

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 147635
 Seq: 1
 Gender: M

 Reported:
 04/01/2000
 Weight:

Hospitalisation: Age: 50Y
Onset Date: 31/12/1999
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caction Details.								
Preferred Term	Severity	Report Description	Treatment					
Aggression Agitation			Zoloft ceased, dose of zyprexa increased to 15mg/day.					

Medicine Details:

Medicine Details.			
ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
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 accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 147911 Seq: 1 Gender: F

Reported: 12/01/2000 Weight: 65.00 Hospitalisation: Age: 26Y

Onset Date: 19/12/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Generalised rash	Telfast 60mg bd.

Medicine Details:

Medicine Details.		
OLANZAPINE (Suspected)		Reason: Schizophrenia
Tablet	15.0 Milligram	Daily Oral
Batch:	Started: 13/12/1999	Stopped:
SERZONE (Suspected)		Reason: Depression
	200.0 Milligram	Daily
Batch:	Started: 13/12/1999	Stopped: 21/12/1999
RANITIDINE (Suspected)		Reason: Ulcer of stomach w/o ment perf
	300.0 Milligram	Daily
Batch:	Started:	Stopped: 21/12/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking oanadol and ibruprofen.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 147929
 Seq: 1
 Gender: M

 Reported:
 12/01/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 80Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Aggression			
Hepatic function abnormal			

Medicine Details:

OLANZAPINE (Suspected) Reason:

0.0

Batch: Started: 08/11/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Ggt - 414, bil - 54.
	International				Inr - 4> 7.

Additional Information:

Pt also taking ranitidine, temazepam, aspirin, ethacrynic acid, cyproheptadine prednisone, panadol.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	etails:					
Reportatisat Onset I Outco	nber: 147933 rted: 12/01/2000 tion: Date: ome: Not yet reco	Seq: 1		Gender: Weight: Age: DOB: Causality:	A4	
eaction D	Details: referred Term	Severity	Reno	t Description	Treatment	
eukopenia		Ceventy	Blood dyscrasia	t Description	rreatment	
Medicine ZYPREXA (S			Reas	on: Unspecified schizophrenia		
ZII KEXA (C	ouspecteu)	20.0		Daily		
Bate	ch:	Started:	Stopped:			
	ry Investigatio					
Date	Type White blood cells	Range Date Test		Detai Vbc - 3, neutrophils - 1.5.	ls	
		•	<u> </u>			

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Case Number: 147934

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 12/01/2000		Weight:				
ospitalisation:			Age:			
Onset Date:		DOB: Causality: Causality possible				
Outcome: Not yet recove	red					
action Details:						
Preferred Term	Severity	Report Description	n Treatment			
stonia		Dystonic tongue movement	Cogentin. zyprexa ceased.			
rskinesia						
eadache						
outh ulceration			L			
edicine Details:						
YPREXA (Suspected)	0.0	Reason: Unspecified schizophrenia				
Batch:	Started:	Stop	nod:			
aboratory Investigations		. [[
Date Type R	ange Date Teste	ed Result	Details			
dditional Information:						
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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 147989 Seq: 1 Gender: F

Reported: 14/01/2000 Weight: 65.00 Hospitalisation: Age: 47Y

Onset Date: 15/12/1999 **DOB**:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			

Medicine Details:

ZYPREXA (Suspected) Reason: Anxiety neurosis

10.0 Milligram Daily

Batch: Started: 14/12/1999 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient needs to keep moving, lasts about 4-5 hour after taking zyprexa. patient history: largactil - tachycardia & most antidepressants - agitation.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 148030
 Seq: 1
 Gender: F

 Reported:
 17/01/2000
 Weight:

Hospitalisation: Age: 90Y
Onset Date: 17/12/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion botains.			
Preferred Term	Severity	Report Description	Treatment
Mouth ulceration		Severe mouth ulcers	
Face oedema		Swelling of lips	
Tongue oedema		Swelling of tongue and mouth.	
Angioedema			Ceased zyprexa. given telfast.

Medicine Details:

TEGRETOL (Other drug)		Reason:		
	0.0			
Batch:	Started:	L TERM	Stopped:	
ZANTAC (Other drug)		Reason:		
	0.0			
Batch:	Started:	L TERM	Stopped:	
ASTRIX 100 (Suspected)		Reason:		
	0.0			
Batch:	Started:	L TERM	Stopped:	
HYDOPA (Suspected)		Reason:		
	0.0			
Batch:	Started:	L TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms within hours of taking first zyprexa. astrix was also withheld, but no reaction when restarted.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation: Onset Date:	17/01/2000 17/12/1999 Recovered	Seq: 1				Gender: Weight: Age: DOB: ausality:	90Y	
Medicine Deta								
ZYPREXA (Suspec	:ted)	1 1	2 Milligram	Reason: Daily	Unspecified ps	ychosis		
Batch:		Started: 1		Dally	Stopped:	17/12/1999)	
Laboratory In	vestigations:							
Additional Inf Patient experience		nours of taking	। first zyprexa. a	astrix was a	also withheld,	but no rea	action when restarted.	

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 148036 Seq: 1 Gender: F

Reported: 14/01/2000 Weight: 80.00 Hospitalisation: Age: 69Y

Onset Date: 29/11/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

,	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Hepatic function abnormal			
	Myalgia			
	Pyrexia			
	Red blood cell sedimentation rate i			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

Tablet 5.0 Milligram Daily Oral

Batch: **Started**: 11/10/1999 **Stopped**: 08/12/1999

Laboratory Investigations:

	. <u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		29/11/1999	61	
	Erythrocyte		29/11/1999	75	
	GGT = SGGT =		29/11/1999	132	

Additional Information:

Patient was also taking chlotride, renitec, pravachol, rocaltrol.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 148042 Seq: 1 Gender: M

 Reported: 13/01/2000
 Weight: 60.00

 Hospitalisation:
 Age: 43Y

 Onset Date: 30/11/1999
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	todotion Botanoi			
	Preferred Term	Severity	Report Description	Treatment
	Skin exfoliation		Loss of skin to soles of feet	
	Gravitational oedema		Oedema feet and ankles	
	Rash maculo-papular			

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified psychosisTablet10.0 MilligramDailyOral

Batch: Started: 01/02/1999 **Stopped:** 17/12/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Dose of zyprexa was increased form 5mg daily in june to 10mg daily. 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 148288	Seq: 1		Gende	
Reported: 24/01/2000			Weight	
ospitalisation:			Age	
Onset Date:			DOI	
Outcome: Unknown			Causanty	y: Causality certain
action Details: Preferred Term	Severity	Report De	scription	Treatment
rthralgia	Ocverty	report be	SCHPRION	ricatilicit
ledicine Details: ZYPREXA (Suspected)		Reason:		
Tablet	30.0 Milli		Oral	
Batch:	Started:		Stopped:	
aboratory Investigatio				
Date Type	Range Date Tested	Result	De	tails
Additional Information:				
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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: 24/ Spitalisation: Onset Date: Outcome: No action Details: Preferred Teutropenia	t yet recovered	Seq: 1			Sender: F Veight: Age:
Onset Date: Outcome: No action Details: Preferred T		Severity			
Outcome: No action Details: Preferred T		Severity			
ction Details: Preferred T		Severity			DOB:
Preferred T		Severity		Ca	usality: Causality possible
	erm	Severity			
utropenia			Rep	ort Description	Treatment
					Zyprexa was discontinued.
edicine Details					
PREXA (Suspected)			Rea	son: Schizophrenia	
Tablet		20.0 Mil			Oral
Batch:		Started:		Stopped:	
boratory Inve	stigations:				
Date Typ	e Range	e Date Tested	Result		Details



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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	er: 148290	Seq: 1			der: F
-	ed: 24/01/200	0		Weig	ht:
Hospitalisatio					ge:
Onset Da	ate:			D	OB:
Outcon	ne: Not yet re	covered		Causa	ity: Causality possible
Reaction De	etails:				
Pre	ferred Term	Severity	Report	Description	Treatment
Angioedema					
Medicine I		0.0	Reaso	n:	
Batch		0.0 Started:		Stopped:	
Laboratory	y Investigat	ions:			
Date	Туре	Range Date Tes	sted Result	I	Details
Additional					

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Onset Date: Outcome: Unknown Causality: Causality possible section Details: Preferred Term Severity Report Description Treatment with ralgia hyperkinesia Medicine Details: ZYPREXA (Suspected) Reason: 20.0 Milligram Daily Batch: Started: Stopped:	Reported: 24/01/2000 ospitalisation: Onset Date: Outcome: Unknown	Seq: 1		Gende	r: M	
Onset Date: Onset Date: Outcome: Unknown Causality: Causality possible section Details: Preferred Term Severity Report Description Treatment orthralgia syperkinesia Indication Details: Indicati	ospitalisation: Onset Date: Outcome: Unknown					
Onset Date: Outcome: Unknown Causality: Causality possible section Details: Preferred Term Severity Report Description Treatment Arthralgia Hyperkinesia Medicine Details: ZYPREXA (Suspected) Batch: Started: Stopped:	Onset Date: Outcome: Unknown			Weigh	t:	
Outcome: Unknown Preferred Term Preferred Term Severity Report Description Treatment Athralgia Report Description Report Description Treatment Apperkinesia All the content of the	Outcome: Unknown			Age	e :	
Preferred Term Severity Report Description Treatment withralgia hyperkinesia Medicine Details: ZYPREXA (Suspected) Reason: 20.0 Milligram Daily Batch: Started: Stopped:				DOI	В:	
Preferred Term Severity Report Description Treatment Althralgia Althralgia Algorithmesia Aledicine Details: ZYPREXA (Suspected) Reason: 20.0 Milligram Daily Batch: Started: Stopped:	action Details:			Causalit	y: Causality possible	
Afficine Details: ZYPREXA (Suspected) Batch: Started: Stopped: Afficine Details: Reason: 20.0 Milligram Daily Batch: Started: Stopped:						
Medicine Details: ZYPREXA (Suspected) Reason: 20.0 Milligram Daily Batch: Started: Stopped:		Severity	Report [Description	Treatment	
Medicine Details: ZYPREXA (Suspected) Reason: 20.0 Milligram Daily Batch: Started: Stopped:	=					
ZYPREXA (Suspected) 20.0 Milligram Daily Batch: Started: Stopped: aboratory Investigations:						
ZYPREXA (Suspected) 20.0 Milligram Daily Batch: Started: Stopped: aboratory Investigations:						
Batch: Started: Stopped:	Medicine Details:					
Batch: Started: Stopped:	ZYPREXA (Suspected)					
aboratory Investigations:			gram Da			
	Batch:	Started:		Stopped:		
	Laboratory Investigation	ns:				
			Result	De	tails	

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 148323
 Seq: 1
 Gender: F

 Reported:
 25/01/2000
 Weight:

Hospitalisation: Age: 42

Onset Date: 31/12/1999 **DOB**: 11/07/1957

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

reaction Betails.	saction betails:								
Preferred Term	Severity	Report Description	Treatment						
Pruritus									
Rash									

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)		Reason: Unspecified ps	sychosis
Tablet	0.0		Oral
Batch:	Started:	Stopped:	
TEGRETOL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1997	Stopped:	28/11/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	ult Details	
	Skin biopsy				Biopsy of the skin showed the following differential diagnosis: 1) pityriasis rosea, 2) chronic superficial dermatitis, 3) spongiotic drug reaction with pityriasis rosea-like features.	

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 necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 148400 Seq: 1 Gender: M

Reported: 27/01/2000 Weight:

Hospitalisation:Hospitalisation prolongedAge: 70YOnset Date:31/01/2000DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia			

Medicine Details:

Medicine Details:			
SINEMET CR (Suspected)		Reason: Paralysis agitans	
Tablet	1.2 Gram	Daily Oral	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	2.5 Milligram	Daily	
Batch:	Started: 01/12/1999	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. 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 148409 Seq: 1 Gender: F

Reported: 31/01/2000 Weight: 100.00 Hospitalisation: Age: 34Y

Onset Date: 02/12/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	teaction Betails.			
	Preferred Term	Severity	Report Description	Treatment
	Gravitational oedema		Feet swelling	
	Flatulence			

Medicine Details:

ZYPREXA (Suspected) Reason:

10.0 Milligram Daily

Batch: Started: 13/10/1999 **Stopped:** 20/12/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Feet swelled so much it was painful to walk. gain of at least 2.5cm in limb diameter. patient also taking efexor xr.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 148523
 Seq: 1
 Gender: F

 Reported:
 02/02/2000
 Weight:

Hospitalisation: Age: 38

Onset Date: DOB: 11/02/1961

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touction bottoms:			
Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Dyspepsia			Losec
Gastric ulcer			
Haematemesis			

Medicine Details:

VENLAFAXINE HYDROCHLORIDE	(Suspected)	Reason: Depression
	275.0 Milligram	Daily
Batch:	Started: 01/12/1998	Stopped:
LORAZEPAM (Suspected)		Reason: Specific disorders of sleep
	2.5 Milligram	Daily
Batch:	Started: 01/01/1999	Stopped:
OLANZAPINE (Suspected)		Reason: Otr spec symp psychopathol nec
	2.5 Milligram	Daily
Batch:	Started: 01/03/1999	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Gastroscopy showed multiple shallow ulcers in stomach and pylorus

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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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 148579
 Seq: 1
 Gender:
 F

 Reported:
 03/02/2000
 Weight:
 81.00

Hospitalisation: Age: 46Y
Onset Date: 01/01/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.	caction betails.							
Preferred Term	Severity	Report Description	Treatment					
Breast enlargement		Breast enlargement with discomfort						
Galactorrhoea		Breast secretion						
Amenorrhoea								
Breast pain								
Weight increased								

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 5.0 Milligram Daily Oral

Batch: Started: 10/11/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

This was the patients first exposure to olanzapine.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Detai	iis.					
Case Number:	: 148661 : 07/02/2000	Seq: 1		Gender: Weight:	F	
ospitalisation:				Age:	70Y	
Onset Date				DOB:		
	: Not yet recover	red			Causality possible	
eaction Deta		-		- Caucanty	caddanty possible	
	red Term	Severity	Report [Description	Treatment	
Dedema periph			'	·		
Medicine De			Reason			
Tablet		5.0 Mi	illigram Da			
Batch:		Started:		Stopped:		
		<u> </u>		Stopped:		
	nvestigațions	:				
_aboratory I			Result	Stopped:	Is	
		:	Result		ls	
	Type Ra	:	Result		Is	

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Case Number: 148767

Reported: 07/02/2000

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Hospitalisa Onset I				Age : 99U DOB :			
	ome: Not yet rec	overed		Causality: Causality possible			
Reaction D		overed			Odus	sality. Causality possible	
	referred Term	Se	verity	Rep	ort Description	Treatment	
Hyperprolad Prolactinom	ctinaemia			- 1-	, , , , , , , , , , , , , , , , , , ,	Olazapine withdrawn, risperidone substituted	
Medicine	Details:						
ZYPREXA (S				Rea	son:		
			0.0				
Bat	ch:	St	arted:		Stopped:		
Laborato	ry Investigatio	ons:					
Date	Туре	Range	Date Tested	Result		Details	
17/12/2002	Radiololgy				Prolactinoma (which was o	detected via an mri scan).	
Additiona	al Information	:					
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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 148769
 Seq: 1
 Gender: F

 Reported:
 07/02/2000
 Weight:

Hospitalisation: Age: 91

Onset Date: DOB: 01/07/1908

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure Confusional state Nightmare			Zyprexa ceased. coversyl treatment was commenced on 30.7.99 and the lasix treatment commenced on 4.8.99 with better control of ccf and paranoia decreased.

