08/1999

Hospitalisation: Admitted to hospital

Age: 17Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Catatonia		Became vague, withdrawn, almost mute.	Withdraw olazapine slowly, reintroduce clozapine.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

7.5 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for details on other drugs: clozapine, sodium valproate. patient got worse when dose of olanzapine was increased from 5 to 7.5 mg daily 4 year history of psychotic illness.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 143376 Seq: 1 Gender: F

Reported: 02/09/1999 Weight: 80.00 Hospitalisation: Age: 63Y

Onset Date: 20/07/1999 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cranial nerve disorder		Cranial nerve 7th palsy (bell's type).	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: **Started**: 12/07/1999 **Stopped**: 20/07/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - fluanxol depot, glibenclamide, lipitor, monopril & zantac. zyprexa was the only new medication introduced. recurred on re-exposure to 5mg daily.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation	ed: 03/09/199 on: ate: ne: Unknown		: 1		We	nder: F ight: Age: DOB: cality: Causality possible
	ferred Term	Se	everity	Rep	ort Description	Treatment
Hepatic funct				vated liver er	·	
Medicine I						
AROPAX (Oth	er drug)		0.0	Rea	son:	
Betek			0.0		Stannadi	
Batch			Started:	Pag	Stopped:	
LITHIUM CAR	BONATE (Other	arug)	0.0	Rea	son:	
Batch	1:	S	o.o Started:		Stopped:	
ZYPREXA (Su	spected)			Rea	son: Unspecified schizo	phrenia
Tablet			15.0 Milli	igram	Daily Ora	ıl
Batch	1:	S	Started:		Stopped:	CONTIN
Laborator Date	/ Investigat Type	ions: Range	Date Tested	Result		Details
Additional	Informatio	n:				

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Pref Pref Orthostatic hy	erred Term potension		Severity	Repo	ort Description	ality: Causality possible
Orthostatic hy	potension	S	Severity	Repo	ort Description	
Orthostatic hy Pancytopenia	•					Treatment
Medicine D	Petails: HYDROCHLORI	IDE (Other dru		Rea	son:	
Batch:			0.0 Started:		Stopped:	
	DROCHLORIDE		otarioa:	Rea	son:	
			0.0			
Batch:			Started:		Stopped:	
ASPIRIN (Othe	r drug)			Rea	son:	
Datab			0.0		Otamo a de	
Batch:		;	Started:	Rea	Stopped:	
ZIOOAIII (OIIIE	urug/		0.0	ivea:	JU	
Batch	:	!	Started:		Stopped:	
ahoratory	Investigati					
Date	Type	Range	Date Tested	Result		Details

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:				
Case Number: 143443 Reported: 03/09/1999 Hospitalisation: Onset Date: Outcome: Not yet recovered Reaction Details:	Seq: 1		Gender: F Weight: Age: DOB: Causality: Causality	possible
Medicine Details:				
ZYPREXA (Suspected)		Reason:		
Tablet	2.5 Milligram	Daily	Oral	
Batch:	Started:	Stopp	ed: CONTI	N
Laboratory Investigations:				
Additional Information:				

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

ZYPREXA (Suspected) Tablet 10.0 Milligram Daily Oral Batch: Started: Stopped: 0 Aboratory Investigations: Date Type Range Date Tested Result Details	eport Details:				
Reported: 03/09/1999	ase Number: 143445	Seq: 1		Gender	F
spitalisation: Onset Date: Outcome: Unknown Causality: Causality possible Interest	Reported: 03/09/1999			Weight:	0.00
Onset Date: Outcome: Unknown Causality: Causality possible action Details: Preferred Term Severity Report Description Treatment cial palsy Facial drop (Bell's palsy) Zyprexa discontinued Preferred Term Severity Report Description Treatment cial palsy Facial drop (Bell's palsy) Zyprexa discontinued Preferred Term Severity Reason: Unspecified psychosis Tablet 10.0 Milligram Daily Oral Batch: Started: Stopped: 0	_			_	
Preferred Term Severity Report Description Treatment (cial palsy Facial drop (Bell's palsy) Zyprexa discontinued (cial palsy Facial drop (Bell's palsy) Zyprexa discontinued (Cial palsy F	_				
Preferred Term Severity Report Description Treatment Acial palsy Facial drop (Bell's palsy) Zyprexa discontinued Predicine Details: Preferred Term Severity Report Description Treatment Acial palsy Zyprexa discontinued Preferred Term Severity Reason: Unspecified psychosis Tablet 10.0 Milligram Daily Oral Batch: Started: Stopped: 0	Outcome: Unknown			Causality	Causality possible
Preferred Term Severity Report Description Treatment acial palsy Facial drop (Bell's palsy) Zyprexa discontinued Professor: Unspecified psychosis Tablet 10.0 Milligram Daily Oral Batch: Started: Stopped: 0	action Details:			•	
Pacial drop (Bell's palsy) Zyprexa discontinued		Severity	Report Des	cription	Treatment
Pedicine Details: Perpress Reason: Unspecified psychosis Tablet	acial palsy				prexa discontinued
Tablet 10.0 Milligram Daily Oral Batch: Started: Stopped: 0 Batch: Started: Stopped: 0 Batch: Started: Stopped: 0					
Batch: Started: Stopped: 0 aboratory Investigations: Date Type Range Date Tested Result Details	ledicine Details: ZYPREXA (Suspected)				
aboratory Investigations: Date Type Range Date Tested Result Details			Milligram Daily		
Date Type Range Date Tested Result Details	Datcii.	Starteu.		эторрец.	0
			ed Result	Deta	ils
dditional Information:	Bate	Trange Date rest	cu result	Deta	113
	Additional Information:				

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Case Number: 143824

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 17/09/1999	9	Weight:					
lospitalisation:			Age:				
Onset Date:			DOB:				
Outcome: Recovered	t		Causality: Causality possible				
eaction Details:		1			_		
Preferred Term	Sev	verity	Repor	t Description	Treatment		
Hepatic function abnormal							
Leukopenia							
Medicine Details:			Reaso	on: Unspecified psychos			
ZYPREXA (Suspected) Tablet		0.0	Reaso	Oral	S		
Batch:	C+	arted:		Stopped:			
Laboratory Investigati	ione:						
Date Type	Range	Date Tested	Result		Details		
Julio Type	. tange	2410 1 00104	. toodiit				
1		<u>.</u>	<u>'</u>				
Additional Information	า:						



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 143825
 Seq: 1
 Gender:
 F

 Reported:
 17/09/1999
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

RISPERIDONE (Other drug)		Reason:	
	12.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophre	enia
Tablet	25.0 Milligram	Daily Oral	
Batch:	Started: 01/11/1998	Stopped:	CONTIN