Medicine Details:

ZYPREXA (Suspected)Reason:Other paranoid statesTablet5.0 MilligramDailyOral

Batch: Started: 10/07/1999 **Stopped:** 10/09/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking lanoxin, normison, lasix, coversyl, cardiprin 100 and premarin. patient commenced zyprexa treatment 2.5mg/day on 10.7.99. the dose was increased to 5mg/day on 27.7.99.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Onset Date: Outcome: Not yet recovered	se Number: 148857 Seq: 1 Gender: F Reported: 11/02/2000 Weight: oitalisation: Age: 74Y Onset Date: DOB: Outcome: Not yet recovered Causality: Causality possible ction Details: Preferred Term Severity Report Description Treatment ary retention Chronic urinary retention Permanent in dwelling cathete Chronic urinary retention Permanent in dwelling cathete dicine Details: PENTHIXOL DECANOATE (Suspected) Reason: Injection 10.0 Milligram 1 time Intramuscular Batch: Started: 17/12/1999 Stopped: ROXETINE HYDROCHLORIDE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 09/03/1999 Stopped: ANZAPINE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 21/05/1999 Stopped:	Danart Dataila								
Reported: 11/02/2000 Weight: ospitalisation: Age: 74Y Onset Date: DOB: Outcome: Not yet recovered Causality: Causality: Causality eaction Details: Preferred Term Severity Report Description Trea Jrinary retention Chronic urinary retention Permanent in a Medicine Details: FLUPENTHIXOL DECANOATE (Suspected) Reason: Injection 10.0 Milligram 1 time Intramuscular Batch: Started: 17/12/1999 Stopped: PAROXETINE HYDROCHLORIDE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 09/03/1999 Stopped: OLANZAPINE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 21/05/1999 Stopped:	Reported: 11/02/2000	-								
Onset Date: Outcome: Not yet recovered Outcome:	Onset Date: Outcome: Not yet recovered Causality: Causality possible extion Details: Preferred Term Severity Report Description Treatment ary retention Chronic urinary retention Permanent in dwelling catheted Permanent in dwelling catheted			Seq:	1					
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Outcome: Not yet recovered	Outcome: Not yet recovered control Details: Preferred Term Severity Report Description Treatment ary retention Chronic urinary retention Permanent in dwelling cathete Chronic urinary retention Permanent in dwelling cathete Discreption 10.0 Milligram 1 time Intramuscular Batch: Started: 17/12/1999 Stopped: ROXETINE HYDROCHLORIDE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 09/03/1999 Stopped: ANZAPINE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 09/03/1999 Stopped: ANZAPINE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 21/05/1999 Stopped:	Hospitalisation:							_	
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Arinary retention Chronic urinary retention Permanent in of the deciding of the property of	dicine Details: JPENTHIXOL DECANOATE (Suspected) Injection Batch: Started: 17/12/1999 Stopped: ROXETINE HYDROCHLORIDE (Suspected) Batch: Started: 09/03/1999 Stopped: ANZAPINE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 09/03/1999 Stopped: ANZAPINE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 09/03/1999 Stopped: ANZAPINE (Suspected) Reason: 20.0 Milligram Daily Stopped: ANZAPINE (Suspected) Started: 21/05/1999 Stopped:									
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Reason: Injection 10.0 Milligram 1 time Intramuscular Batch: Started: 17/12/1999 Stopped:	Injection 10.0 Milligram 1 time Intramuscular Batch: Started: 17/12/1999 Stopped: ROXETINE HYDROCHLORIDE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 09/03/1999 Stopped: ANZAPINE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 21/05/1999 Stopped: Doratory Investigations:									
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20.0 Milligram Daily Batch: Started: 09/03/1999 Stopped:	Batch: Started: 09/03/1999 Stopped: ANZAPINE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 21/05/1999 Stopped:	Batch:		St	arted: 17/12	/1999		Stopped:		
Batch: Started: 09/03/1999 Stopped: OLANZAPINE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 21/05/1999 Stopped:	Batch: Started: 09/03/1999 Stopped: ANZAPINE (Suspected) 20.0 Milligram Daily Batch: Started: 21/05/1999 Stopped:	PAROXETINE HYDR	OCHLORIDE (S	Suspected)		Re	ason:			
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20.0 Milligram Daily Batch: Started: 21/05/1999 Stopped:	20.0 Milligram Daily Batch: Started: 21/05/1999 Stopped: Doratory Investigations:			St	arted: 09/03/			Stopped:		
Batch: Started: 21/05/1999 Stopped:	Batch: Started: 21/05/1999 Stopped: Doratory Investigations:	OLANZAPINE (Susp	ected)							
	poratory Investigations:						Daily			
		Batch:		St	arted: 21/05	/1999		Stopped:		
_aboratory Investigations: Date Type Range Date Tested Result Details					Date Tested	Result			Details	
			•	_ ~		1	1			
Additional Information:										

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 149018
 Seq: 1
 Gender:
 F

 Reported:
 14/02/2000
 Weight:

Hospitalisation: Age: 72

Onset Date: 01/02/2000 **DOB**: 02/09/1927

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Anaemia			
Purpura			

Medicine Details:

CLOPIDOGREL (Suspected)		Reason:	
	75.0 Milligram	Daily	
Batch:	Started: 19/01/2000	Stopped: 02/02/2000	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	

2.5 Milligram Daily

Batch: Started: 24/01/2000 **Stopped:** 08/02/2000

Laboratory Investigations:

-						
	Date	Туре	Range	Date Tested	Result	Details
		Haematology				Decrease of hb by 02/02/00 137> 112g/l, with decreased haematocrit increased mean cell volume and macrocytes on film.

Additional Information:

All other drugs were ceased - epilim, aurorix, ditropan, aspirin. recovery highly unlikely , now on palliative care regime (severe dementia).

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 149070
 Seq: 1
 Gender: F

 Reported:
 14/02/2000
 Weight:

Hospitalisation: Age: 75Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 7.5 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The zyprexa was rechallenged with a 5mg dose and the patient experienced another seizure.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 149266 Seq: 1 Gender: F

Reported: 18/02/2000 Weight:
Hospitalisation: Age: 48Y

Onset Date: 04/03/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

Medicine Details.						
OLANZAPINE (Interaction)		Reason:				
	20.0 Milligram	Daily				
Batch:	Started: 01/12/1998		Stopped:	05/03/1999		
EPILIM (Interaction)		Reason:				
	1.2 Gram	Daily				
Batch:	Started: 04/03/1999		Stopped:	05/03/1999		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				Neutropenia 1.75 on 4/03/1999

Additional Information:

Patient also taking haldol, marijuana, accuphase. 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 149274 Seq: 1 Gender: M
Reported: 18/02/2000 Weight: 93.00

Hospitalisation: Age: 49

Onset Date: 26/10/1999

Outcome: Not yet recovered

DOB: 09/04/1950

Causality: Causality possible

Reaction Details:

7	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Hepatic function abnormal		Elevation of liver function tests.		
	Influenza like illness			Supportive - serzone and zyprexa ceased on 28.10.99.	

Medicine Details:

Medicine Details.				
SERZONE (Suspected)		Reason:	Depression	
	600.0 Milligram	Daily		
Batch:	Started: 02/06/1999		Stopped:	28/10/1999
ZYPREXA (Suspected)		Reason:	Depression	
	10.0 Milligram	Daily		
Batch:	Started: 11/08/1999		Stopped:	28/10/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		26/10/1999	444	
	AST = SGOT		26/10/1999	162	
	Bilirubin		26/10/1999	18	
	GGT = SGGT =		26/10/1999	1566	
	SAP = ALP		26/10/1999	236	

Additional Information:

Patient also taking oroxine, rivotril and imovane. patient history: treatment resistant major depression, nil known allergies and no previous exposure to these drugs.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 149284
 Seq: 1
 Gender:
 F

 Reported:
 18/02/2000
 Weight:

Hospitalisation:
Onset Date: 31/01/2000
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			1
	Preferred Term	Severity	Report Description	Treatment
	Pyrexia		Swinging fevers for 10/7.	Olanzepine stopped.
	Anaemia			

Medicine Details:

 OLANZAPINE (Suspected)
 Reason:
 Unspecified schizophrenia

 Tablet
 20.0
 Milligram
 Daily
 Oral

 Batch:
 Started:
 Stopped:
 02/02/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Comments				Increased inflammatory markers.

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 149472 Seq: 1 Gender: F

Reported: 18/02/2000 Weight: 80.00 Hospitalisation: Age: 37

Onset Date: 05/02/2000 **DOB**: 10/08/1962

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Headache	Severe		

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

5.0 Milligram Daily

Batch: Started: 04/02/2000 Stopped: 06/02/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking flupenthixol, benztropine, clonazepam. p/h of allergy to risperidone - headache.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 149488 Seq: 1 Gender: F

Reported: 21/02/2000 Weight: 61.00 Hospitalisation: Age: 23Y

Onset Date: 28/01/2000 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Ceased chlorpromazine. used zuclopenthixol tab. started clozapine 12/2/2000 and zuclopenthixol withdrawn.

Medicine Details:

CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason:		
Oral application	50.0 Milligram	As neces	sary	Oral
Batch:	Started: 25/01/2000		Stopped:	02/02/2000
CHLORPROMAZINE HYDROCHLOF	RIDE (Suspected)	Reason: Ot	r spec symp	psychopathol nec
Oral application	225.0 Milligram	Daily		Oral
Batch:	Started: 25/01/2000		Stopped:	02/02/2000
OLANZAPINE (Suspected)		Reason: De	pression	
Tablet	15.0 Milligram	Daily		Oral
Batch:	Started: 12/01/2000		Stopped:	04/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		21/12/1999	23	
	ALT = SGPT		28/12/1999	28	
	ALT = SGPT		28/01/2000	108	
	ALT = SGPT		01/02/2000	164	
	ALT = SGPT		04/02/2000	188	
	ALT = SGPT		08/02/2000	81	
	ALT = SGPT		09/02/2000	62	

Additional Information:

Patient also taking moclobemide, clonazepam, propranolol and benztropine.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 149488 Seq: 1 Gender: F

Reported: 21/02/2000 Weight: 61.00 Hospitalisation: Age: 23Y

Onset Date: 28/01/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason:	
Oral application	50.0 Milligram	As necessary	Oral
Batch:	Started: 25/01/2000	Stoppe	d : 02/02/2000
CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason: Otr spec sy	mp psychopathol nec
Oral application	225.0 Milligram	Daily	Oral
Batch:	Started: 25/01/2000	Stoppe	d : 02/02/2000
OLANZAPINE (Suspected)		Reason: Depression	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 12/01/2000	Stoppe	d : 04/02/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		11/02/2000	55	
	Bilirubin				Bilirubin always normal.
	GGT = SGGT =		21/12/1999	12	
	GGT = SGGT =		01/02/2000	23	
	GGT = SGGT =		04/02/2000	26	
	GGT = SGGT =		08/02/2000	25	
	GGT = SGGT =		11/02/2000	21	

Additional Information:

Patient also taking moclobemide, clonazepam, propranolol and benztropine.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 149488 Seq: 1 Gender: F

Reported: 21/02/2000 Weight: 61.00 Hospitalisation: Age: 23Y

Onset Date: 28/01/2000 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason:	
Oral application	50.0 Milligram	As necessary	Oral
Batch:	Started: 25/01/2000	Stoppe	ed: 02/02/2000
CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason: Otr spec sy	mp psychopathol nec
Oral application	225.0 Milligram	Daily	Oral
Batch:	Started: 25/01/2000	Stoppe	ed: 02/02/2000
OLANZAPINE (Suspected)		Reason: Depression	1
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 12/01/2000	Stoppe	ed: 04/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =		09/02/2000	23	
	GGT = SGGT =		28/01/2000	18	
	GGT = SGGT =		28/12/1999	16	
	SAP = ALP		21/12/1999	83	
	SAP = ALP		28/12/1999	95	
	SAP = ALP		28/01/2000	108	
	SAP = ALP		01/02/2000	108	

Additional Information:

Patient also taking moclobemide, clonazepam, propranolol and benztropine.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 149488 Seq: 1 Gender: F

Reported: 21/02/2000 Weight: 61.00 Hospitalisation: Age: 23Y

Onset Date: 28/01/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason:		
Oral application	50.0 Milligram	As necessa	ry Oral	
Batch:	Started: 25/01/2000	5	Stopped: 02/02/2000	
CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason: Otr	spec symp psychopathol nec	
Oral application	225.0 Milligram	Daily	Oral	
Batch:	Started: 25/01/2000	5	Stopped: 02/02/2000	
OLANZAPINE (Suspected)		Reason: Dep	ression	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 12/01/2000	5	Stopped: 04/02/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		04/02/2000	112	
	SAP = ALP		08/02/2000	101	
	SAP = ALP		09/02/2000	96	
	SAP = ALP		11/02/2000	103	

Additional Information:

Patient also taking moclobemide, clonazepam, propranolol and benztropine.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 149549 Seq: 1 Gender: F

Reported: 23/02/2000 Weight: 67.00 Hospitalisation: Age: 38

Onset Date: 31/08/1999 **DOB**: 03/08/1961

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		Secondary amenorrhoea	
Weight increased			

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: Started: 01/05/1999 Stopped: CONTIN

Laboratory Investigations:

Dat	е	Туре	Range	Date Tested	Result	Details
	0	ther data				Prolactin level measured.

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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 149555 Seq: 1 Gender: F

Reported: 24/02/2000 Weight: 80.00
Hospitalisation: Age: 26Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

caction betains.			
Preferred Term	Severity	Report Description	Treatment
Increased appetite			Reducing dose to 5mg nocte. pt wishes to cease medication.

Medicine Details:

OLANZAPINE (Suspected) Reason:

Oral application 10.0 Milligram Daily Oral

Batch: Started: 15/12/1999 **Stopped:** 05/01/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt also taking haloperidol.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	tails:				
Case Numb	er: 149572	Seq: 1		G	ender: M
	ed: 24/02/2000	_		W	/eight:
ospitalisatio					Age:
Onset Da	ate:				DOB:
Outcon	ne: Not yet rec	overed		Cau	sality: Causality possible
eaction De					T
Pre granulocyto.	ferred Term	Severity	Report I	Description	Treatment
ledicine [Details:				
		0.0	Reason	:	
	spected)	0.0 Started:	Reason	Stopped:	
ZYPREXA (Su Batch	spected)	Started:	Reason		
ZYPREXA (Su Batch	spected)	Started:	Reason		Details

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 149709
 Seq: 1
 Gender: M

 Reported:
 28/02/2000
 Weight:

Hospitalisation: Age: 25

Onset Date: DOB: 28/09/1974

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Dotanoi			
	Preferred Term	Severity	Report Description	Treatment
	Dystonia		Lips wide apart and couldn't open his mouth.	
	Bruxism			Cogentin

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 25.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The event occurred whilst the patient was on leave from hospital. patient also taking sodium valproate.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Hospitalisati Onset D Outcor	ate: ne: Not yet re		1		We	ender: M eight: Age: DOB: sality: Causality possible	
Reaction D	etalis: eferred Term	Se	verity	Reno	ort Description	Treatment	
Ejaculation f			verity	Тер	or Description	ricaliiciit	
Medicine CIPRAMIL (O				Poo	2001		
CIPRAINIL (U	ther drug)		0.0	Rea	Reason:		
Batc	h:	St	arted:	Stopped:			
ZYPREXA (Si				Rea			
			0.0				
Batc	h:	St	tarted:		Stopped:		
Laborator Date	y Investigat ^{Type}	ions: Range	Date Tested	Result		Details	
Additiona	l Informatio	n:					

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 149739
 Seq: 1
 Gender: M

 Reported:
 28/02/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 54

Onset Date: 15/02/2000 **DOB**: 03/05/1945

Outcome: Recovered Causality: Causality possible

Reaction Details:

١,	<u>leaction Details.</u>			
	Preferred Term	Severity	Report Description	Treatment
	Catatonia			Treated with benztropine.
	Constipation			
	Dystonia			
	Pollakiuria			

Medicine Details:

ZYPREXA (Suspected) Reason:

5.0 Milligram Daily

Batch: Started: 01/09/1999 **Stopped:** 28/02/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking anafranil. 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 149771
 Seq: 1
 Gender:
 F

 Reported:
 28/02/2000
 Weight:

Hospitalisation: Age: 73

Onset Date: DOB: 22/03/1926

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Arms and legs twitching.	
Dizziness		Patient experienced frequent falls.	
Back pain		Patient has increased stoop.	
Agitation			
Hot flush			Patient was given oxazepam 15mg twice daily. zyprexa was ceased.

Medicine Details:

ZYPREXA (Suspected)		Reason:	Unspecified psychosis
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 26/11/1999		Stopped : 02/12/1999

Laboratory Investigations:

ĺ	Date	Туре	Range	Date Tested	Result	Details
ĺ		Creatine		10/12/1999	169	

Additional Information:

Patient also taking tazac and panamax. patient medical history is severe dementia.

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Case Number: 150250

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 10/03/2000				Weight:						
Iospitalisati						Age: 40Y				
Onset Da						DOB:				
Outcor	ne: Unknown	I			usality: Cau	Causality possible				
eaction D	etails:		1			ı,				
	eferred Term	Se	everity	Rep	ort Description		Treatment			
Hypertonia										
Tremor										
/omiting										
/ledicine l	Details:									
ZYPREXA (Su	uspected)				ason:					
			5.0 Milli	igram	Daily					
Batcl	h:		Started:		Stopped:					
	y Investiga									
Date	Туре	Range	Date Tested	Result		Details				
		<u> </u>								
Additional	l Informatio	n:								
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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 150251
 Seq: 1
 Gender:
 F

 Reported:
 10/03/2000
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

toaction Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight increased to 90kg from 52kg in 1980.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 1.5 Milligram Daily Oral

Batch: Started: 01/10/1999 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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Case Number: 150252

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 10/03/2000	J			Weigl	ht:	
Hospitalisation:				_		
Onset Date:						
Outcome: Recovered		Severity Report Description Treatment Homicidal thoughts Therapy changed to mo Reason: 5.0 Milligram Daily Oral Started: Stopped: 3D Date Tested Result Details				
					_	
	Severity			n	Treatment	
_		Homicidal thou	ghts		Therapy changed to mode	cate.
Medicine Details:		D.	acon:			
	5.0			Oral		
		wiiiigram			3D	
		ted Result	1			\neg
Date Type	Nange Date res	teu Result			Cialis	_
Onset Date: Outcome: Recovered						
eport Run: 04/06/2007 04:53PM	Database: pusime02		ADRS004		Page 43 of 44	10



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 150253
 Seq: 1
 Gender: M

 Reported:
 10/03/2000
 Weight:

Hospitalisation: Age: 73Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	todotion Botanoi				
	Preferred Term	Severity	Report Description	Treatment	l
	Eosinophilia				l

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
	Eosinophils	0.1			Eosinophils increased to 0.5.

Additional Information:

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Case Number: 150254

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 10/03/20	000		Weight:						
espitalisation:			Age:						
Onset Date:					DB:				
Outcome: Not yet r				Causali	ty: Causality possib	ole			
action Details:	I 0.		Danie	1 December	#i.a.m	Too atoo and			
Preferred Term eight increased	Se	verity	Repor	t Descrip	tion	Treatment Zyprexa dose reduce			
						5mg/d.			
edicine Details: YPREXA (Suspected)			Reaso	on:					
Tablet		10.0 Millio	gram	Daily	Oral				
Batch:	St	tarted:		S	topped:	CONTIN			
aboratory Investiga		Data Tostad	Popult			otoilo			
Date Type	Range	Date Tested	Result			etails			
dditional Informatio	on:								
ort Run: 04/06/2007 04:53F	PM Database: pu			RS004		Page 45			



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	Seq: 1		Gender: ⊦
Reported: 10/03/2000		,	Weight:
spitalisation:			Age: 24Y
Onset Date:			DOB:
Outcome: Unknown		Ca	usality: Causality possible
action Details:			
Preferred Term	Severity	Report Description	Treatment
cne			
ledicine Details:			
ZYPREXA (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
aboratory Investigatior	is:		
aboratory Investigation Date Type	Range Date Tested	Result	Details

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Case Number: 150267

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 10/03/200	0		V	Veight:			
ospitalisation:		Age: 67Y					
Onset Date:		DOB:					
Outcome: Unknown		Causality: Causality possible					
eaction Details:							
Preferred Term	Severity	Rep	oort Description	Treatment			
Cardiac disorder		Cardiac proble					
Extrapyramidal disorder		Extrapyramidal					
Hepatocellular damage		Hepatotoxicity.					
Medicine Details:							
ZYPREXA (Suspected)		Re	eason:				
	20.0) Milligram	Daily				
Batch:	Started:		Stopped:				
Laboratory Investigat	ions:						
Date Type	Range Date Te	sted Result		Details			
Additional Informatio	n:						
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Case Number: 150268

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 10/03/2000			Weight:	
espitalisation:			Age:	
Onset Date:			DOB:	
Outcome: Not yet recov	ered		Causality: C	ausality possible
action Details:	•	1	•	
Preferred Term	Severity	Report Desc		Treatment
pochromic anaemia		Decreased haemoglobin		
ukopenia		White blood cell decrease	ed.	
edicine Details:		Reason:		
EARLAI INE (Ouspecteu)	0.0	Reason.		
Batch:	Started:		Stopped:	
aboratory Investigation			D. 1. "	
Date Type	Range Date Tes	ted Result	Details	
dditional Information:				
ort Run: 04/06/2007 04:53PM [Database: pusime02	ADRS004		Page 48 of 440



Case Number: 150420

Reported: 10/03/2000

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight:

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

spitalisation:						Age:	27Y			
Onset Date:	nset Date:				DOB:					
Outcome: Not yet rec		Causality: Causality possible								
action Details:		•								
Preferred Term	Sever	ity	R	eport Desc	ription		Treatment			
ohasia		I	nability to tal	k						
aralysis		l	nability to wa	ılk						
gitation		(Obsession wi	th pulling a	rms/legs.					
somnia										
edicine Details:										
AURORIX (Other drug)		4 5 00 -		Reason:						
			/lilligram	Daily						
Batch:	Starte	d:			Stopped:					
YPREXA (Suspected)		50 N		Reason:		Orol				
Tablet Batch:	Starte		/lilligram	Daily	Stopped:	Oral	CONTIN			
obovotowy lovootiwati.										
aboratory Investigation Date Type		te Teste	d Result			Deta	ile			
Date Type	range Da	ic resic	d Result			Deta	113			
dditional Information	ı:									



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 150421 Seq: 1 Gender: F

Reported: 15/03/2000 Weight:
Hospitalisation: Age: 81Y

Onset Date: 06/03/2000 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia			

Medicine Details:

OLANZAPINE (Suspected) Reason:

5.0 Milligram Daily

Batch: **Started**: 09/02/2000 **Stopped**: 06/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils				Decreased to 1.6.
	White blood cells				Decreased to 2.8.

Additional Information:

Patient also taking imdur, liquifilm tears, coloxyl & senna, oxazepam and panadol.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 150547 Seq: 1 Gender: F
Reported: 21/03/2000 Weight:
Hospitalisation: Admitted to hospital Age: 24Y

Onset Date: 31/03/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			Zyprexa, fluoxetine,diazepam,sodium valproate and chlorpromazine ceased.
Neutropenia			

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other dru	g)		Reason:	
Capsule	20.0	Milligram	Daily	Oral
Batch:	Started:			Stopped:
ZYPREXA (Suspected)			Reason:	
Tablet	5.0	Milligram	Daily	Oral
Batch:	Started:			Stopped:
DIAZEPAM (Suspected)			Reason:	
	10.0	Milligram	Daily	
Batch:	Started:			Stopped:
SODIUM VALPROATE (Suspected)			Reason:	
	800.0	Milligram	Daily	
Batch:	Started:			Stopped:

Laboratory Investigations:

Euboratory invoctigations:						
Date		Туре	Range	Date Tested	Result	Details
		Neutrophils				Neutrphils / 0.49 x 1000000 cells/ml / mar-200/ below, resulted in 49000000 cell/l.

Additional Information:

The patient has no haematological history and has an eating disorder. - 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	150547	Seq: 1			Gender:	F
Reported:	21/03/2000				Weight:	
Hospitalisation:	Admitted to hospi	tal			Age:	24Y
Onset Date:	31/03/2000				DOB:	
Outcome:	Recovered				Causality:	Causality possible
Reaction Detai	ls:					
Medicine Deta		<u> </u>				
CHLORPROMAZIN	IE HYDROCHLORIDE		Milligram	Reason: Daily		
Batch:		Started:	Willigram	Dally	Stopped:	
Laboratory In	vestigations:					
Additional Inf The patient has no that onset occurred		ory and has an ne month.	eating disord	der the date	e of onset is not neces	sarily accurate but indicates

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Case Number: 150549

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 21/03/2000		Weight:						
ospitalisation:		Age: 23Y DOB:						
Onset Date:								
Outcome: Not yet red	overed							
eaction Details:		.,			. ,.	- , ,		
Preferred Term	Se	everity		ort Desci		Treatment		
urpura		Pir	1 nead lesion	is on arms	chest and back.			
ledicine Details: ZYPREXA (Suspected)			Re	ason:				
Tablet		5.0 Mill	igram	Daily	Oral			
Batch:	S	Started: 13/02/2	2000	Stopped:		CONTIN		
aboratory Investigati Date Type	ONS: Range	Date Tested	Result		De	etails		
Туре Туре	Range	Date Tested	Result		De	calls		
Additional Information	1:							
ort Run: 04/06/2007 04:53PM	Database: p	ousime02		ADRS004		Page 53 of 440		



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 150550 Seq: 1 Gender: F

Reported: 21/03/2000 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain of 8-9 kg	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

15.0 Milligram Daily

Batch: Started: 01/04/1999 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 150551
 Seq: 1
 Gender: M

 Reported:
 21/03/2000
 Weight:

Reported: 21/03/2000 Weight:
Hospitalisation: Age: 19

Onset Date: DOB: 12/03/1981

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope		Transient loss of consciousness.	Zyprexa therapy ceased.

Medicine Details:

	Reason: Unspecified se	chizophrenia
10.0 Milligram	Daily	Oral
Started: 14/12/1999	Stopped:	10/02/2000
	Reason: Depression	
100.0 Milligram	Daily	Oral
Started: 14/12/1999	Stopped:	CONTIN
	10.0 Milligram Started: 14/12/1999 100.0 Milligram	10.0 Milligram Daily Started: 14/12/1999 Stopped: Reason: Depression 100.0 Milligram Daily

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has a medical history of depression, family conflict, behavioural disturbances. the patient was found later by his parents unconscious on the bathroom floor with a minor graze to the head.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 151057
 Seq: 1
 Gender: M

 Reported:
 28/03/2000
 Weight:

Hospitalisation: Age: 54

Onset Date: 16/02/2000 **DOB**: 03/05/1945

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u>leaction Details.</u>			
Preferred Term	Severity	Report Description	Treatment
Apathy		Flat effect.	
Aggression		Increased aggression.	
Speech disorder		Slowed speech.	Cogentin 2mg imi given. olanzapine ceased.
Gait disturbance		Stooping gait.	
Confusional state			
Coordination abnormal			
Hypertension			

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspec	cified schizophrenia	
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started:	Sto	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		17/02/2000	312	

Additional Information:

Patient also taking - anaframil and ranitidine. patient has a medical history of obsessive compulsive disorder - schizophrenia.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 151103 Seq: 1 Gender: M
Reported: 31/03/2000 Weight:

Hospitalisation: Treated in outpatient department only.

Onset Date:

DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Swollen limbs and scrotum.	
Angioedema		Swollen tongue	Pt taken to emergency department and treated. zyprexa ceased.
Dyspnoea			
Somnolence			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 14/02/2000 Stopped: 21/02/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking sodium valproate, lithium carbonate, serzone.

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Case Number: 151104

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 31/03/2000			Weight:				
spitalisation:			Age:				
Onset Date:			DOB:				
Outcome: Not yet recov	vered			Causal	ity: Causality possible		
action Details:	0		Danant Dari	winding.	Traction		
Preferred Term	Severity		Report Desc	ription	Treatment		
edema peripheral		Swollen fee	τ.		Zyprexa dose was reduced to 5mg/d.		
edicine Details:							
YPREXA (Suspected)			Reason:				
Tablet		0.0 Milligram	Daily	Oral			
Batch:	Started:			Stopped:	CONTIN		
aboratory Investigation	ns:						
Date Type	Range Date 1	Tested Resu	lt		Details		
dditional Information:							
					_		
ort Run: 04/06/2007 04:53PM	Database: pusime02		ADRS004				



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 151526 Seq: 1 Gender: M

Reported: 11/04/2000 Weight: 79.00 Hospitalisation: Age: 39Y

Onset Date: 31/10/1999 **DOB:**

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Cpk to 600's	
Confusional state			
Hyperhidrosis			
Hypertonia			
Neuroleptic malignant syndrome			
Pyrexia			Zyprexa was rechallenged and then ceased.
Salivary hypersecretion			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

2.5 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Severe stiffiness on low dose of risperidone. patient also taking valium. - 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 151533
 Seq: 1
 Gender:
 F

 Reported:
 12/04/2000
 Weight:

Hospitalisation: Age: 45

Onset Date: 31/03/2000 DOB: 10/01/1955

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged			

Medicine Details:

Medicine Details.				
CLOZARIL (Other drug)		Reason:		
Tablet	300.0 Milligram	Daily	Oral	
Batch:	Started: 10/03/2000	s	topped:	
BECLOMETHASONE DIPROPIONA	TE (Other drug)	Reason:		
Inhalation	50.0 Microgram	Daily	Inhalation	
Batch:	Started:	s	topped:	
OLANZAPINE (Suspected)		Reason:		
	5.0 Milligram	Daily		
Batch:	Started:	S	topped: 02/04/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Electrographics				Pre-clozapine: qtc = 455ms; on clozapine: qtc = 475ms (after 3 wks clozapine)

Additional Information:

Patient also taking puffers. patient had pre-existing long qt, however this is increasing.