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 143826 Seq: 1				Gender: M				
	eported: 17/09/1999				Weight:			
ospitalisation:						Age:		
Onset Date:						DOB:		
Outcome:	Recovered					Causality:	Causality poss	ible
eaction Detai	ls:							
Preferre	ed Term	Severit	у	Repo	rt Description		Treatmer	nt
Hallucination								
Medicine Deta				Reas	on: Unenocific	d schizophrenia		1
Tablet	iteu)		0.0	Reas	on. Onspecifie	Oral		
Batch:		Started			Stoppe			
								•
_aboratory In	vestigatio	15:						
Date	Туре		e Tested	Result		Details	3	
Additional Inf	ormation:							
Mullionai IIII	ormation:							
oort Run: 04/06/200	07 04:31PM	Database: pusime	02	A	DRS004		Page 455	of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 143954 Seq: 1 Gender: F

Reported: 23/09/1999 Weight:
Hospitalisation: Age: 24Y

Onset Date: 25/08/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			

Medicine Details:

Medicine Details.			
EFEXOR (Other drug)	F	Reason: Depression	
Tablet	150.0 Milligram	Fortnightly	Oral
Batch:	Started: 01/08/1997	Stopped:	CONTIN
ZYPREXA (Suspected)	F	Reason: Depression	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 25/06/1999	Stopped:	26/08/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 144047
 Seq: 1
 Gender:
 F

 Reported:
 27/09/1999
 Weight:

Hospitalisation: Age: 80

Onset Date: DOB: 05/01/1919

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

toaction Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Bronchospasm	Development of exercise induced breathlessness		

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

0.0

Batch: Started: 15/01/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has ischaemic heart disease and anxiety. see original report for details of other drugs - doxepin, slow k, cogentin, lasix, diabex, capoten.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 144062 Seq: 1 Gender: F

Reported: 27/09/1999 Weight: 77.00 Hospitalisation: Age: 63Y

Onset Date: 20/07/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysarthria			Withdrawal of zyprexa

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: **Started**: 05/07/1999 **Stopped**: 10/08/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Commenced zyprexa 5/7/99 5mg then increased to 10mg. see original report for details of other drugs - fluanxol, lipitor, daonil, monopril, zantac.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 144136
 Seq: 1
 Gender: M

 Reported:
 28/09/1999
 Weight: 92.00

Hospitalisation: Age: 32Y
Onset Date: 16/09/1999
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

i teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Chest pain			
Hyperhidrosis			
Pyrexia			
Tachycardia			

Medicine Details:

MEGICINE DELANS.			
LUVOX (Other drug)	•	Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 04/06/1998	Stopped:	CONTIN
ZYPREXA (Suspected)		Reason: Hallucinations	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 03/09/1999	Stopped:	16/09/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		17/09/1999	75	
	ALT = SGPT		20/09/1999	88	
	AST = SGOT		17/09/1999	42	
	Creatine		17/09/1999	1902	
	Creatine		20/09/1999	376	
	GGT = SGGT =		17/09/1999	73	
	GGT = SGGT =		20/09/1999	100	

Additional Information:

Pt was on serzone but become drowsy on increased dose - so therapy changed to zyprexa.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 144136 Seq: 1 Gender: M

 Reported: 28/09/1999
 Weight: 92.00

 Hospitalisation:
 Age: 32Y

Onset Date: 16/09/1999 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

MEGICINE DELANS.			
LUVOX (Other drug)			
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 04/06/1998	Stopped:	CONTIN
ZYPREXA (Suspected)		Reason: Hallucinations	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 03/09/1999	Stopped:	16/09/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	LDH		17/09/1999	261	

Additional Information:

Pt was on serzone but become drowsy on increased dose - so therapy changed to zyprexa.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 144225
 Seq: 1
 Gender: M

 Reported:
 30/09/1999
 Weight:

Hospitalisation: Age: 71

Onset Date: DOB: 24/12/1927

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
Renal failure acute			Acute on chronic renal failure.	
			Hydration, laxatives. melleril & modecate ceased.	

Medicine Details:

MODECATE (Suspected)			Reason:	Unspecified so	hizophrenia
Injection	50.0	Milligram	Month	nly	Intramuscular
Batch:	Started:	LT	ERM	Stopped:	17/08/1999
STELAZINE (Suspected)			Reason:	Unspecified so	hizophrenia
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started:	LT	ERM	Stopped:	
MELLERIL (Suspected)			Reason:	Unspecified so	hizophrenia
Tablet	400.0	Milligram	Daily		Oral
Batch:	Started:	LT	ERM	Stopped:	17/08/1999
OLANZAPINE (Suspected)			Reason:	Unspecified so	hizophrenia
T-1-1-4		Milliarom	Daily		Oral
Tablet	5.0	Milligram	Daily		Orai

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:					
Case Number: 144225 Reported: 30/09/1999 Hospitalisation: Onset Date: Outcome: Recovered Reaction Details:	Seq: 1				
Medicine Details: COGENTIN (Suspected)			Reason:	Unspecified schizophrenia	
Tablet Batch:	2.0 Started:	Milligram	Daily TERM	Oral Stopped :	
Laboratory Investigations:					
Additional Information:					

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 144285 Seq: 1 Gender: M

Reported: 01/10/1999 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Arthritis		Polyarthritis in hands (small joints) and feet.	Therapy with olanzapine discontinued.

Medicine Details:

OLANZAPINE (Suspected) Reason: Depression

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/06/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred after patient commecned therapy with olanzapine for one month after the dosage was increased to 10mg/day. patient has a medical history of taking venlafaxine. see original report for details of other drug. venlafaxine. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 144286 Seq: 1 Gender: M

Reported: 01/10/1999

Hospitalisation:
Onset Date:

Weight:
Age: 35Y
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Losing control of his bladder, twice a week.	

Medicine Details:

OLANZAPINE (Suspected) Reason:

Tablet 25.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

=aboratory invoctigationor						
	Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has a medical history which includes incontinence while receiving valium treatment in hospital

Report Run: 04/06/2007 04:31PM Database: pusime02 ADRS004 Page 464 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 144287 Seq: 1 Gender: F
Reported: 01/10/1999 Weight:
Hospitalisation: Treated in outpatient department only.

Age:

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction betails.			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Decrease in cpk levels.	
Dystonia			Therapy with benztropine given. therapy with olanzapine discontinued.

Medicine Details:

OLANZAPINE (Suspected)		Reason:		
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started:	St	opped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Cpk, creatine phosphokinase 5,500

Additional Information:

See original report for details of other drug. - clonazepam, contraceptive nos patient has previously taking zyprexa 5mg/day for 9 months. patient is intellectually disabled with an agitated mixed manic condition and short depressive episodes.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 144496 Seq: 1 Gender: F

 Reported: 11/10/1999
 Weight:

 Hospitalisation:
 Age: 38Y

 Onset Date: 01/10/1999
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
Urticaria Severe Pa		Patient experienced severe urticaria.		

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Tablet 10.0 Milligram Daily Oral

Batch: Started: 27/09/1999 **Stopped:** 04/10/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - temazepam. presented with relapse of psychosis. no previous exposure to this drug. patient history: reactions to trifluoperazine causing anethisia & chlorpropamide causing increased sedation.