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Case Number: 151574

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

pitalisation: Admitted to hos Onset Date: Outcome: Not yet recovered ction Details: Preferred Term od alkaline phosphatase incre			_			
Outcome: Not yet recovered ction Details: Preferred Term od alkaline phosphatase increa	ed		Weight: Age:			
ction Details: Preferred Term od alkaline phosphatase incre	ed		DOB:			
Preferred Term od alkaline phosphatase incre		Causality: Causality possible				
od alkaline phosphatase incre						
	Severity	Report	Description	Treatment		
mma-glutamyltransferase incre	ea					
patic function abnormal				Ceased zyprexa		
July and David He						
dicine Details: PREXA (Suspected)		Reaso	n:			
TREAT (Guopootou)	0.0	Nouso	dSUII.			
Batch:	Started:		Stopped:			
		Dogult	r	Potoilo		
	ange Date rested					
2.00		ph	oshatase (alp) and gamma	glutamyl transferase (ggt).		
boratory Investigations Date Type Ra Biochemistry	: ange Date Tested	Result El	evated liver function tests.	Details elevated paticul glutamyl transt		



Date Range: 1 Jan 2000 To 31 Dec 2002 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: 151755 Seq: 1 Gender: F
Reported: 17/04/2000 Weight:
Hospitalisation: Age: 41Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

rtoaction Botano.			
Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			
Galactorrhoea			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

0.0

Batch: Started: 01/09/1999 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 151756 Seq: 1 Gender: F

Reported: 17/04/2000 Weight:
Hospitalisation: Age: 76Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/12/1999 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking efexor and prednisone. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 63 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 151802 Seq: 1 Gender: F
Reported: 17/04/2000 Weight:
Hospitalisation: Age: 48Y

Onset Date: 16/02/2000 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

ZYPREXA (Suspected)		Reason:	Otr spec symp psychopathol nec
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:		Stopped: 28/02/2000 12M
AURORIX (Suspected)		Reason:	
	600.0 Milligram	Daily	
Batch:	Started:		Stopped:
CAPTOPRIL (Suspected)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started:		Stopped:
LUVOX (Suspected)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		16/02/2000	79	
	ALT = SGPT		13/03/2000	61	
	AST = SGOT		16/02/2000	82	
	AST = SGOT		13/03/2000	58	
	GGT = SGGT =		16/02/2000	493	
	GGT = SGGT =		13/03/2000	409	
	SAP = ALP		16/02/2000	175	

Additional Information:

Patient has just been diagnosed with diabetes and the doctor now believes this is the cause of the elevated lft's.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 151802
 Seq: 1
 Gender:
 F

 Reported:
 17/04/2000
 Weight:

Hospitalisation: Age: 48Y
Onset Date: 16/02/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)		Reason:	Otr spec symp psychopathol nec
Tablet	10.0 Milligram	Daily	y Oral
Batch:	Started:		Stopped: 28/02/2000 12M
AURORIX (Suspected)		Reason:	
	600.0 Milligram	Daily	y
Batch:	Started:		Stopped:
CAPTOPRIL (Suspected)		Reason:	
	100.0 Milligram	Daily	y
Batch:	Started:		Stopped:
LUVOX (Suspected)		Reason:	
	100.0 Milligram	Daily	y
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP		13/03/2000	155	

Additional Information:

Patient has just been diagnosed with diabetes and the doctor now believes this is the cause of the elevated lft's.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 151812
 Seq: 1
 Gender: F

 Reported:
 17/04/2000
 Weight:

Hospitalisation: Age: 52Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Gravitational oedema		Legs.	
Pain		Sore legs.	Olanzapine discontinued.
Abdominal distension		Swollen abdomen.	
Weight increased		Weight gain.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 15.0 Milligram Daily Oral

Batch: Started: 25/02/2000 **Stopped:** 08/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking - epilim, baclofen, sertraline and benzhexol.

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 66 of 440



Case Number: 152232

Reported: 01/05/2000

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight:

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Hospitalisati	on:					A	.ge: 40		
Onset Date:				DOB : 24/03/1960					
	ne: Recovered		Causality: Causality certain						n
eaction De							1		
	ferred Term	Se	verity		ort Descrip	tion	+	reatmen	
Osteoarthritis	S		Sw	28/01 recha 03/02			Zyprexa wa 28/01/2000 rechallenge 03/02/2000 ceased aga 14/03/2000	and was d on the zvprexa	was
Arthralgia									
Medicine I				n.		- 2C - d l			
ZYPREXA (Su			5.0 Mill		son: Unsp Daily	ecified psychos Oral	IS		
Batch		91	arted: 16/12/1		-	topped: 28/01	/2000		
l abayataw									
Date	y Investigati Type	Range	Date Tested	Result			Details		
	Nr.	3.							
Additional	Information	:							
eport Run: 04/0	6/2007 04:54PM	Database: pu	sime02	A	ADRS004		Р	age 67	of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Detail	s:
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 Case Number:
 152233
 Seq: 1
 Gender:
 F

 Reported:
 01/05/2000
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Hypergalactinemia (female lactation).	Zyprexa therapy was reduced to 5mg/day.

Medicine Details:

ZYPREXA (Suspected) Reason:

10.0 Milligram Daily

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking - zoloft.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 152382 Seq: 1 Gender: F

Reported: 04/05/2000 Weight:
Hospitalisation: Age: 47Y

Onset Date: 18/02/2000 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Seventy	report Bescription	Treatment
Diabetes mellitus			
Hyperglycaemia			Metformin 1gm bd. sugar level
,, ,,			still high (14-18). commenced
			on daonil 5mg mane

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 20.0 Milligram Daily Oral

Batch: Started: 05/05/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Serum glucose				Bsl was 17.7 (fasting).

Additional Information:

Patient gained 10-12 kg in weight since commenced on zyprexa. patient has long history of schizophrenia, has been treated for more than 5yea rs with depot antipsychotics. pt also taking fluanxol, noten.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 152465
 Seq: 1
 Gender:
 F

 Reported:
 05/05/2000
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest			

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: Started: 15/04/2000 S TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking avapro, noten, logynon ed and risperdal. the patient was previously taking risperdal and was changed to olanzapine 10mg on 15.4.00. approximately one week later the patient experienced a cardiac arrest and died.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 152574
 Seq: 1
 Gender:
 M

 Reported:
 12/05/2000
 Weight:
 0.00

 Hospitalisation:
 Age: 55Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction betails.			
Preferred Term	Severity	Report Description	Treatment
Speech disorder		Difficulty speaking	
Nasal polyps		Nose polyps	
Paralysis		Paralysis in both legs	Olanzapine withdrawn
Conjunctivitis		Pussy eyes	

Medicine Details:

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

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient has a medical history of obsessive compulsive disorder and sinus troubles. Patient also taking Anafranil and Cogentin. Patient was taking Zyprexa when symptoms occurred.

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 71 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 152576
 Seq: 1
 Gender:
 F

 Reported:
 12/05/2000
 Weight:

Hospitalisation: Age: 16Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Electrocardiogram abnormal		Ventricular extrasystole.	
	Extrasystoles		Ventricular extrasystoles.	Ecg monitoring.

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified schizophreniaTablet10.0 MilligramDailyOral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Electrographics				Ventricular extrasystoles confirmed by ecg.

Additional Information:

Patient has a medical history of a heart murmur. patient also taking diazepam. symptoms occurred 3 months after commencing olanzapine therapy.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report L	etails:
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Case Number: 152577 Seq: 1 Gender: F
Reported: 12/05/2000 Weight:
Hospitalisation: Age:

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

redection Detaile.					
	Preferred Term	Severity	Report Description	Treatment	
	Abdominal distension		Swelling of the abdomen.		
	Gravitational oedema		Swelling of the ankles.		
			Swelling of the face.	Olanzapine ceased.	

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred while patient was taking olanzapine therapy.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 152578 Seq: 1 Gender: F
Reported: 12/05/2000 Weight:

Hospitalisation: Age: 64

Onset Date: DOB: 10/06/1935

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Lip smacking.	

Medicine Details:

ZYPREXA (Suspected)		Reason: L	Inspecified schizophre	enia
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 01/11/1998		Stopped:	CONTIN
EFEXOR (Suspected)		Reason:		
	150.0 Milligram	Daily		
Batch:	Started:		Stopped:	
XANAX (Suspected)		Reason:		
	6.0 Milligram	Daily		
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred after patient commenced therapy with olanzapine. patient's medical history includes previous treatment with thioridazine in 1994 and she has been trialled on chlorpromazine. 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: 152589

Reported: 12/05/2000

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight:

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

ospitalisati	ion:							Age: 33Y	
Onset D	ate:		DOB:						
Outco	me: Not yet re	covered		Causali			sality: Causality pos	ity: Causality possible	
action D				1					
	eferred Term	Se	everity		Repor	t Des	scription	Treatme	ent
edema per	ipheral							Dose was reduced night. the symptom subside so the patiswitched to risperior	ns did not ient was
edicine	Details:	OF (Other drug)			Reas	<u></u>			
Table		L (Other drug)	20.0	Milligram		Daily	Ora	al	
Batc		S	tarted:	······g· •····		,	Stopped:		
PREXA (S	uspected)				Reas	on:	Unspecified schize	phrenia	
Table			10.0	Milligram		Daily	Ora		
Batc		S	tarted:	-	S TERM	,	Stopped:		
ahorator	ry Investigat	iione:							
Date	Type	Range	Date Tes	ted R	esult			Details	
24.0	. , p c	. tallige	24.0 . 00					2 otalio	
				<u> </u>					
dditiona	l Informatio	n:							
ort Run : 04/0	06/2007 04:54PN	M Database: ры	usime02		ΑĽ	RS00)4	Page 75	of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 152617
 Seq: 1
 Gender:
 F

 Reported:
 15/05/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 55Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Torsade de pointes		Rapid irregular cardiac arrythmia.	

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/03/2000 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient has a history of cardiac problems. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 76 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 152699 Seq: 1 Gender: F

Reported: 18/05/2000 Weight: 55.00 Hospitalisation: Age: 72

Onset Date: 30/04/2000 **DOB**: 15/08/1927

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance		Dystonic movements walking.	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

2.5 Milligram Daily

Batch: Started: 24/04/2000 Stopped: 01/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking cogentin and neulactil. no upper limb involvement.

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 77 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 152713
 Seq: 1
 Gender:
 F

 Reported:
 18/05/2000
 Weight:

Hospitalisation: Hospitalisation prolonged
Onset Date:

DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caction Details.			
Preferred Term	Severity	Report Description	Treatment
Oedema peripheral			
Weight increased			

Medicine Details:

OLANZAPINE (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: 01/02/2000 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.

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 78 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 152731 Seq: 1 Gender: F

Reported: 19/05/2000 Weight:
Hospitalisation: Age: 65Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Atrioventricular block			
Bradycardia			Reduced dose of zyprexa from 20mg to 10mg daily.

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified psychosisTablet20.0 MilligramDailyOral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient does not have any previous history of bradycardia or hear block. was rechallenged on olanzapine and bradycardia returned.

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 79 of 440



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:		Seq:	1				ler: F	
-	: 26/05/200	0				Weig		
spitalisation							ge: 70Y	
Onset Date							OB:	
	Recovere	d				Causal	ity: Causality prob	able
action Deta			.,				- ,	
	red Term	Se	verity		ort Desc		Treatmen	nt
stonia			Pte	experienced	зит песк		Zyprexa ceased.	
edicine De YPREXA (Suspe					son:			
Tablet			5.0 Milligram			Oral Stopped:		
Batch:		St	arted:					
aborato <u>ry l</u>	nvestigat							
Date	Туре	Range	Date Tested	Result			Details	
dditional Ir	ıformatio	n:						
ort Run : 04/06/20	007 04:54PN	1 Database: pu	sime02		ADRS004		Page 80	of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 153119
 Seq: 1
 Gender:
 F

 Reported:
 26/05/2000
 Weight:

Hospitalisation: Admitted to hospital Age:
Onset Date:
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation			Zyprexa ceased. given sotalol.

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 5.0 Milligram Daily Oral

Batch: Started: 24/03/2000 Stopped: 24/04/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient has had a previous history of cardiac problems.

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 81 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 153192 Seq: 1 Gender: F

Reported: 29/05/2000 **Weight**: 53.00

 Hospitalisation:
 Age: 77

 Onset Date: 31/03/2000
 DOB: 17/12/1922

Outcome: Recovered Causality: Causality certain

Reaction Details:

•	todotion Dotanoi			
	Preferred Term	Severity	Report Description	Treatment
	Bradycardia			Reduction then cesation of zyprexa.
	Hypotension		90/60 bp	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

20.0 Milligram Daily

Batch: Started: Stopped: 28/04/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Rechallenge on 05/00 resulted in return of symptoms. - 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.

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 82 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	port	Detai	ls:
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 Case Number:
 153350
 Seq: 1
 Gender:
 F

 Reported:
 02/06/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 64

Onset Date: DOB: 15/10/1935

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

'	caction betails.						
	Preferred Term	Severity	Report Description	Treatment			
	Delirium						
	Delusion						
	Drug ineffective			Flupenthixol deconoate 50mg for 2 weeks, oral thiothixene 10mg/day, diazepam 5mg/bd.			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 20.0 Milligram Daily Oral

Batch: Started: 03/11/1999 **Stopped:** 13/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 83 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 153389 Seq: 1 Gender: F

Reported: 05/06/2000 Weight: 58.00 Hospitalisation: Age: 17Y

Onset Date: 31/03/2000 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lymphopenia			

Medicine Details:

ZYPREXA (Suspected) Reason: Schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/03/2000 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 153488 Seq: 1 Gender: F

Reported: 08/06/2000 Weight: 49.00 Hospitalisation: Admitted to hospital Age: 77

Onset Date: 13/05/2000 DOB: 27/12/1922

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state		Deterioration in mental state.	Olanzapine ceased.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

5.0 Milligram Daily

Batch: Started: 10/05/2000 **Stopped:** 16/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking carbimazole, temazepam and oxazepam.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 153489 Seq: 1 Gender: F

Reported: 08/06/2000 Weight: 65.00 Hospitalisation: Admitted to hospital Age: 71

Onset Date: 04/05/2000 DOB: 01/03/1929

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state		Deterioration in mental state.	