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Case Number: 144506

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 11/10/1999			Weight:					
spitalisation:		Age:						
Onset Date:								
Outcome: Unknown		Causality: Causality possible						
eaction Details: Preferred Term	Soverity	Panart Day	ecription	Treatment				
uicide attempt	Severity	Report Des Intentional overdose.	scription	пеашеш				
ledicine Details:								
OLANZAPINE (Suspected)		Reason:						
Tablet	150.0 N	Milligram Daily	Oral					
Batch:	Started:		Stopped:					
_aboratory Investigation	ie.							
	Range Date Teste	ed Result	Deta	ails				
Additional Information:								
oort Run: 04/06/2007	Database: pusime02	ADRS00	4	Page 467 of 52				



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 144744 Seq: 1 Gender: F

Reported: 18/10/1999 Weight:
Hospitalisation: Age: 38Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dry mouth		Dry mouth after 4wks on olanzapine.	

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Tablet 10.0 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient medical history includes smoking.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 144745 Seq: 1 Gender: M
Reported: 18/10/1999 Weight:
Hospitalisation: Age:

Onset Date: 19/09/1999 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Patient experienced a grand mal fit.	

Medicine Details:

EFEXOR (Suspected)		Reason:		
	0.0			
Batch:	Started:	Sto	pped:	
ZYPREXA (Suspected)		Reason:		
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started:	Sto	pped:	CONTIN
TEMAZEPAM (Suspected)		Reason:		
	10.0 Milligram	Daily		
Batch:	Started:	Sto	pped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient history: previous fits when withdrawing form benzodiazepine treatment. on 14.9.99, the patient took 10mg of temazepam. on 19.9.99, the patient experienced a grand mal fit.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 144746 Seq: 1 Gender: M
Reported: 18/10/1999 Weight:
Hospitalisation: Age:

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	toaction Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Tachycardia			Patient treated with valium and the tachycardia resolved.
	Tardive dyskinesia			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient experienced tachycardia when treatment was increased from 5mg to 10mg daily. after taking valium the patient then experienced shaking and stiffness of the neck. the patient's doctor is considering reducing the dose of zyprexa to 5mg but does not intend to cease it completely. doctor is also considering treating the shaking and stiffness of the neck with kemadrin.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 144747
 Seq: 1
 Gender: M

 Reported:
 18/10/1999
 Weight:

Hospitalisation: Age: 43Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Patient experienced abnormal tongue movements.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 17.5 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Abnormal tongue movements described as a "sideways tongue movement". patient history: history of receiving anti-psychotic treatment since 15 years of age.

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Report Details:

Case Number: 145014

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

ospitalisatior Onset Date		3 9	2/10/1999 Weight:					
Onset Date				Age:				
Outcome	e:			DOB:				
	e: Unknown			Causality: Causality possible				y: Causality possible
action Det								
	erred Term	Se	everity	Repo	rt De	escription		Treatment
iapism								
ledicine De				Reas	son:	Depression		
Tablet			0.0				Oral	
Batch:		S	tarted:			Stopped:		
LANZAPINE (S	Suspected)			Reas	son:			
Oral app	olication		0.0				Oral	
Batch:		S	tarted:			Stopped:		
aboratory Date	Investigat Type	tions: Range	Date Tested	Result			De	etails

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Date Range: 1 Jan 1960 To 31 Dec 1999 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: 145136 Seq: 1 Gender: M
Reported: 11/10/1999 Weight:

Hospitalisation: Admitted to hospital **Age:** 63

Onset Date: 17/08/1999 **DOB**: 28/02/1936

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			Clozaril was ceased and g-csg and iv antibiotics commenced and transferred to a haematology ward. ceased olanzapine and commenced on haloperidol 20mg at night.
Pyrexia			

Medicine Details:

	Reason:				
300.0 Milligram	300.0 Milligram Daily				
Started: 20/05/1999	Stopped	10/08/1999			
	Reason:				
20.0 Milligram	Daily				
Started: 10/08/1999	Stopped	17/08/1999			
	300.0 Milligram Started: 20/05/1999 20.0 Milligram	300.0 Milligram Daily Started: 20/05/1999 Stopped: Reason: 20.0 Milligram Daily			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		17/08/1999	0.1	

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 145168 Seq: 1 Gender: F

Reported: 28/10/1999 Weight:
Hospitalisation: Age: 58

Onset Date: 08/10/1999 **DOB**: 17/12/1940

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Intentional overdose.	

Medicine Details:

ZYPREXA (Suspected) Reason: Other paranoid states

Tablet 15.0 Milligram Daily Oral

Batch: Started: 08/02/1999 **Stopped:** 28/10/1999 8M

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

The patient expereinced nausea, light headedness and tingling around her lips and on the tips of her fingers. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisatio	ed: 01/11/199 n: te: ne: Recovere		1		Weig A D	der: F ght: age: OB: lity: Causality possible	
	erred Term	Se	verity	Repo	ort Description	Treatment	
Confusional s	tate			octurnal confus	·		
Urinary incont	inence						
Medicine D							
EPILIM (Other	drug)		0.0	Rea	son:		
Batch		St	0.0 arted:		Stopped:		
	SONATE (Other		arteu.	Rea			
LITTION OAK	OTATE (Other	ui ug)	0.0	i (Ca	3011.		
Batch		St	arted:		Stopped:		
ZYPREXA (Sus	spected)			Rea	son:		
			0.0				
Batch		St	arted:		Stopped:		
Laboratory Investigations: Date Type Range Date Tested Result Details							
Additional Information:							

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 145234
 Seq: 1
 Gender: M

 Reported:
 01/11/1999
 Weight:

Hospitalisation: Age: 43

Onset Date: DOB: 10/08/1956

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•					
	Preferred Term	Severity	Report Description	Treatment	
	Gravitational oedema		Pedal oedema extended two thirds up the ankle.	Ceased zyprexa	

Medicine Details:

ZYPREXA (Suspected) Reason: Schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 22/09/1999 **Stopped:** 27/09/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drugs: lithium, valproate sodium, chlorpromazine, clonazeapm. patient started on 5mg/night of zyprexa, then dose was increased to 10mg/night and patient experienced symptoms.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 145237
 Seq: 1
 Gender: M

 Reported:
 01/11/1999
 Weight:

Hospitalisation: Age: 33

Onset Date: 24/10/1999 **DOB**: 09/05/1966

Outcome: Death Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Sudden death		Date of death 24/10/99.	
Suicide attempt			

Medicine Details:

CLOZARIL (Other drug) Reason:

Tablet 0.0 Oral

Batch: Started: 24/03/1995 **Stopped:** 24/08/1999

OLANZAPINE (Suspected) Reason:

20.0 Milligram Daily

Batch: Started: 01/07/1999 Stopped: 24/10/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Date of death: 24/10/1999. patient has history of suicide attempts prior to clozapine treatment but not during treatment. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 145260
 Seq: 1
 Gender: M

 Reported:
 01/11/1999
 Weight:

Hospitalisation: Age: 32

Onset Date: DOB: 17/08/1967

Outcome: Not yet recovered Causality: Causality probable

Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
	Blood creatine phosphokinase incr			
	Neuroleptic malignant syndrome			Zyprexa discontinued.