Medicine Details:

OLANZAPINE (Suspected) Reason:

5.0 Milligram Daily

Batch: Started: 01/05/2000 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking aspirin, metoprolol, cimetidine, gtn patch and sertraline.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 153490 Seq: 1 Gender: U

Reported:08/06/2000Weight:69.00Hospitalisation:Admitted to hospitalAge:75

Onset Date: 28/04/2000 DOB: 05/10/1924

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state		Deterioration in mental state.	Olanzapine ceased.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

5.0 Milligram Daily

Batch: Started: 26/04/2000 **Stopped:** 09/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking aspirin, felodipine and fluphenazine.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 153537
 Seq: 1
 Gender: M

 Reported:
 09/06/2000
 Weight:

Hospitalisation: Age: 40Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Raised liver enzymes.	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

0.0

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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Severity	Report Description		44Y Causality possible Treatment
Severity	Report Description	Causality:	
Severity	Report Description		
Severity	Report Description	on	Treatment
seventy	кероп резсприо	71	Пеашепц
•			
	Reason: Unspec	ified schizophrenia	
5.0 Milligram	Daily		
Started: 20/01/2000	Sto	pped:	CONTIN
Date Tested Re	esult	Detail	S
	Started: 20/01/2000	5.0 Milligram Daily Started: 20/01/2000 Sto	5.0 Milligram Daily Started: 20/01/2000 Stopped:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 153539 Seq: 1 Gender: M

Reported: 09/06/2000 **Weight:**

Hospitalisation: Age: 25Y
Onset Date: 31/05/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression		Attack and stabbing (hostility).	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: Started: 01/01/1999 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. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 153541 Seq: 1 Gender: M
Reported: 09/06/2000 Weight:
Hospitalisation: Age: 85Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Tachycardia		Heart rate 100-110 beats / min.	
Confusional state			
Convulsion			
Hallucination			
Hyperreflexia			
Hypertonia			
Neuroleptic malignant syndrome			Intravenous ceftriaxone and erythromycin were administered. zyprexa was discontinued.
Paranoia			
Pyrexia			

Medicine Details:

MEGICINE Details.						
ZYPREXA (Suspected)			Reason:			•
Tablet	10.0	Milligram	Daily	Oral		
Batch:	Started:			Stopped:	1W	
NEFAZODONE HYDROCHLORIDE (Suspected)			Reason:			
	300.0	Milligram	Daily			
Batch:	Started:			Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Serum creatine kinase was normal.
	Lactate - lactic				Lactate dehydrogenase was elevated at 289 u/l.

Additional Information:

Patient also taking clonazepam, haloperidol, morphine, omeprazole, cisapride and betaxolol. literature: annals of pharmacotherapy, title: possible neuroleptic malignant syndrome associated with olanzapine, vol: 34, date: 1/5/2000, page 667, author: karin nyforthansen.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

_			
Repo	>rt Γ)etai	ile:

 Case Number:
 153541
 Seq: 1
 Gender: M

 Reported:
 09/06/2000
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

-	oution botano								
	Preferred Term	Severity	Report Description	Treatment					
	Urinary incontinence								

Medicine Details:

Micalcinic Details.						
ZYPREXA (Suspected)			Reason:			
Tablet	10.0	Milligram	Daily	Oral		
Batch:	Started:			Stopped:	1W	
NEFAZODONE HYDROCHLORIDE (Suspected)			Reason:			
	300.0	Milligram	Daily			
Batch:	Started:			Stopped:		

Laboratory Investigations:

Additional Information:

Patient also taking clonazepam, haloperidol, morphine, omeprazole, cisapride and betaxolol. literature: annals of pharmacotherapy, title: possible neuroleptic malignant syndrome associated with olanzapine, vol: 34, date: 1/5/2000, page 667, author: karin nyforthansen.

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Report Details:

Case Number: 153551

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 09/06/2000		Weight:				
ospitalisation:		Age:				
Onset Date:		DOB:				
Outcome: Unknown			Causality: Causality possible			
eaction Details: Preferred Term	Severity	Report Description	Treatment			
kin striae	Seventy	Stretch marks under the axilla	Patient has ceased the			
KIII SUIGE		Stretch marks under the axilla	olanzapine.			
Medicine Details: OLANZAPINE (Suspected)	0.0	Reason:				
Batch:	Started:	Stoppe	ad.			
_aboratory Investigatior	ns:					
Date Type	Range Date Test	ted Result	Details			
Additional Information:						
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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 153552 Seq: 1 Gender: F

Reported: 09/06/2000 Weight:
Hospitalisation: Age: 50Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence	Severe	Severe urinary incontinence	Zyprexa ceased

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

 Tablet
 10.0 Milligram
 Daily
 Oral

 Batch:
 Started: 01/02/2000
 Stopped: 28/04/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking melleril, captopril, rocaltrol, caltrate. 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report De						
Case Num	ber: 153553	Seq: 1		Ger	nder: M	
Repor	ted: 09/06/2000			Wei	ght:	
łospitalisat	ion:			Age: 32Y		
Onset Date:				1	OOB:	
Outcome: Not yet recovered				Causa	ality: Causality possible	
eaction D	etails:					
Pro	eferred Term	Severity	Report D	escription	Treatment	
	rance impaired					
Weight incre	ased					
			Parace			
Medicine ZYPREXA (S		0.0	Reason:			
	uspected)	0.0 Started:	Reason:	Stopped:	CONTIN	
	uspected)		Reason:		CONTIN	
ZYPREXA (S	uspected)	Started:	Reason:		CONTIN	

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Date Range: 1 Jan 2000 To 31 Dec 2002 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: 153554 Seq: 1 Gender: M
Reported: 09/06/2000 Weight:

Hospitalisation: Age: 58Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Glucose tolerance impaired			
Weight increased			

Medicine Details:

ZYPREXA (Suspected) Reason:

0.0

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Family history of diabetes. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 153555
 Seq: 1
 Gender:
 F

 Reported:
 09/06/2000
 Weight:

Hospitalisation: Age: 32Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Weight increased		Gain of 3.5kg	
Oedema			

Medicine Details:

PROZAC (Other drug)	Reason:					
	0.0					
Batch:	Started:	Stopped:				
ZYPREXA (Suspected)		Reason:				
	7.5 Milligram	Daily				
Batch:	Started: 01/04/2000	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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 153608 Seq: 1 Gender: M

Reported: 13/06/2000 Weight:
Hospitalisation: Age: 60

Onset Date: 31/05/2000 **DOB**: 15/07/1939

Outcome: Unknown Causality: Causality possible

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment	l
Sor	nnolence			Olanzapine ceased.	l

Medicine Details:

OLANZAPINE (Suspected) Reason:

0.0

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking thiamine, aspirin and caltrate. patient history of alcohol abuse, osteoporosis and blindness.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 153788
 Seq: 1
 Gender:
 F

 Reported:
 09/06/2000
 Weight:

Hospitalisation: Age: 48

Onset Date: DOB: 30/05/1952

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
Photophobia		Intolerance to light.		

Medicine Details:

OLANZAPINE (Suspected) Reason: Manic depressive psycho, depre

Tablet 10.0 Milligram Daily Oral

Batch: Started: 14/01/2000 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient constantly quints and is unable to drive constantly during the day. the patient states that vision is much better at night time.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 154035 Seq: 1 Gender: F

Reported: 23/06/2000 Weight:
Hospitalisation: Age: 17Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

<u> </u>	y mroonga				
Date	Туре	Range	Date Tested	Result	Details
	Lymphocytes				1) lymphocytes / 1.11 k/ul/ / within 2) lymphocytes / 0.88 k/ul/ / below 3) lymphocytes / 0.92 k/ul/ / below

Additional Information:

Symptoms occurred after begining the olanzapine 10mg treatment. patient's medical history includes baseline lymphocyte count of 1.11 prior to commencing the olanzapine treatment. The patient had previously been treated with pericyazine and risperidone.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 154036 Seq: 1 Gender: F

Reported: 23/06/2000 Weight:
Hospitalisation: Age: AE
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic movements.	Zyprexa discontinued.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 2.5 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred 10 days after commencing olanzapine therapy (2.5mg/day). the patient's medical history includes no previous antipyschotic treatment.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	po	rt	De	tai	ls:
	\sim		-	u	

Case Number: 154037 Seq: 1 Gender: M
Reported: 23/06/2000 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage		Gastro-intestinal bleeding.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was taking olanzapine (halving the tablets) when symptoms occurred.

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Report Details:

Case Number: 154074

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 26/06/2000			Weight:					
spitalisation: Hospitalisation	on prolonged		Age:					
Onset Date:			DOB:					
Outcome: Unknown		Causality: Causality possible						
action Details:			1					
Preferred Term	Severity	Report Descr	ription	Treatment				
thralgia								
rexia								
edicine Details:		Reason:						
Tablet	15.0 Milli	gram Daily	Oral					
Batch:	Started:		Stopped:	CONTIN				
aboratory Investigatio	ns:							
Date Type	Range Date Tested	Result	Deta	ils				
Additional Information:								
port Run: 04/06/2007 04:54PM	Database: pusime02	ADRS004		Page 103 of 44				



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 154087 Seq: 1 Gender: M

Reported: 27/06/2000 **Weight:** 180.00

Hospitalisation: Age: 25Y
Onset Date: 06/06/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

104011011 D 0141101			
Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Enuresis with an increased dose of 10mg of zyprexa	

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 04/06/2000	Stopped:	
ANTENEX (Suspected)		Reason: Anxiety neurosis	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 04/06/2000	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking nocturne, lithicarb. initially zyprexa commenced on 23/05/00 at 5mg/day.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 154164 Seq: 1 Gender: M

Reported: 23/06/2000 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chromatopsia		Brightening of colours.	

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:

Patient also taking temazepam, diazepam and valproate sodium. reporter's assessment is that the patient is non-compliant and is having delusional thoughts about the colours and believes it could be a result of the disease.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Rei	nort	: De	tai	ls:

 Case Number:
 154165
 Seq: 1
 Gender:
 F

 Reported:
 23/06/2000
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 7.5 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

<u> </u>	y mroonga				
Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Zyprexa dose was reduced to 5mg/day.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	Jei. 134 100	Seq.	. 1			uer. r
	ted: 23/06/200	0			Weig	
ospitalisat						ige:
Onset D						OB:
Outco	me: Unknown				Causa	lity: Causality possible
eaction D	etails:					
Pre	eferred Term	Se	everity	Repo	rt Description	Treatment
Dedema						
	_					
Medicine ZYPREXA (S				Reas	on:	
Table			0.0	Neds	Oral	
Batc		9	tarted:		Stopped:	
aborator	ny Invoctiont	iono.				
_aborator Date	y Investigati Type	Range	Date Tested	Result		Details
24.0	.,,,,	90	Jule : Golda			2 ((3.11)
Additiona	l Information	1:				
eport Run · 04/0	06/2007 04:54PM	Database: n	usime02	Al	DRS004	Page 107 of 440

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 154167
 Seq: 1
 Gender:
 F

 Reported:
 23/06/2000
 Weight:

Hospitalisation: Age: 65Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Agitation			
	Insomnia			

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified psychosisTablet2.5 MilligramDailyOral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient received 2.5mg olanzapine, crushed and then in food, typically ice cream, by her husband for four nights. after each treatment the patient became very agitated (she was described as being on a high).

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Report Details:

Case Number: 154176

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 23/06/2000			Weigh	nt:
ospitalisation:			Ag	e:
Onset Date:			DC	
Outcome: Unknown			Causali	ty: Causality possible
eaction Details:				
Preferred Term	Severity		Description	Treatment
Aggression		abusive.	pine & became verbally	
Orug withdrawal syndrome		Sertraline was beir	ng withdrawn at the time.	
Medicine Details:				
ZYPREXA (Suspected)		Reaso	n:	
		Milligram D	aily	
Batch:	Started:		Stopped:	CONTIN
ZOLOFT (Suspected)		Reaso		
		Milligram D	Paily	
Batch:	Started:		Stopped:	
_aboratory Investigation Date Type	1S: Range Date Test	ted Result	Do	etails
Additional Information:				
oort Run: 04/06/2007 04:54PM	Database: pusime02	ADF	RS004	Page 109 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 154224 Seq: 1 Gender: F
Reported: 26/06/2000 Weight:

Hospitalisation: Age: 39

Onset Date: DOB: 23/06/1961

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intra-uterine death			A curette was performed.

Medicine Details:

Medicine Details.				
ZYPREXA (Suspected)		Reason:	Depression	
Tablet	20.0 Milligram	Daily		Oral
Batch:	Started: 01/01/2000		Stopped:	31/05/2000
ANAFRANIL (Suspected)		Reason:	Depression	
	100.0 Milligram	Daily		
Batch:	Started: 17/03/2000		Stopped:	CONTIN

Laboratory Investigations:

Dat	e	Туре	Range	Date Tested	Result	Details
		Radiololgy				Mid april 2000 the patient had a miscarriage with a non viable foetus on scan.

Additional Information:

Patient also taking atovastatin, nitrazepam, lipitor and mogadon. the patient's medical history includes an overdose and one normal infant prior to commencing atorvastatin and nitrazepam. the patient has been taking the olanzapine for the entire pregnancy. on 1/6/00, it was reported that the patient lost her baby. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 110 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:	
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 Case Number:
 154269
 Seq: 1
 Gender:
 F

 Reported:
 28/06/2000
 Weight:

Reported: 28/06/2000 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			

Medicine Details:

OLANZAPINE (Suspected) Reason:

20.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms when dose of olanzapine was increased to 20mg daily. patient is an insulin dependent diabetic.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 154517 Seq: 1 Gender: M

Reported: 05/07/2000 Weight: 76.00 Hospitalisation: Age: 24Y

Onset Date: 15/03/2000 **DOB:**

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia		Bilateral.	Drug withdrawal.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 01/01/2000 **Stopped:** 15/03/2000

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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 154586
 Seq: 1
 Gender: M

 Reported:
 06/07/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 25

Onset Date: 23/05/2000 DOB: 02/11/1974

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Tablet 10.0 Milligram Daily Oral

Batch: Started: 23/05/2000 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking lithium carbonate. medical history: substance abuse (cannabis).

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 113 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report De	etalis:							
Case Num	ber: 154621	Seq: 1					Gende	r: F
Repor	ted: 10/07/200	0					Weigh	t:
ospitalisat	ion:						Age	e: 65Y
Onset D	ate:						DOI	В:
Outco	me: Recovered	t				C	ausalit	y: Causality possible
eaction D								
	eferred Term	Seve	erity	Rep	ort Descrip	tion		Treatment
Anaemia							Z	Zyprexa ceased.
Orug level ir	creased							
J adicina	Dotaile							
				Rea	son:			
Medicine ZYPREXA (S Table	uspected)		0.0	Rea	son: Daily		Oral	
ZYPREXA (S	uspected) et	Star		Rea	Daily	Stopped:	Oral	
Table	uspected) et	Star		Rea	Daily	Stopped:	Oral	
ZYPREXA (S Table Batc	uspected) et	ons:		Rea	Daily	Stopped:		tails

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 114 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 154622
 Seq: 1
 Gender: U

 Reported:
 10/07/2000
 Weight:

Hospitalisation: Age: 77

Onset Date: DOB: 27/12/1922

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Personality disorder		Behavioural disturbance requiring restaint.	Patient required ect to settle.

Medicine Details:

 OLANZAPINE (Suspected)
 Reason:
 Unspecified psychosis

 Tablet
 2.5 Milligram
 Daily
 Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

From the 10.5.00 till the 16.5.00 the patient was taking 2.5mg zyprexa per day. the dose was then increased to 2.5mg twice a day.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 154623 Seq: 1 Gender: U

Reported: 10/07/2000 Weight:

Hospitalisation: Age: 71

Onset Date: 31/05/2000 **DOB**: 01/03/1929

Outcome: Recovered Causality: Causality possible

Reaction Details:

caction Details.			
Preferred Term	Severity	Report Description	Treatment
Personality disorder		Disturbed behaviour.	Zyprexa discontinued.
Confusional state			

Medicine Details:

ZYPREXA (Suspected) Reason:

10.0 Milligram Daily

Batch: Started: 01/05/2000 **Stopped:** 11/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient's medical history includes ischaemic heart disease, hypertension, a long history of thioridazine use (diagnosis uncertain) and tardive dyskinesia. - 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Ran	ort	Deta	ile:
Reb	DIL	Deta	115.

 Case Number:
 154624
 Seq: 1
 Gender: M

 Reported:
 10/07/2000
 Weight:

Hospitalisation: Age: 68

Onset Date: DOB: 09/09/1931

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation		Calling out behaviour.	

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History includes frontal lobe dementia.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 154696 Seq: 1 Gender: M

Reported: 10/07/2000 Weight:
Hospitalisation: Age: 75

Onset Date: 31/05/2000 DOB: 05/10/1924

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Details.				
Preferred Term	Severity	Report Description	Treatment	l
Confusional state				l
Delirium			Zyprexa ceased.	l
Personality disorder				l

Medicine Details:

ZYPREXA (Suspected)Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 26/04/2000 Stopped: 09/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient's medical history includes schizophrenia, dementia, normal pressure hydrocephalus, epilepsy and hypertension. patient was a major management problem and required restraint. - 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 2000 To 31 Dec 2002 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:
 154697
 Seq: 1
 Gender:
 F

 Reported:
 10/07/2000
 Weight:

Hospitalisation: Age: 40Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Zyprexa ceased.

Medicine Details:

Medicine Details.					
ZYPREXA (Suspected)			Reason:		
Tablet	20.0	Milligram	Daily	Oral	
Batch:	Started:		St	opped:	
SERZONE (Suspected)			Reason:		
Tablet	300.0	Milligram	Daily	Oral	
Batch:	Started:		St	opped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient restarted risperidone therapy.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Numb							
Report		Seq: 1		Gende			
_	ted: 19/07/2000			_	:: 60.00		
spitalisati				_	9: 16		
	ate: 15/06/2000				3: 25/09/1983		
	ne: Recovered			Causality	: Causality possible		
action De		Coverity	Danart Da	corintion	Trootmont		
	eferred Term	Severity	Report De	scription	Treatment		
izziness ry mouth							
lausea							
Somnolence				F	Reduced olanzapine dose to		
0111110101100				1	5mg daily.		
/ledicine I	Details:						
	(Suspected)		Reason:	Unspecified schizophrer	nia		
Tablet		20.0 M	20.0 Milligram Daily Oral				
Batch	n:	Started: 10/06/	Started: 10/06/2000 Stopped:				
a ha wata w	v lovostinstin						
Laborator Date	y Investigatio	o ns: Range Date Tested	Result	Dei	ails		
Date		Range Date Tested	Result	Det	ails		

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 120 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 155127 Seq: 1 Gender: F

 Reported:
 20/07/2000
 Weight:

 Hospitalisation:
 Age:
 81Y

 Onset Date:
 04/03/2000
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
Į	Leukopenia			Olanzapine ceased.

Medicine Details:

Medicine Details.		
OLANZAPINE (Suspected)	Reason:	Hallucinations
Tablet	2.5 Milligram Daily	Oral
Batch:	Started: 20/01/2000	Stopped: 09/02/2000
OLANZAPINE (Suspected)	Reason:	Hallucinations
Tablet	5.0 Milligram Daily	Oral
Batch:	Started: 09/02/2000	Stopped : 04/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	2-8	09/02/2000	2.42	
	Neutrophils	2-8	26/02/2000	2.26	
	Neutrophils	2-8	07/03/2000	2.16	
	Neutrophils	2-8	04/03/2000	1.61	
	White blood cells	3.5-11	09/02/2000	3.8	
	White blood cells	3.5-11	26/02/2000	3.4	
	White blood cells	3.5-11	04/03/2000	2.8	

Additional Information:

Patient also taking citalopram, oxazepam, paracetamol, aspirin, imdur, coloxyl with senna, durolax and vitamin b12. previously on risperidone - hypotension and haloperidol - ineffective.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 155127
 Seq: 1
 Gender:
 F

 Reported:
 20/07/2000
 Weight:

Reported: 20/07/2000 Weight:
Hospitalisation: Age: 81Y

Onset Date: 04/03/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.			
OLANZAPINE (Suspected)		Reason: Hallucinations	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started: 20/01/2000	Stopped:	09/02/2000
OLANZAPINE (Suspected)		Reason: Hallucinations	,
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 09/02/2000	Stopped:	04/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells	3.5-11	07/03/2000	3.3	

Additional Information:

Patient also taking citalopram, oxazepam, paracetamol, aspirin, imdur, coloxyl with senna, durolax and vitamin b12. previously on risperidone - hypotension and haloperidol - ineffective.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 155217
 Seq: 1
 Gender: M

 Reported:
 21/06/2000
 Weight:

Hospitalisation: Age: 34Y

Onset Date: 18/05/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

i todotion Betans.			
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			
Hepatomegaly			

Medicine Details:

Medicine Details:				
ALCOHOL (Suspected)	Reason:			
	0.0			
Batch:	Started:	Sto	pped:	
ZYPREXA (Suspected)		Reason: Schizop	phrenia	
	10.0 Milligram	Daily		
Batch:	Started: 01/01/1999	Sto	pped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient history of heavy alcohol intake, and smokes 3 packets of cigarettes per day. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Ren	ort	Deta	ils:
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 Case Number:
 155301
 Seq: 1
 Gender: F

 Reported:
 21/06/2000
 Weight:

Hospitalisation: Treated in outpatient department only. Age: 73Y

Onset Date: 15/05/1999

Outcome: Recovered

Causality: Causality probable

Reaction Details:

action betails.							
Preferred Term	Severity	Report Description	Treatment				
Dizziness							
Fatigue							
Hypotension							

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 10/05/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking risperidone, lithicarb, premarin, aurorix.

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 124 of 440



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation: Onset Date: Outcome: Not yet recovered Reaction Details: Preferred Term Severity Report Description Treatment Muscle spasms Occasional leg cramps in the middle of the Quinine. Medicine Details: ZYPREXA (Suspected) Reaction Started: Started: Reason: Unspecified schizophrenia Tablet 10.0 Milligram Daily Oral Batch: Started: Stopped: CONTIN Laboratory Investigations: Date Type Range Date Tested Result Details Additional Information:							
ange	Date Tested	Result		De	etails		
s:							
St	arted:			Stopped:	CONTIN		
	10.0 Milli						
		Pos	son:	Unspecified schizophra	nia		
<u> </u>	riig	iit.					
	Oc	casional leg					
Se	verity	Ren	ort Des	cription	Treatment		
red			DOB:				
Reported: 21/06/2000		Weight:					
	St	Severity Oc nig	Rea 10.0 Milligram Started:	Severity Report Des Occasional leg cramps night. Reason: 10.0 Milligram Daily Started:	Severity Report Description Occasional leg cramps in the middle of the night. Reason: Unspecified schizophre 10.0 Milligram Daily Oral Started: Stopped:		



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

pitalisation: Hospitalisation prolonged Onset Date: Outcome: Unknown Causality: Causality poss action Details: Preferred Term Severity Report Description Treatmer ncreatitis Preferred Term Reason: Unspecified schizophrenia Oral application Batch: Started: Stopped: DIUM VALPROATE (Suspected) Reason: 1.4 Gram Daily Batch: Started: Stopped: Divide Stopped: Stopped: Divide Sto	Gender: F				
Onset Date: Outcome: Unknown Causality: Causality poss ction Details: Preferred Term Severity Report Description Treatmer Increatitis Hospitalisation prote dictine Details: LANZAPINE (Suspected) Oral application Oral application Batch: Started: Stopped: DIUM VALPROATE (Suspected) 1.4 Gram Daily Batch: Started: Stopped: Batch: Started: Stopped:	Weight:				
Outcome: Unknown Causality: Causality poss action Details: Preferred Term Severity Report Description Treatmen noreatitis Hospitalisation prote Bedicine Details: LANZAPINE (Suspected) Oral application Batch: Started: Stopped: DDIUM VALPROATE (Suspected) 1.4 Gram Daily Batch: Started: Stopped: Stopped: Double Started: Stopped: Double Batch: Started: Stopped: Stopped:					
Preferred Term Severity Report Description Treatment	lity nossible				
Preferred Term Severity Report Description Treatmer Increatitis Hospitalisation prolo Batch: Started: Stopped: ODIUM VALPROATE (Suspected) Reason: Unspecified schizophrenia Daily Oral Stopped: ODIUM VALPROATE (Suspected) Reason: 1.4 Gram Daily Batch: Stopped: Stopped: ODIUM VALPROATE (Suspected) Started: Stopped:	Josibic				
edicine Details: ILANZAPINE (Suspected) Oral application Batch: Started: Started: Started: Stopped: ODIUM VALPROATE (Suspected) Batch: Started: Started: Stopped: 1.4 Gram Daily Batch: Started: Stopped: Stopped:	nent				
Dedicine Details: LANZAPINE (Suspected) Oral application Batch: Started: DDIUM VALPROATE (Suspected) 1.4 Gram Daily Batch: Stopped: 1.5 Gram Daily Batch: Stopped: Stopped: Daily Batch: Stopped:	rolonged				
ANZAPINE (Suspected) Oral application Batch: Started: Starped: DDIUM VALPROATE (Suspected) Batch: Started: Starped: 1.4 Gram Daily Batch: Stopped: Stopped: Doily Batch: Bat					
Batch: Started: Stopped: ODIUM VALPROATE (Suspected) 1.4 Gram Daily Batch: Started: Stopped:					
ODIUM VALPROATE (Suspected) 1.4 Gram Daily Batch: Started: Stopped:					
1.4 Gram Daily Batch: Started: Stopped: boratory Investigations:					
Batch: Started: Stopped:					
boratory Investigations:					
Date Type Range Date Tested Result Details					

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 155863
 Seq: 1
 Gender:
 F

 Reported:
 04/08/2000
 Weight:

Hospitalisation:
Onset Date:
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure.	

Medicine Details:

ZYPREXA (Suspected) Reason: Paranoia

0.0

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Medical history epilepsy. patient also taking - risperidone.

Report Run: 04/06/2007 04:54PM Database: pusime02 ADRS004 Page 127 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 155864
 Seq: 1
 Gender: M

 Reported:
 04/08/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 61Y

Onset Date: 31/03/2000 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Convulsion		Myoclonic jerks (movement disorder).	01/03/2000 admitted to hospital. olanzapine treatment decreased to 10mg/day and ceased on 23/03/2000.

Medicine Details:

ZYPREXA (Suspected)Reason: Unspecifid affective psychosis

20.0 Milligram Daily

Batch: **Started**: 01/03/2000 **Stopped**: 23/03/2000 3W

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has no medical history of myoclonic jerks. patient also taking - lithium, rocaltrol and methotrexate. olanzapine treatment was decreased to 10mg/day and then ceased on the 23/03/00 - 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 155865 Seq: 1 Gender: M
Reported: 04/08/2000 Weight:
Hospitalisation: Age: A2

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Breast pain			Zyprexa discontinued.
Gynaecomastia			

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:

Patient has no relevant medical history. the patient has approached the doctor regarding a mastectomy.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

eport Details:						
case Number: 155878 Reported: 07/08/2000 spitalisation:	Seq: 1		Gender: Weight:	62.00		
Spitalisation: Onset Date:			Age: DOB:			
Outcome: Unknown				Causality possible		
ction Details:			- ausumy.	caacamy possible		
Preferred Term	Severity	Report [Description	Treatment		
mnolence						
edicine Details: YPREXA (Suspected)	05. [Reason:	•			
Batch:		0.5 Dose Unspecified Daily Started: 20/06/2000 Stopped: 21/06				
aboratory Investigati Date Type	ons: Range Date Teste	d Result	Deta	ils		
.,,,,,						
dditional Information	1:					
ort Run: 04/06/2007 04:54PM	Database: pusime02	ADRS	S004	Page 130 of 440		



Report Details:

Case Number: 155941

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 04/08/2000		Weight:						
ospitalisation:		Age:						
Onset Date:					DOB:			
Outcome: Not yet recovered	ed	Causality: Causality possib Severity Report Description Treatment	usality: Causality possible					
eaction Details:								
Preferred Term	Severity		Report [Description	Treatment			
Drug ineffective Tremor								
Medicine Details:								
ZYPREXA (Suspected)			Reason	Depression				
		0.0 Milligr	ram Da					
Batch:	Started:			Stopped:	CONTIN			
PROZAC (Suspected)			Reason	·				
		0.0 Milligr	ram Da					
Batch:	Started:			Stopped:	CONTIN			
Laboratory Investigations: Date Type Rai		Tested	Result		Details			
I								
Additional Information:								
port Run: 04/06/2007	abase: pusime02	<u> </u>	ADRS	6004	Page 131 of 4			



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number : 155942 Reported : 04/08/2000	Seq: 1	1 Gender: F Weight:		
ospitalisation:				kge:
Onset Date:				OB:
Outcome: Not yet reco	vered		Causa	lity: Causality possible
eaction Details: Preferred Term	Severity	Penr	ort Description	Treatment
Rash			ad skin rash on the legs.	Epilim discontinued.
Medicine Details: OLANZAPINE (Suspected)		Reas	son:	
OLANEAI INE (Guopeoteu)	0.0	rtou.		
Batch:	Started:		Stopped:	CONTIN
EPILIM (Suspected)		Reas	son:	
	0.0			
Batch:	Started:		Stopped:	
_aboratory Investigatio				
Date Type	Range Date Tester	d Result		Details
Additional Information:	,			
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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 156069
 Seq: 1
 Gender:
 F

 Reported:
 11/08/2000
 Weight:

Hospitalisation: Admitted to hospital **Age**: 35

Onset Date: DOB: 03/12/1964

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

radion betans.					
Preferred Term	Severity	Report Description	Treatment		
Apathy		Flat mood and panic feelings.			
Fatigue		Low energy and motivation & feeling of pessimism.			
Depression		Worsening of depression & anxiety symptoms.	Patient hospitalised.		

Medicine Details:

Medicine Details.				
OLANZAPINE (Suspected)		Reason: Depres	ssion	
Tablet	6.0 Milligram	Daily	Oral	
Batch:	Started: 03/08/2000	Sto	opped:	
FLUOXETINE HYDROCHLORIDE (S	uspected)	Reason: Depres	ssion	
Tablet	50.0 Milligram	Daily	Oral	
Batch:	Started: 03/08/2000	Sto	opped:	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 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: 156244 Seq: 1 Gender: F
Reported: 14/08/2000 Weight:
Hospitalisation: Age: 77Y

Onset Date: 25/07/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Unconscious and fitting.	
Hyponatraemia			Olanzapine and zopiclone ceased. hypertonic saline and fluid restriction.

Medicine Details:

<u>Medicine Details.</u>		
OLANZAPINE (Suspected)		Reason:
	0.0	
Batch:	Started:	Stopped : 25/07/2000
ZOPICLONE (Suspected)		Reason:
	0.0	
Batch:	Started:	Stopped: 25/07/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Normal thyroid and adrenal function.
	Radiololgy				Normal chest x-ray and normal ct head.
	Sodium				Na 113.