Medicine Details:

 ZYPREXA (Suspected)
 Reason:
 Unspecified psychosis

 Tablet
 5.0 Milligram
 Daily
 Oral

 Batch:
 Started:
 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
Creatine					Creatine kinase (ck) levels raised to 1902.

Additional Information:

The patient has a medical history of a motor vehicle accident in 1988 and developed organic psychosis.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repor Hospitalisat Onset D	ate: me: Unknown		Gender: F Weight: Age: A5 DOB: Causality: Causality possib				
	eferred Term	Severity	Repo	ort Description	Treatment		
Dyskinesia				nents of her head and			
Medicine ZOLOFT (Ott			Rea	son:			
Bato	.h.	0.0					
SEREPAX (C		Started:	Stopped: Reason:				
OLINEI AX (O	ther drug,	0.0	Nea	5011.			
Bato	:h:	Started:	Stopped:				
ZYPREXA (S	uspected)		Rea	son:			
		0.0					
Bato	:h:	Started:	Stopped:				
Laboratory Investigations: Date Type Range Date Tested Result Details							
Additiona	ıl Informatio	n:					

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Patient had been on olanzapine for approximately three years. in the last 2 to 3 months the report has noticed that the patient has developed abnormal movements of her head and hadns.



Report Details:

Case Number: 145262

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 01/11/1999		Weight:							
ospitalisation:	Age:								
Onset Date:			1	DOB:					
Outcome: Not yet recover	ed	Causality: Causality possible							
action Details:		1		1					
Preferred Term	Severity		oort Description	Treatment					
epatic function abnormal		Elevated liver f	unction tests.						
izziness ausea									
ledicine Details:									
ZYPREXA (Suspected)			ason:						
	20.0	Milligram	Daily						
Batch:	Started:		Stopped:	CONTIN					
_aboratory Investigations Date Type Ra	ange Date Tes	sted Result		Details					
Date Type No	alige Date les	Result		Details					
Additional Information:									
oort Run: 04/06/2007	tabase: pusime02		ADRS004	Page 480 of 526					



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 145356 Seq: 1 Gender: F

Reported: 05/11/1999 Weight: 60.00 Hospitalisation: Age: 44Y

Onset Date: 15/10/1999 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness		"head spins".	
Hyperhidrosis		Hot sweats.	Ceased therapy with zyprexa (bed rest). ceased therapy with efexor-xr
Headache		Severe headaches.	
Chills		Shivers.	
Tremor		Uncontrollable body shakes.	
Fatigue			
Palpitations			
Tachycardia			
Vertigo			

Medicine Details:

modionio Botanoi			
ZYPREXA (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 13/10/1999	Stopped:	15/10/1999
EFEXOR-XR (Suspected)		Reason: Depression	
Capsule	300.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1999	Stopped:	13/10/1999

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

See original report for details of other drug. - valpro. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 145536 Seq: 1 Gender: M

Reported: 08/11/1999 Weight: 90.00 Hospitalisation: Age: 18

Onset Date: 20/09/1999 **DOB**: 28/11/1980

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism		Prolonged painful erections lasting up to 4 hours.	

Medicine Details:

Medicine Details.			
ZOLOFT (Other drug)		Reason: Depression	
Tablet	100.0 Milligram	Daily Oral	
Batch:	Started: 15/06/1999	Stopped:	
ZYPREXA (Suspected)		Reason: Othr&unspec metabolic diseases	
Tablet	30.0 Milligram	Daily Oral	
Batch:	Started: 20/09/1999	Stopped: 13/10/1999	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Previously on 25mg olanzapine, commenced at 10mg 26/5/99.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 145602
 Seq: 1
 Gender: M

 Reported:
 11/11/1999
 Weight:

Hospitalisation: Age: 43Y

Onset Date: 31/10/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	<u>toaotioii Botaiioi</u>			
	Preferred Term	Severity	Report Description	Treatment
	Speech disorder		Involuntary vocal & unpredictable utterances.	
	Hallucination			

Medicine Details:

OLANZAPINE (Suspected) Reason:
20.0 Milligram Daily

Batch: Started: 01/10/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 145679
 Seq: 1
 Gender:
 F

 Reported:
 10/11/1999
 Weight:

Reported: 10/11/1999

Hospitalisation:
Onset Date:

Weight:
Age: 40Y

DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

odotion Botano.								
Preferred Term	Severity	Report Description	Treatment					
Confusional state		Nocturnal confusion						
Delirium		Nocturnal delirium						
Urinary incontinence		Urinary incontinence at night.						

Medicine Details:

Medicine Details.					
LITHIUM CARBONATE (Suspected)			Reason:	Unspecified ps	sychosis
	750.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	
ZYPREXA (Suspected)			Reason:	Unspecified ps	sychosis
Tablet	10.0	Milligram	Daily		Oral
Batch:	Started: 01	/06/1999		Stopped:	28/07/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Lithium was reintroduced with dramatic improvement and resolution of her manic symptomatology. however she continued to have nocturnal confusion/delirium with persistent nocturnal incontinence, she was discharged home on lithium, epilim and zyprex, her improvement was such that after about two weeks, the zyprexa was reduced from 10mg to 5 mg and then ceased, as soon as zyprexa was ceased, the nocturnal confusion, delirium and incontinence disappeared, see original report for details of other drugs: melleril, serenace, navane and epilim the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month, the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 145691 Seq: 1 Gender: M

Reported: 11/11/1999 **Weight:**

Hospitalisation: Age: 53Y
Onset Date: 04/11/1999
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

reaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Leukopenia			
Lymphopenia			
Neutropenia			

Medicine Details:

OLANZAPINE (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: Stopped: 04/11/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells				Wcc 2.6

Additional Information:

See original report for details of other drugs: vigabatrim, carbemazepin, valproate, diazepam and oxazepam.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 145703
 Seq: 1
 Gender: M

 Reported:
 12/11/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 78Y
Onset Date: 31/12/1999
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment				
Coordination abnormal		Acute onset of parkinsonian type ataxia					
Extrapyramidal disorder		Extrapyramidal syndrome					
Hypotension							

Medicine Details:

ZYPREXA (Suspected)				
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started:	Sto	opped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 145704 Seq: 1 Gender: F
Reported: 12/11/1999 Weight:

Hospitalisation: Age: 43

Onset Date: DOB: 14/12/1955

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Decreased white blood cell count	Ceased zyprexa

Medicine Details:

ZYPREXA (Suspected)		Reason:	Unspecified psychosis
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:		Stopped: 05/10/1999

Laboratory Investigations:

<u>Laborato</u>	i y ilittootiga				
Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		01/09/1999	1.8	
	Neutrophils		28/09/1999	1.9	
	Neutrophils		04/10/1999	1.4	
	Neutrophils		09/11/1999	2.0	
	Neutrophils		08/10/1999	1.9	
	White blood cells		01/09/1999	3.2	
	White blood cells		28/09/1999	3.1	

Additional Information:

Patient history: chronic mood disorder, suicidality, alcohol abuse and the use of venlafaxine for a period of 7 months. the reporter states that the patient has experienced previous neutropenia and leukopenia not associated with olanzapine treatment. patient was also taking alprazolam, temazeapm.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 145704
 Seq: 1
 Gender:
 F

 Reported:
 12/11/1999
 Weight:

Hospitalisation: Age: 43

Onset Date: DOB: 14/12/1955

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)		Reason:	Unspecified psychosis	
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped: 05/10/1999	

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ		White blood cells		04/10/1999	2.5	
١		White blood cells		08/10/1999	3.3	
ı		White blood cells		09/11/1999	2.9	

Additional Information:

Patient history: chronic mood disorder, suicidality, alcohol abuse and the use of venlafaxine for a period of 7 months. the reporter states that the patient has experienced previous neutropenia and leukopenia not associated with olanzapine treatment. patient was also taking alprazolam, temazeapm.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 145711 Seq: 1 Gender: F
Reported: 15/11/1999 Weight:
Hospitalisation: Age: 77Y

Onset Date: 31/10/1999 **DOB:**

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

D (17	1	5 (5)	_ , ,
Preferred Term	Severity	Report Description	Treatment
Rectal haemorrhage		Pr bleeding	
Hypertonia		Upper limb jerking	
Consciousness fluctuating			Ceased olanzapine and cipramil. given ceftriaxone
Hepatitis			
Oedema			
Paresis			
Renal impairment			
Urinary retention			
Vomiting			

Medicine Details:

ORGARAN (Suspected)		Reason:	Phleb&thrombophleb lowr extrem	
	0.0			
Batch:	Started:		Stopped:	
OLANZAPINE (Suspected)		Reason:	Plasma protein abnormalities	
	7.5 Milligram	Daily		
Batch:	Started: 01/07/1999		Stopped: 17/10/1999	
CIPRAMIL (Suspected)		Reason:	Depression	
	30.0 Milligram	Daily		
Batch:	Started:		Stopped: 17/10/1999	
FRAGMIN (Suspected)		Reason:	Phleb&thrombophleb lowr extrem	
	5.0 Thousand I	nternat Daily		
Batch:	Started: 10/10/1999		Stopped: 15/10/1999	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ		ALT = SGPT		17/10/1999	970	
		AST = SGOT		17/10/1999	2720	
		Bilirubin		17/10/1999	79	
		GGT = SGGT =		17/10/1999	60	
		SAP = ALP		17/10/1999	156	

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:						
Seq: 1	Weight: Age: DOB:	77Y				
Reason:						
1.0 Gram Dai	ly					
Started: 11/10/1999	Stopped: 13/10/1999)				
Additional Information: - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.						
	Reason: 1.0 Gram Dail Started: 11/10/1999	Reason: 1.0 Gram Daily Started: 11/10/1999 Stopped: 13/10/1999				

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 145819 Seq: 1 Gender: M

Reported: 12/11/1999 Weight:
Hospitalisation: Age: 37Y

Onset Date: 31/05/1997 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Patient experienced a rash on his buttocks	Zyprexa ceased

Medicine Details:

Medicine Details.			
COGENTIN (Other drug)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1997	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:					
Case Number: 145821	Seq: 1		Gend	er: F	
Reported: 12/11/19	99	Weight:			
Hospitalisation: Admitted	to hospital		Age:		
Onset Date:			DOB:		
Outcome: Not yet re	ecovered		Causali	ty: Causality possible	
Reaction Details:					
Preferred Term	Severity	Repo	ort Description	Treatment	
Vasodilatation		Hot flushes			
Euphoric mood		Hyperarousal			
Insomnia		Impaired sleep			
Hyperacusis		Sensitivity to sou	ınd		
Drug withdrawal syndrome					
Nausea					
Medicine Details: DIAZEPAM (Other drug) Reason:					
	0.0				
Batch: Started:		Stopped:			
LORAZEPAM (Other drug)		Reason:			
	0.0				
Batch:		Started: Stopped:			
OESTROGENS NOS (Other dr	o.0	Rea	son:		
Batch:		Started: Stopped:			
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia			
Tablet	5.0	5.0 Milligram Daily Ora			
Batch:	Started:		Stopped:		
Laboratory Investiga	tions				
Date Type	Range Date Tes	ted Result	D	etails	
7.					
Additional Information		on.			

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 145822
 Seq: 1
 Gender:
 F

 Reported:
 12/11/1999
 Weight:

Hospitalisation: Age: 64Y
Onset Date: 08/10/1999
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vaginal haemorrhage		Substantial bleed	

Medicine Details:

WARFARIN SODIUM (Interaction)				
	0.0			
Batch:	Started:		Stopped:	
ZYPREXA (Interaction)		Reason:		
Tablet	5.0 Milligram	Daily	Ora	al
Batch:	Started: 01/01/1999		Stopped:	CONTIN
IMDUR (Other drug)		Reason:		
	0.0			
Batch:	Started:		Stopped:	
METOPROLOL TARTRATE (Other drug)		Reason:		
	0.0			
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Medical history included hysterectomy. the patient had been on zyprexa for approximately 1 week. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: Reported: Hospitalisation:	145822 12/11/1999	Seq: 1		Gender: Weight:		
Onset Date:	08/10/1000			Age: DOB:		
	Not yet recovered	1			Causality possible	
Reaction Detai		1		Causanty.	Causality possible	
Neaction Detai	13.					
Madiaina Date	oilo.					
Medicine Deta			Reason:			
120112102 (011101	u. u.g,	0.0	110000111			
Batch:		Started:		Stopped:		
CLONAZEPAM (Ot	ther drug)		Reason:			
		0.0				
Batch:		Started:		Stopped:		
HALOPERIDOL (O	ther drug)		Reason:			
		0.0				
Batch:		Started:		Stopped:		
Laboratory Investigations:						
•	J					
Additional Inf	ormation:					
		the patient had been on z	yprexa for appro	oximately 1 week. the	e dosage start date is not	
Medical history included hysterectomy. the patient had been on zyprexa for approximately 1 week. the dosage start date is not accurate but indicates that start occurred sometime during the year.						

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Gender: F Case Number: 145823 Seq: 1 Weight: Reported: 12/11/1999 **Hospitalisation:** Age: A3

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touction Botalio.					
	Preferred Term	Severity	Report Description	Treatment	
	Neuropathy		Reflex sympathetic dystrophy (reflexes decreased)		
	Pain		Twisted ankle	Zyprexa ceased	

Medicine Details:			
NITRAZEPAM (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient now has no movement below the knee.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 145963 Seq: 1 Gender: M

Reported: 18/11/1999 Weight:
Hospitalisation: Age: 53Y

Onset Date: 04/11/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

caction betains.				
Preferred Term	Severity	Report Description	Treatment	l
Leukopenia			Olanzapine ceased on 5/1/99 and patient recovered.]