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:					
Case Number: 156360	Seq: 1	Gender: F			
Reported: 11/08/2000		Weight:			

Hospitalisation: Admitted to hospital Age: 65Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

deaction Details.							
Preferred Term	Severity	Report Description	Treatment				
Pneumonia		Strep a pneumonia.					
Hepatic function abnormal			Patient was transferred to a general medical ward. blood tests, isolation, zyprexa has been discontinued.				

Medicine Details:

Micalcinic Details.			
FRUSEMIDE (Other drug)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
PERINDOPRIL (Other drug)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
AMIODARONE HYDROCHLORIDE (Other drug)	Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
METOPROLOL TARTRATE (Other d	rug)	Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

<u> </u>	j invocagationol					
Date	Туре	Range	Date Tested	Result	Details	

Additional Information:

The patient's medical history includes a myocardial infarction, ventricular fibrillation and pneumonia in december 1999. there were no known liver problems prior to commencing zyprexa.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:							
	156360	Seq: 1				Gender:	F
Reported:	11/08/2000					Weight:	
Hospitalisation:	Admitted to hospi	tal				Age:	65Y
Onset Date:						DOB:	
Outcome:	Not yet recovered	i				Causality:	Causality possible
Reaction Detail	ils:						
Medicine Det					Reason:	Unspecified psychosis	
Tablet				Milligram	Daily	Oral	
Batch:		Started	l:			Stopped:	
Laboratory Ir	vestigations:						

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Date Range: 1 Jan 2000 To 31 Dec 2002 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:
 156508
 Seq: 1
 Gender:
 F

 Reported:
 18/08/2000
 Weight:

Hospitalisation: Age: 42

Onset Date: 09/08/2000 **DOB**: 17/12/1957

Outcome: Recovered Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Leukopenia			Date of recovery: 14/8/2000.
Neutropenia			

Medicine Details:

Medicine Details:			
EFEXOR-XR (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped: 03/08/2000	
ZYPREXA (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	Stopped: 10/08/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils				Low neutrophils 1.4.
	White blood cells				W.c.c. 3.3.

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	156515	Seq: 1		Gen	der: F
	18/08/2000	-		Wei	ght:
ospitalisation:					Age: A3
Onset Date:					OOB:
Outcome:	Not yet reco	vered		Causa	ality: Causality possible
eaction Detai					
	ed Term	Severity		ort Description	Treatment
Diabetes mellitus	S		Niddm.		
Medicine Det		40.0		ison:	
Batch:		10.0 Started:	Milligram	Daily Stopped:	CONTIN
_aboratory Ir	ivestigatio	ns: Range Date Test	ted Result		Details
	. , , , ,	range Date reet	- Hours		
Additional In	formation:				
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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 156516
 Seq: 1
 Gender: M

 Reported:
 18/08/2000
 Weight:

Hospitalisation:
Onset Date:

Onset Date:

DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Niddm after 2.5 years of taking zyprexa.	

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 patients medical history includes previously taking modecate.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 156558 Seq: 1 Gender: M
Reported: 21/08/2000 Weight:
Hospitalisation: Admitted to hospital Age:

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Severe		Zyprexa discontinued. admitted to the acute care unit.

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Medical history - lactose intolerance.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 156559
 Seq: 1
 Gender:
 F

 Reported:
 21/08/2000
 Weight:

Reported: 21/08/2000 Weight:
Hospitalisation: Admitted to hospital Age: 32Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia			Patient admitted to hospital.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/12/1997 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking - valproate sodium. medical history - obesity and a smoker. 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 156575 Seq: 1 Gender: F

Reported: 21/08/2000 Weight:
Hospitalisation: Age:
Onset Date: 31/08/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapeutic response decreased			

Medicine Details:

Medicine Details.					
CLOZARIL (Suspected)			Reason:	Unspecified schizophrenia	
Tablet	375.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN
OLANZAPINE (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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

R	er	n	rt	D	eta	il	S	•

 Case Number:
 156616
 Seq: 1
 Gender: M

 Reported:
 23/08/2000
 Weight: 87.00

Hospitalisation: Admitted to hospital Age: 47

Onset Date: 01/08/2000 **DOB**: 20/12/1952

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Olanzapine ceased. patient hospitalised. cogentin given

Medicine Details:

OLANZAPINE (Suspected) Reason:

5.0 Milligram Daily

Batch: Started: 31/07/2000 **Stopped:** 01/08/2000

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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Donortod:		Seq. 1		Weigh			
Reported: spitalisation:	18/08/2000						
Onset Date:		Age: DOB:					
Outcome: Unknown					y: Causality possible		
ction Deta					,		
	ed Term	Severity	Report De	escription	Treatment		
eight increase	d						
edicine Det YPREXA (Suspe		0.0	Reason:	Oral			
Batch:		Started:		Stopped:			
	nvestigation		- ·· I				
Date	Type F	Range Date Tested	Result	De	tails		
Additional In							
oort Run : 04/06/20	07 04·55PM D	atabase: pusime02	ADRS0	04	Page 144 of 44		

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 157172 Seq: 1 Gender: F

Reported: 31/08/2000 Weight:
Hospitalisation: Age: 76Y

Onset Date: 03/08/2000 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
He	patic function abnormal			Date of recovery 22/08/00

Medicine Details:

OLANZAPINE (Suspected) Reason:

5.0 Milligram Daily

Batch: Started: 31/07/2000 **Stopped:** 07/08/2000

Laboratory Investigations:

<u>Laborato</u>	i y iii vootiga				
Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		07/06/2000	25	
	ALT = SGPT		02/08/2000	171	
	ALT = SGPT		22/08/2000	9	
	AST = SGOT		07/06/2000	-	
	AST = SGOT		22/08/2000	16	
	AST = SGOT		02/08/2000	129	
	Bilirubin		07/06/2000	5	

Additional Information:

Patient also taking premarin, coloxyl with senna.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 157172 Seq: 1 Gender: F

Reported: 31/08/2000 Weight:
Hospitalisation: Age: 76Y

Onset Date: 03/08/2000 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected) Reason:

5.0 Milligram Daily

Batch: Started: 31/07/2000 **Stopped:** 07/08/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin		02/08/2000	5	
	Bilirubin		22/08/2000	4	
	GGT = SGGT =		07/06/2000	42	
	GGT = SGGT =		02/08/2000	126	
	GGT = SGGT =		22/08/2000	54	
	SAP = ALP		07/06/2000	83	
	SAP = ALP		02/08/2000	184	

Additional Information:

Patient also taking premarin, coloxyl with senna.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 157172
 Seq: 1
 Gender:
 F

 Reported:
 31/08/2000
 Weight:

Hospitalisation: Age: 76Y

Onset Date: 03/08/2000 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected) Reason:

5.0 Milligram Daily

Batch: Started: 31/07/2000 **Stopped:** 07/08/2000

Laboratory Investigations:

ĺ	Date	Туре	Range	Date Tested	Result	Details
ĺ		SAP = ALP		22/08/2000	100	

Additional Information:

Patient also taking premarin, coloxyl with senna.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: 31/08/2000 Hospitalisation: Admitted to hospital Onset Date: Outcome: Not yet recovered Reaction Details: Preferred Term	eq: 1			ender: M
Onset Date: Outcome: Not yet recovered Reaction Details: Preferred Term				eight: Age:
Outcome: Not yet recovered eaction Details: Preferred Term				DOB:
eaction Details: Preferred Term			Cau	sality: Causality possible
Preferred Term			Juli	canty: Caddanty possible
Haadaaha	Severity	Repo	ort Description	Treatment
Headache Se		Severe headach		
Chest pain				Patient admitted to hospital.
Electrocardiogram abnormal				
Medicine Details: ZYPREXA (Suspected)		Reas	son:	
Tablet	0.0	11000	O:	ral
Batch:	Started:		Stopped:	
Laboratory Investigations:				
Date Type Range	Date Tested			Details
Electrocardiograph		1	Electrocardiogram showe	d st elevation.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 157268 Seq: 1 Gender: M

Reported: 01/09/2000 Weight:
Hospitalisation: Age: 69

Onset Date: 30/06/2000 DOB: 19/09/1930

Outcome: Recovered Causality: Causality probable

Reaction Details:

٠,	todotion botano			
	Preferred Term	Severity	Report Description	Treatment
	Oedema peripheral	Required Specialist Consultation	Hand swelling mild	

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

 Tablet
 2.5 Milligram
 Daily
 Oral

 Batch:
 Started: 16/06/2000
 Stopped: 20/07/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking prazisin, atenolol, cartia, dothiepin, norflex, moduretic.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 157269 Seq: 1 Gender: F

Reported: 01/09/2000 Weight:
Hospitalisation: Age: 79

Onset Date: 07/06/2000 **DOB**: 24/08/1920

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension			Olanzapine ceased

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

 Tablet
 5.0 Milligram
 Daily
 Oral

 Batch:
 Started: 05/06/2000
 Stopped: 13/06/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking haloperidol.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 157270
 Seq: 1
 Gender:
 F

 Reported:
 01/09/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 41Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

<u> </u>			1
Preferred Term	Severity	Report Description	Treatment
Euphoric mood		Increased mood.	
Weight increased			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 15.0 Milligram Daily Oral

Batch: Started: 01/02/2000 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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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 15727	71 Seq :	: 1		Gend	er: F
Reported: 01/09	/2000			Weigl	nt:
ospitalisation:					je : 80Y
Onset Date:					DB:
Outcome: Recov	vered			Causali	ty: Causality probable
eaction Details:	1 -				Т
Preferred Terr	m Se	everity	Repo	ort Description	Treatment
Catatonia Fardive dyskinesia					
Medicine Details:					
ZYPREXA (Suspected)				son: Unspecified psychosis	
Detah.		5.0 Milli	igram	Daily	
Batch:	<u> </u>	tarted:		Stopped:	
aboratory Investi		I	l	_	
Date Type	Range	Date Tested	Result	D	etails
		1			
Additional Informa	ition:				

Rep



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Iospitalisati Onset Da		Seq: 1		Gender: F Weight: Age: 36Y DOB: Causality: Causality possible			
eaction De	etails: eferred Term	Coverity	Dono	rt Description	Trootmont		
remor	nerred renn	Severity		ort Description one leg and both arms.	Treatment		
Medicine I	(Suspected)		Reas	·	sychosis		
Tablef Batch		10.0 Started:	Milligram	Daily Oral Stopped:	Oral CONTIN		
aborator	y Investigatio	ons:					
Date	Type	Range Date Test	ed Result	[Details		
Additional	Information	1:					
port Run: 04/0	6/2007 04:55PM	Database: pusime02	A	DRS004	Page 153 of 440		



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 157292 Seq: 1 Gender: M

Reported: 01/09/2000 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea		In the middle of the night.	

Medicine Details:

ZYPREXA (Suspected) Reason:

20.0 Milligram Daily

Batch: Started: 01/06/2000 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patients medical history includes smoking cigarettes. patient began the treatment at 10mg and was increased to 20mg. patient smokes just prior to going to sleep. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Case Number: 157296

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 01/09/2000)			Weight:			
ospitalisation:					Age:		
Onset Date:				DOB:			
Outcome: Not yet rec	overed			Causa	ality: Causality possible		
eaction Details:							
Preferred Term	S	everity	Rep	ort Description	Treatment		
pistaxis							
hinitis							
ladiaina Dataila:							
ledicine Details: ZYPREXA (Suspected)			Rea	ason:			
		10.0 Milli		Daily			
Batch:		Started:	3	Stopped:	CONTIN		
aboratory Investigatio	one:						
Date Type	Range	Date Tested	Result		Details		
		•					
dditional Information):						

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 157297 Seq: 1 Gender: M

Reported: 01/09/2000 Weight:
Hospitalisation: Age: 53

Onset Date: 31/08/2000 **DOB**: 17/06/1947

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			Zyprexa ceased.

Medicine Details:

ZYPREXA (Suspected) Reason: Transient situational disturb

10.0 Milligram Daily

Batch: Started: 01/08/2000 Stopped: CONTIN

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
Ī		Biochemistry				Elevated blood sugar levels.

Additional Information:

Patients medical history includes diabetes, hypothyroid and post traumatic stress disorder. patient also taking tritace, lipitor and oroxine. zyprexa treatment was rechallenged and the blood sugar levels were elevated again. - 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 157537 Seq: 1 Gender: F

Reported: 11/09/2000 Weight:
Hospitalisation: Age: 60Y

Onset Date: 31/01/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		3 seizures.	

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: Started: 06/08/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking benztropine, diazepam and temazepam. - 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 157782
 Seq: 1
 Gender: M

 Reported:
 13/09/2000
 Weight:

Hospitalisation: Age: 27Y
Onset Date: 12/08/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

<u>leaction Details.</u>			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Chills			
Confusional state			
Nervousness			
Neuroleptic malignant syndrome			Olanzapine and sertraline ceased.

Medicine Details:

Medicine Details.					
OLANZAPINE (Suspected)		Reason:			
Oral application	10.0 Milligram	Daily		Oral	
Batch:	Started: 05/06/2000		Stopped:	12/08/2000	
SERTRALINE HYDROCHLORIDE (S	uspected)	Reason:			
Oral application	25.0 Milligram	Daily		Oral	
Batch:	Started: 28/07/2000		Stopped:	14/08/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details	
	Creatine				Ck 1100	
	Serum drug level			Lithium levels 12/08/00 0.8 (0.5 - 1.0).		