Medicine Details:

OLANZAPINE (Suspected) Reason: Otr spec symp psychopathol nec

Tablet 5.0 Milligram Daily Oral

Batch: Started: Stopped: 08/11/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				Leucopenia wcc = 2.6

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Numb							
		Seq:	1			Gender:	F
-	ed: 19/11/19					Weight:	
lospitalisatio		I to hospital				Age:	
Onset Da		_				DOB:	
	ne: Not yet r	ecovered				Causality:	Causality possible
eaction De						<u> </u>	
	ferred Term	Se	everity	•	ort Description		Treatment
Muscle twitch	•		Bab	by expereince	ed twitching in leg		
Convulsion no							
Drug withdra\ Nervousness	•	e neonati					
Medicine D	etails:						
		RIDE (Suspected)		Rea	son:		
			0.0				
Batch	:	S	tarted:		Stopped	l:	
CHLORPROM	AZINE HYDRO	CHLORIDE (Susp		Rea	son:		
			0.0				
Batch		Si	tarted:		Stopped	l:	
METHYLDOPA	(Suspected)		0.0	Rea	son:		
			0.0		Stopped	1.	
D-4-1	_	•				I:	
Batch		Si	tarted:	Doo			
ZYPREXA (Su	spected)	S			son:		c transfor
ZYPREXA (Sur	spected) oplication	<u></u>	10.0 Milli		son: Daily	Breast mill	< transfer
ZYPREXA (Su	spected) oplication	<u></u>			son:	Breast mill	c transfer
ZYPREXA (Sur Oral al Batch	spected) oplication : / Investiga	s ations:	10.0 Milli tarted:	gram	son: Daily	Breast mill	
ZYPREXA (Sur	spected) oplication	Si	10.0 Milli		son: Daily	Breast mill	
ZYPREXA (Sur Oral al Batch	spected) oplication : / Investiga	s ations:	10.0 Milli tarted:	gram	son: Daily	Breast mill	
ZYPREXA (Sur Oral al Batch	spected) oplication : / Investiga	s ations:	10.0 Milli tarted:	gram	son: Daily	Breast mill	
ZYPREXA (Sur Oral al Batch	spected) oplication : / Investiga	s ations:	10.0 Milli	gram	son: Daily	Breast mill	
ZYPREXA (Sur Oral al Batch	spected) oplication : / Investiga	s ations:	10.0 Milli	gram	son: Daily	Breast mill	
ZYPREXA (Sur Oral al Batch	spected) oplication : / Investiga	s ations:	10.0 Milli	gram	son: Daily	Breast mill	
ZYPREXA (Sur Oral al Batch	spected) oplication : / Investiga	s ations:	10.0 Milli	gram	son: Daily	Breast mill	
ZYPREXA (Sur Oral al Batch Laboratory Date	spected) oplication : / Investiga Type	stions: Range	10.0 Milligtarted: Date Tested	Result	son: Daily Stopped	Breast mill	
ZYPREXA (Sur Oral al Batch Laboratory Date	spected) oplication : / Investiga Type	sintions:	10.0 Milligtarted: Date Tested	Result	son: Daily Stopped	Breast mill	
ZYPREXA (Sur Oral al Batch Laboratory Date	spected) oplication : / Investiga Type	stions: Range	10.0 Milligtarted: Date Tested	Result	son: Daily Stopped	Breast mill	
Oral al Batch Laboratory Date	spected) oplication : / Investiga Type	stions: Range	10.0 Milligtarted: Date Tested	Result	son: Daily Stopped	Breast mill	

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 146177	Seq: 0		Gende	r: M
Reported: 25/11/1999	•		Weigh	t: 85.00
spitalisation:			Age	e: 51Y
Onset Date:			DO	B:
Outcome: Recovered			Causalit	y: Causality probable
action Details:			T-	
Preferred Term	Severity	Repo	ort Description	Treatment
ypercalcaemia			ļ	Stopped zyprexa
ledicine Details:				
YPREXA (Suspected)	0.0	Reas	son:	
Batch:	0.0 Started:		Stopped:	
aboratory Investigation				
	Range Date Tested	Result		tails
Calcium			Increased ca to 3.4.	
Additional Information:				
ort Run: 04/06/2007 04:31PM D	atabase: pusime02	Α	DRS004	Page 498 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 146186
 Seq: 1
 Gender:
 F

 Reported:
 25/11/1999
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 99U
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		Mastectomy

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily Oral

Batch: Started: 01/01/1998 L TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt I	Det	tail	ls:

Case Number: 146287 Seq: 1 Gender: M
Reported: 29/11/1999 Weight:

Reported: 29/11/1999 Weight:
Hospitalisation: Age: 53Y
Onset Date: 04/11/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

			
Preferred Term	Severity	Report Description	Treatment
Leukopenia		Wcc=2.6, decreased pmn and decreased lymphocytes	Olanzapine was ceased

Medicine Details:

TEGRETOL (Other drug)			Reason:	Other&unspecified epilepsy	
Tablet	400.0	Milligram	Daily	Oral	
Batch:	Started:		L TERM	Stopped:	CONTIN
VIGABATRIN (Other drug)			Reason:	Other&unspecified epilepsy	
	1.5	Gram	Daily		
Batch:	Started:			Stopped:	CONTIN
SODIUM VALPROATE (Other drug)			Reason:	Other&unspecified epilepsy	
	700.0	Milligram	Daily		
Batch:	Started:			Stopped:	CONTIN
OLANZAPINE (Suspected)			Reason:	Explosive personality disorde	r
Tablet	5.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped: 05/11/1999	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 146531 Seq: 1 Gender: F

Reported: 02/12/1999 Weight: 56.00 Hospitalisation: Age: 31Y

Onset Date: 17/11/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

toaction Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Urticaria			Prednisone reducing dose and claratyne 1 x daily.
Face oedema			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 15.0 Milligram Daily Oral

Batch: Started: 19/10/1999 **Stopped:** 18/11/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

This was the first exposure to zyprexa.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 146787
 Seq: 1
 Gender:
 F

 Reported:
 09/12/1999
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 31/12/1999
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Torsade de pointes			Ceased celebrex and admitted to coronary care
Ventricular tachycardia			

Medicine Details:

Medicine Details.					
CELEBREX (Suspected)			Reason:		
Capsule	200.0	Milligram	Daily	Oral	
Batch:	Started:		s	topped:	
OLANZAPINE (Suspected)			Reason:		
Tablet	2.5	Milligram	Daily	Oral	
Batch:	Started:		S	topped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 146817 Seq: 1 Gender: M Reported: 13/12/1999 Weight:

Hospitalisation: Age: 55Y Onset Date: 30/11/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

CALTRATE (Other drug) Reason: Other diseases of bone Daily

1.8 Gram

Batch: Started: 01/01/1998 Stopped: CONTIN

AURORIX (Suspected) Reason:

0.0

Started: 28/10/1999 Batch: Stopped:

OLANZAPINE (Suspected) Reason: Depression

1.0 Dose Unspecified 1 time

Batch: Started: 01/10/1999 29/11/1999 Stopped:

VALIUM (Suspected) Reason: Depression

1.0 Dose Unspecified 1 time

Batch: Started: 01/10/1999 Stopped: 29/11/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	(0-55)	30/11/1999	114	
	ALT = SGPT	(0-55)	07/12/1999	70	
	GGT = SGGT =	(0-60)	30/11/1999	113	
	GGT = SGGT =	(0-60)	07/12/1999	86	
	SAP = ALP	(30-110)	30/11/1999	109	
	SAP = ALP	(30-110)	07/12/1999	117	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month, the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 146817 Seq: 1 Gender: M
Reported: 13/12/1999 Weight:

Hospitalisation: Age: 55Y
Onset Date: 30/11/1999
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

AROPAX (Suspected)		Reason:	Depression		
	40.0 Milligram	Daily			
Batch:	Started: 01/10/1999		Stopped:	CONTIN	
RANITIDINE (Suspected)		Reason:	Otr disorders stomach	function	
	300.0 Milligram	Daily			
Batch:	Started: 01/10/1999		Stopped:	CONTIN	

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the wonth. The dosage start date is not accurate but indicates that start occurred sometime during the wonth.

Report Run: 04/06/2007 04:31PM Database: pusime02 ADRS004 Page 504 of 526



Case Number: 146845

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 13/12/1999				weig	nt:	
ospitalisation:			Age:			
Onset Date:				DO	OB:	
Outcome: Unknown		Causality: Causality possible				
eaction Details:						
Preferred Term	Severity	R	Report Des	cription	Treatment	
Synaecomastia				3-4mth developed	Olanzapine ceased.	
Medicine Details:			Reason:			
OLANZAPINE (Suspected) Tablet	7	.5 Milligram		Oral		
Batch:	Started:	.5 Milligram	Daily	Stopped:		
aboratory Investigation						
Date Type	Range Date T	Tested Result			Details	
	I					
additional Information:						
dditional information:						
oort Run: 04/06/2007 04:31PM	Database: pusime02		ADRS004	ı	Page 505 of 526	



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 146846 Reported: 13/12/1999	Seq: 1		Gender: M Weight:				
spitalisation:			•	Age:			
Onset Date:			DOB:				
Outcome: Unknown			Ca	usality: Causality possible			
action Details:				•			
Preferred Term	Severity	Rep	ort Description	Treatment			
vnaecomastia		Patient develop	ed breasts.	Olanzapine treatment was discontinued.			
edicine Details: LANZAPINE (Suspected)		Rea	ason:				
Tablet	7.5	Milligram		Oral			
Batch:	Started:	J •	Stopped:				
boratory Investigation	ns:						
Date Type	Range Date Test	ted Result		Details			
dditional Information:							
ort Run: 04/06/2007 04:31PM	Database: pusime02		ADRS004	Page 506 of 526			



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 146847 Seq: 1 Gender: M

Reported: 13/12/1999 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Pt experienced a decrease in sodium levels.	

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Tablet	0.0	Daily	Oral
Batch:	Started:	Sto	pped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium				Sodium levels from 135 to 123.

Additional Information:

Patient also taking valproate sodium & chlorpromazine.

Report Run: 04/06/2007 04:31PM Database: pusime02 ADRS004 Page 507 of 526



Case Number: 146848

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 13/12/1999	weight:					
lospitalisation:		Age:				
Onset Date:			I	OOB:		
Outcome: Not yet recov	ered		Causality: Causality possible			
eaction Details:				,		
Preferred Term	Severity	Report D	escription	Treatment		
Irinary retention		Urinary retention after olanzapine		Patient had to be catheterised four time in 24 hours.		
Medicine Details: OLANZAPINE (Suspected)		Reason:	Unspecified schizop			
Tablet Batch:	5.0 Started:	Milligram Dai	y Oral Stopped:			
_aboratory Investigation						
Date Type	Range Date Tes	ted Result		Details		
dditional Information:						
ort Run: 04/06/2007 04:31PM [Database: pusime02	ADRS	004	Page 508 of 526		



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 146849 Seq: 1 Gender: M

Reported: 13/12/1999 Weight:
Hospitalisation: Age: 46Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Oedema on legs which was quite marked.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient is also taking cipramil. the oedema is starting to spread to his hands.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 146850 Seq: 1 Gender: M
Reported: 13/12/1999 Weight:
Hospitalisation: Age:

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

٠,	todotion botanoi			
	Preferred Term	Severity	Report Description	Treatment
	Gynaecomastia			Zyprexa was reduced to 5mg and patient continues to receive this lowered dosage.

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Alternating-other Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Prolactin level was not elevated and was within normal range.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 146851
 Seq: 1
 Gender: M

 Reported:
 13/12/1999
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Hepatic function abnormal		Elevated liver function tests.	
	Pyrexia		Patient developed a fever.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/08/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking serzone. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

_aboratory Investigation Date Type	Range Date Tes	ted Result	De	tails
		tod Booult	D-	taile
Batch:	Started:		Stopped:	CONTIN
Tablet		Milligram	Daily Oral	
ledicine Details: ZYPREXA (Suspected)		Reas	on: Unspecified schizophre	nia
Periorbital oedema		Pt experienced o	edema in feet and ankles.	
Preferred Term	Severity		rt Description	Treatment
action Details:			Causani	y: Causality possible
			DO	
Onset Date: Outcome: Unknown			Age	e: 22Y
Reported: 13/12/1999 pspitalisation: Onset Date:			Weigh	



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 146853
 Seq: 1
 Gender: M

 Reported:
 13/12/1999
 Weight:

Hospitalisation: Age: 18

Onset Date: 20/09/1999 **DOB**: 28/11/1980

Outcome: Recovered with sequelae Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism		Pt developed priapism for upto four hours.	Zyprexa ceased.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

 Tablet
 30.0 Milligram
 Daily
 Oral

 Batch:
 Started: 20/09/1999
 Stopped: 13/10/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient is also taking zoloft. patient had been on zyprexa for 4 months at 25mg/day.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number:146901Seq: 1Gender: FReported:13/12/1999Weight:Hospitalisation:Age:

Onset Date: 31/10/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash	Severe	Rash on trunk, upper arms and upper legs	

Medicine Details:

ASPIRIN (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
CARBAMAZEPINE (Other drug)		Reason:	
Oral application	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CONTRAST MEDIUM NOS (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 15/10/1999	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Case Number: 146902

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 13/12/1	999				Weigh	t:	
lospitalisation:		Age: 43Y DOB: Causality: Causality possible					
Onset Date:							
Outcome: Unknow	wn						
eaction Details:							
Preferred Term	. S	everity		oort Descri		Treatment	
ardive dyskinesia		Ab mo	onormal tong ovements	ue moveme	ents- sideway		
Medicine Details: ZYPREXA (Suspected)			Re	eason:			
Tablet		17.5 Mil	ligram	Daily	Oral		
Batch:		Started:			Stopped:	CONTIN	
aboratory Investig	ations:						
Date Type	Range	Date Tested	Result		De	etails	
						_	
Additional Informat	ion:						
oort Run: 04/06/2007 04:3	1PM Database: p	ousime02		ADRS004		Page 515 of 526	



Case Number: 146903

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 13/12/1999				We	ight:			
lospitalisation:		Age : 92Y						
Onset Date:			DOB:					
Outcome: Recovered			Causality: Causality possible					
eaction Details:								
Preferred Term	Seve	rity	Report	Description	Treatment			
Agitation								
Confusional state								
Mania								
Medicine Details:								
ZYPREXA (Suspected)			Reaso					
Tablet		2.5 Millig	gram D	aily Ora	l			
Batch:	Start	ed:		Stopped:				
Laboratory Investigation								
Date Type	Range Da	ate Tested	Result		Details			
Added								
Additional Information:								
	D-t-b	00	•==	20004				
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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	146904	Seq:	1			Gender	: M	
Reported:	13/12/199	9				Weight:		
ospitalisation:						Age:	A2	
Onset Date:						DOB	:	
Outcome:	Not yet re	covered				Causality:	Causality prob	able
eaction Detai	ls:							
Preferre	ed Term	Se	everity	Repo	ort Description		Treatmer	nt
Neuroleptic malio	gnant synd	rome						
Madiaina Dat	-:I-·							
Medicine Det				Rea	son:			
Tablet	iou)		0.0	Noa	3011.	Oral		
Batch:		S	tarted:		Stoppe			
					•			
Laboratory In	vestigat	ions:						
Date	Туре	Range	Date Tested	Result		Deta	ils	
Additional Inf	formatio	n:						
oort Run: 04/06/200	07 04:31PN	1 Database: pu	usime02	Д	.DRS004		Page 517	of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Ren	ort	Deta	ils:
-----	-----	------	------

 Case Number:
 146906
 Seq: 1
 Gender: U

 Reported:
 13/12/1999
 Weight:

Hospitalisation: Age:

Onset Date: 04/11/1999 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cataract			

Medicine Details:

 OLANZAPINE (Suspected)
 Reason:
 Unspecified schizophrenia

 Tablet
 0.0
 Oral

Batch: Started: 01/03/1998 Stopped:

FELODIPINE (Suspected) Reason:

0.0

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 147045 Seq: 1 Gender: F

Reported: 17/12/1999 Weight:
Hospitalisation: Age: 74Y

Onset Date: 07/09/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation		Increased agitation	Ceased sertraline.

Medicine Details:

OLANZAPINE (Suspected) Reason: Depression

Tablet 2.5 Milligram Daily Oral

Batch: **Started**: 03/09/1999 **Stopped**: 07/09/1999

SERTRALINE HYDROCHLORIDE (Suspected) Reason:

 Tablet
 25.0 Milligram
 Daily
 Oral

 Batch:
 Started: 01/09/1999
 Stopped: 07/09/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Dose of sertraline was increased from 25mg to 50mg daily.

Report Run: 04/06/2007 04:31PM Database: pusime02 ADRS004 Page 519 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 147085
 Seq: 1
 Gender: M

 Reported:
 17/12/1999
 Weight: 77.00

Hospitalisation: Age: 34

Onset Date: 31/03/1999 **DOB**: 05/12/1964

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation			
Blood creatine phosphokinase inci			
Confusional state			
Hepatic function abnormal			
Hypertonia			
Leukocytosis			
Neuroleptic malignant syndrome	Life threatening		

Medicine Details:

Medicine Details.			
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	25.0 Milligram	Daily	
Batch:	Started: 01/01/1998	Stopped: 28/03/1999	
LARGACTIL (Suspected)		Reason:	
	400.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Ck increased to 4900.

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Run: 04/06/2007 04:31PM Database: pusime02 ADRS004 Page 520 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 147150 Seq: 1 Gender: M

Reported: 21/12/1999 Weight: 90.00 Hospitalisation: Age: 56Y

Onset Date: 12/12/1999 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	todotion Dotails.			
	Preferred Term	Severity	Report Description	Treatment
	Dry mouth			
	Speech disorder			

Medicine Details:

ZYPREXA (Suspected) Reason: Depression

10.0 Milligram Daily

Batch: Started: 12/02/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt also taking efexor, kapanol.

Report Run: 04/06/2007 04:32PM Database: pusime02 ADRS004 Page 521 of 526



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 147336
 Seq: 1
 Gender: M

 Reported:
 16/12/1999
 Weight:

Hospitalisation: Age: A4
Onset Date: 31/12/1999
DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Papart Description	Trootmont
Preferred Term	Seventy	Report Description	Treatment
Convulsion	The patient experienced a seizure and died.		

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)			
	25.0 Milligram	Daily	
Batch:	Started: 01/01/1997	Stopped:	
KEMADRIN (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient has no prior history of epilepsy. the patients medical history includes being on largactil 1.6gm most of his life (no longer taking it). the patient was previously on risperidone. - the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 147339
 Seq: 1
 Gender:
 F

 Reported:
 13/12/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 71Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

,	caction Details.	action betails.								
	Preferred Term	Severity	Report Description	Treatment]					
	patic function abnormal		Zyprexa ceased.							
	Jaundice									

Medicine Details:

 ZYPREXA (Suspected)
 Reason:
 Unspecified psychosis

 Tablet
 7.5 Milligram
 Daily
 Oral

 Batch:
 Started:
 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient initially commenced zyprexa at 5mg/day and the increased the dose to 7.5mg/day.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

<u>-aboratory Investigations</u> Date Type F	S: Range Date Tested	Result		Details	
Batch:	Started : 19/10/1	999	Stopped: 18/11/	1999	
Tablet	15.0 Mill	-			
ledicine Details: ZYPREXA (Suspected)		Reason: l	Jnspecified schizoph	renia	
Irticaria				Reducing dose of prednisc claratyne, zyprexa ceased	
ace oedema	Required Specialist Consultation				
action Details: Preferred Term	Severity	Report Desc	cription	Treatment	
Outcome: Unknown			Causal	ity: Causality possible	
	DOB: 07/11/1967				
Onset Date:			_	ge: 32	
Reported: 30/12/1999 spitalisation: Onset Date:			Weig		



Date Range: 1 Jan 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Rep	ort	Detail	ls:
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Case Number: 147501 Seq: 1 Gender: F

Reported: 30/12/1999 Weight:
Hospitalisation: Age: 33

Onset Date: 18/06/1999 **DOB**: 14/04/1966

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation			Zyprexa ceased

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

Tablet 12.5 Milligram Daily Oral

Batch: **Started**: 13/05/1999 **Stopped**: 18/06/1999

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 1960 To 31 Dec 1999 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

ase Number: 147502	Seq: 1		Gender: M		
Reported: 30/12/1999		1	Weight:		
spitalisation:			Age:		
Onset Date:		DOB:			
Outcome: Unknown		Са	usality: Causality possible		
action Details:					
Preferred Term	Severity	Report Description	Treatment		
edema peripheral					
ladicina Dataila:					
ledicine Details: ZYPREXA (Suspected)		Reason:			
	0.0				
Batch:	Started:	Stopped:			
aboratory Investigation Date Type	ns: Range Date Tested	Result	Details		
Date Type	Nange Date rested	Result	Details		
I		_			
Additional Information:					

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