Additional Information:

Patient also taking lithium, diazepam.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 157795
 Seq: 1
 Gender: M

 Reported:
 15/09/2000
 Weight:

Hospitalisation: Age: 25Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancreatitis			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

0.0

Batch: Started: 01/01/1999 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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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

ase Number:	157796	Seq: 1		Gender: M				
	•			Weight				
spitalisation:			Age:					
Onset Date:			DOB:					
Outcome:	Recovered					ty: Causality probable		
ction Detai	ls:							
Preferre	ed Term	Severity	Rep	ort Descripti	on	Treatmen	nt	
pertension					C	Dlanzapine ceased		
edicine Deta				ason:				
Tablet Batch:		5.0 M Started:	lilligram	Daily	Oral opped:			
					••			
aboratory In	vestigatio Type	ns: Range Date Tested	I Result	T	Det	ails		
Date	Туре	Range Date resteu	Result		Dei	alls		
dditional Inf	ormation:							
ort Run: 04/06/200	07 04:55PM	Database: pusime02		ADRS004		Page 160	of 440	



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	Seq:	1		Gender: F						
	d: 15/09/2000			Weight:						
pitalisation:				Age:						
Onset Date:				DO			DOB:			
Outcome:	Recovered						ausality: (ausality prob	able	
action Detai	ls:									
Preferre	ed Term	Se	everity	Rep	ort Desc	cription		Treatmer	nt	
pertension							Olan	zapine ceased		
edicine Deta DLANZAPINE (Sus Tablet			2.5 Milli		son:		Oral			
Batch:		9	tarted:	igrain	Daily	Stopped:	Olai			
boratory In	vestigati Type	ONS: Range	Date Tested	Result			Details			
	.) -									
dditional Inf	ormation	ı:								
ort Run: 04/06/200	07 04:55PM	Database: pu	usime02	ļ	ADRS004			Page 161	of 440	



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

ase Number:	157798	Seq: 1		Ge	nder: F
	15/09/2000	•	Weight:		
spitalisation:					Age:
Onset Date:				!	DOB:
	Recovered			Caus	ality: Causality probable
<u>ction Detai</u>					
	ed Term	Severity	Report I	Description	Treatment
pertension					Olanzapine ceased
edicine Det		Q.F. Mill	Reason		
Tablet Batch:		2.5 Mill Started:	ıgram Da	aily Ora Stopped :	
boratory In	vestigatio	ns: Range Date Tested	Result		Details
	,,				
dditional Inf	ormation:				
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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

oer: 157799	Seq	ı: 1		Ge	ender: F		
ted: 15/09/200			Weight:				
on:			Age: 82Y				
ate:			DOB:				
me: Not yet re	covered		Causality: Causality possible				
etails:							
	S	everity	Repo	ort Description	Treatment		
state					Zyprexa reduced, valproate increased.		
Details:	drug)		Rea	son:			
(33.3.3	3,	0.0					
h:	;	Started:		Stopped:	CONTIN		
M (Other drug)			Rea	son:			
		0.0					
h:	;	Started:		Stopped:			
Other drug)			Rea	son:			
		0.0					
h:	,	Started:					
uspected)							
_			gram	-			
h:	;	Started:		Stopped:			
y Investigat	ions:						
	Range	Date Tested	Result		Details		
Туре							
	ted: 15/09/200 on: ate: me: Not yet re etails: eferred Term state Details: PROATE (Other of the content of the	ted: 15/09/2000 on: ate: me: Not yet recovered etails: eferred Term S state Details: PROATE (Other drug) h: M (Other drug) h: Other drug) h: uspected)	Details: PROATE (Other drug) h: Started: M (Other drug) h: Started: Other drug) 0.0 Started: Other drug) 12.5 Millight: 12.5 Millight: Started:	ted: 15/09/2000 on: ate: me: Not yet recovered etails: eferred Term Severity Reportstate Details: PROATE (Other drug) Rea 0.0 h: Started: M (Other drug) Rea 0.0 h: Started: Other drug) Rea 12.5 Milligram h: Started:	ted: 15/09/2000 Woon: ate: me: Not yet recovered Cause etails: beferred Term Severity Report Description State Details: PROATE (Other drug) Reason: 0.0 h: Started: Stopped: M (Other drug) Reason: 0.0 h: Started: Stopped: bther drug) Reason: 0.0 h: Started: Stopped:		

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	157812	Seq: 1		Gend	ler: F
Reported:	15/09/2000)		Weig	ht:
ospitalisation:				A	ge:
Onset Date:				DO	OB:
Outcome:	Not yet rec	overed		Causal	ity: Causality possible
eaction Detai					_
	ed Term	Severity		ort Description	Treatment
Hypochromic and	aemia		Iron deficiency v	vhich had a rapid onset.	
Medicine Deta		0.0	Rea	son:	
Batch:		Started:		Stopped:	CONTIN
_aboratory In	vestigation	ons: Range Date Teste	ed Result	Т	Details
Date	Турс	range Date rest	su result		retails
Additional Inf	ormation	:			
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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	157813	Seq: 1		Gend	der: F
Reported:	15/09/2000	-		Weig	ht:
ospitalisation:				A	ge:
Onset Date:				D	OB:
Outcome:	Not yet reco	overed		Causal	ity: Causality possible
eaction Detai					
	ed Term	Severity		ort Description	Treatment
Hypochromic and	aemia		Iron deficiency v	vhich had a rapid onset.	
Medicine Deta ZYPREXA (Suspec		0.0	Rea	son:	
Batch:		Started:		Stopped:	CONTIN
aboratory In	vestigation	Ons: Range Date Teste	ed Result	Г	Details
Date	Турс	range Date rest	su result		7Ctalis
Additional Inf	ormation	:			
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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	157814	Seq: 1		Gend	er: M
	15/09/2000	-	Weight:		
ospitalisation:		Age:			e:
Onset Date:				DC	B:
Outcome:	Not yet reco	vered		Causali	ty: Causality possible
action Detai					
Preferre	ed Term	Severity	Rep	ort Description	Treatment
lypochromic ana	ıemia		ron deficiency v	vhich had a rapid onset.	
Medicine Deta ZYPREXA (Suspec		0.0	Rea	son:	
Batch:		Started:		Stopped:	CONTIN
aboratory In	vestigatio	ns: Range Date Teste	d Result	I 5	etails
Date	Туре	Range Date reste	d Result		etalis
Additional Inf	ormation:				
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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	157815	Seq: 1		Gend	ler: M
Reported:	15/09/2000)		Weig	ht:
ospitalisation:				Ag	ge:
Onset Date:				DO	OB:
Outcome:	Not yet rec	overed		Causal	ity: Causality possible
eaction Detai	ls:				
Preferre	ed Term	Severity	Repo	ort Description	Treatment
Hypochromic and	aemia		Iron deficiency v	vhich had a rapid onset.	
Medicine Deta ZYPREXA (Suspec		0.0	Rea	son:	
Batch:		Started:		Stopped:	CONTIN
_aboratory In	Type	Ons: Range Date Teste	ed Result	Г	Details
Bute	Турс	Trange Bate rest	3d Result		retune
Additional Inf	ormation	:			
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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	157816	Seq: 1		Ger	nder: F		
	15/09/2000	-	Weight:				
ospitalisation:				Age:			
Onset Date:				OOB:			
Outcome:	Not yet reco	vered		Causa	ality: Causality possible		
eaction Detai	ls:						
Preferre	ed Term	Severity	Rep	ort Description	Treatment		
Galactorrhoea			Lactating breast	S.			
Medicine Det		7.5		son: Unspecified schizop	hrenia		
Batch:		Started:	Milligram	Daily Stopped:			
_aboratory In			had Daault	Т	Dataila		
Date	Туре	Range Date Test	ted Result		Details		
Additional Inf	ormation:						
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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 157858 Seq: 1 Gender: M
Reported: 18/09/2000 Weight:
Iospitalisation: Admitted to hospital Age: 75Y

Hospitalisation: Admitted to hospital Age: 75
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Patient was admitted to hospital, treated with iv fluids, pressure area care and supportive care. zyprexa and lithium were ceased.

Medicine Details:

LITHIUM CARBONATE (Interaction)

Reason: Unspecified psychosis

0.0

Batch: Started: 01/08/2000 Stopped: 28/09/2000

ZYPREXA (Interaction) Reason: Unspecified psychosis

 Tablet
 10.0
 Milligram
 Daily
 Oral

 Batch:
 Started: 26/08/2000
 Stopped: 27/08/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of deep vein thrombosis approximately 6 months ago. patient experienced symptoms when dose of olanzapine was increased to 5mg bd 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 158192 Seq: 1 Gender: F

Reported: 03/10/2000 Weight: 70.00 Hospitalisation: Age: 50

Onset Date: 08/09/2000 DOB: 16/03/1950
Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia		Numbness of left face.	Required a visit to doctor.

Medicine Details:

ZYPREXA (Suspected) Reason: Schizophrenia

Tablet 2.5 Milligram Daily Oral

Batch: Started: 03/09/2000 Stopped: 18/09/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reintroduction of zyprex and same sympoms occurred. patient recovered 20/9/00.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 158213
 Seq: 1
 Gender: M

 Reported:
 03/10/2000
 Weight:

Hospitalisation: Age: 55

Onset Date: 31/05/2000 **DOB**: 21/02/1945

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botans.			
Preferred Term	Severity	Report Description	Treatment
Dystonia		Acute dystonic reaction.	
Amnesia		Needing constant reminders to 'do things'.	
Coordination abnormal		Unsteady on his feet.	
Thinking abnormal			

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)		Reason: Unspecified schizophi	renia
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1997	Stopped:	CONTIN
SERZONE (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking amprace, diazepam, panadeine and deralin. marked psychomotor retardation, getting 'slower and slower' needing constant remiders to 'do things'. he had poor attempts at self care, was unsteady on his feet and was noted to be leaning to one side when ambulating. the patient was referred to the movement disorder clinic where the zyprexa treatment is progressively being decreased with an aim to cease treatment. - 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 vear.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 158345
 Seq: 1
 Gender:
 F

 Reported:
 09/10/2000
 Weight:

Hospitalisation: Age: 73

Onset Date: 28/08/2000 **DOB**: 03/05/1927

Outcome: Unknown Causality: Causality possible

Reaction Details:

١,	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	1
	Confusional state				1
	Hypotension			Olanzapine and venlafaxine ceased.	ì

Medicine Details:

OLANZAPINE (Suspected) Reason: Depression

2.5 Milligram Daily

Batch: Started: 01/10/1999 **Stopped:** 28/08/2000

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason: Depression

37.5 Milligram Daily

Batch: Started: 28/08/2000 Stopped: 29/08/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking famotidine and frusemide. sequelae: falls. history: chronic depression and dementia. 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 158372 Seq: 1 Gender: F

Reported: 09/10/2000 Weight: 53.00 Hospitalisation: Age: 24

Onset Date: 30/03/2000 **DOB**: 14/04/1975

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Details.			
Preferred Term	Severity	Report Description	Treatment
Coma			
Dizziness			
Tinnitus			
Visual disturbance			

Medicine Details:

ZYPREXA (Suspected) Reason: Depression

1.0 Dose Unspecified Daily Oral

Batch: Started: 28/03/2000 Stopped: 30/03/2000

TEGRETOL (Suspected) Reason: Depression

0.5 Dose Unspecified Daily

Batch: Started: 28/03/2000 Stopped: 30/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking avopro, st johns wort. patient recovered 31/3/00.

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Case Number: 158484

Reported: 09/10/2000 **Hospitalisation:** Admitted to hospital

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Age: 51

Weight:

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Outcome: Not your action Details: Preferred Tendiarrhoea omiting Iedicine Details: PROZAC (Other drug)		Severity	Report D	escription	Treatment Patient was admitted to hospital, was treated with iv maxolon, nasogastric tube, morphine 5mg.
Preferred Tender arrhoea omiting edicine Details:	m S	Severity	Report D	escription	Patient was admitted to hospital, was treated with iv
edicine Details:	n S	Severity	Report D	escription	Patient was admitted to hospital, was treated with iv
edicine Details:					hospital, was treated with iv
			Reason:		
		0.0			
Batch:		Started:		Stopped:	
YPREXA (Suspected)					
		0.0			
Batch:		Started:		Stopped:	
aboratory Investi Date Type	gations:	Date Tested	Result		Details



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 158502 Seq: 1 Gender: M
Reported: 12/10/2000 Weight:

Hospitalisation: Age: 54Y
Onset Date: 31/07/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
lleus			Metoclopramide
Malaise			
Vomiting			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

0.0

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking sodium valproate, temazepam, droperidol, chlorpromazine, carbamazepine. - 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 158975
 Seq: 1
 Gender: M

 Reported:
 01/11/2000
 Weight:

Hospitalisation: Age: 42

Onset Date: 26/10/2000 **DOB:** 04/12/1957

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Dyskinesia			Slowly reduce zyprexa from 20mg to 15mg or to change to risperdol or sequinal.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 20.0 Milligram Daily Oral

Batch: Started: 27/03/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient is so much better on zyprexa that the does not which to take a lower dose at present as hallucinations and delirum set in under 20mg.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 158985
 Seq: 1
 Gender:
 F

 Reported:
 02/11/2000
 Weight:

Hospitalisation: Hospitalisation prolonged Age: 72

Onset Date: 12/10/2000 **DOB**: 05/09/1928

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Caction Betails.				
Preferred Term	Severity	Report Description	Treatment	
Dystonia			Prolonged hospitalisation.	
Somnolence				l

Medicine Details:

TEMAZEPAM (Suspected) Reason: Unspecified psychosis

10.0 Milligram As necessary

Batch: Started: 09/10/2000 **Stopped:** 11/10/2000

ZYPREXA (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 11/05/2000 Stopped: 13/10/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking trimethoprim, coloxyl & senna, panadol and tears naturale. patient continues to be sedated and dystonic with poor oral intake, drooling. 6 year history of dementia with aggressive behaviour.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 159193
 Seq: 1
 Gender:
 F

 Reported:
 10/11/2000
 Weight:

Hospitalisation: Age: 64

Onset Date: 01/11/2000 DOB: 07/11/1935

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia			

Medicine Details:

LOSEC (Other drug)	Re	ason:	Other diseases of esophagus
	40.0 Milligram	Daily	1
Batch:	Started: 25/10/2000		Stopped:
FERRO-GRADUMET (Other drug)	Re	ason:	Unspecified anemia
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started: 25/10/2000		Stopped:
COLOXYL WITH SENNA (Other drug)	Re	ason:	Constipation
Tablet	4.0 Dose Unspecified	Daily	oral Oral
Batch:	Started: 20/10/2000		Stopped:
LACTULOSE (Other drug)	Re	ason:	Constipation
Oral Liquid	40.0 Millilitre	Daily	Oral
Batch:	Started: 20/10/2000		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells		21/10/2000	2.8	Zyprexa ceased on 26/10/2000.
	White blood cells		26/10/2000	4.2	Zyprexa ceased on 26/10/2000.
	White blood cells		01/11/2000	3.2	Zyprexa ceased on 26/10/2000.

Additional Information:

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Case Number: 159193

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 10/11/2000				Weight:		
ospitalisation:				Age:		
Onset Date: 01/11/2000				DOB:	07/11/1935	
Outcome: Not yet recovered			C	ausality:	Causality poss	ible
action Details:						
la diaina Dataila.						
ledicine Details:		D	Consider discou	lawa af alaaw		
TEMAZEPAM (Other drug)	40.0 Millianasa	Reason:	Specific disord			
Oral application	10.0 Milligram	Daily		Oral		
Batch:	Started:		Stopped:			
OUROLAX (Other drug)		Reason:	Constipation			
Suppository	1.0 Dose Unspe	cified Alterr	nate days	Rectal		
Batch:	Started: 20/10/2000		Stopped:			
ZYPREXA (Suspected)		Reason:	Unspecified p	sychosis		
	5.0 Milligram	Daily				
Batch:	Started: 27/10/2000		Stopped:	31/10/2000		
aboratory Investigations:						
dditional lufowaation.						
dditional Information:						
ort Run : 04/06/2007 04:55PM Databas	se: nusime02	ADRS0	n 4		Page 179	of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 159194 Seq: 1 Gender: F

 Reported:
 10/11/2000
 Weight:
 57.00

 Hospitalisation:
 Age:
 43Y

 Onset Date:
 13/10/2000
 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Cease olanzapine.

Medicine Details:

BACLOFEN (Other drug)		Reason:	Pain	
	0.0			
Batch:	Started:	L TERM	Stopped:	
DUROGESIC (Other drug)		Reason:	Pain	
	0.0			
Batch:	Started:	L TERM	Stopped:	
CLONAZEPAM (Other drug)		Reason:	Anxiety neurosis	
	0.0			
Batch:	Started:	L TERM	Stopped:	
FLUOXETINE HYDROCHLORIDE (O	ther drug)	Reason:	Depression	
	80.0 Milli	gram Daily	1	
Batch:	Started: 02/10/20	000	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		13/10/2000	44	
	ALT = SGPT		20/10/2000	136	
	ALT = SGPT		02/11/2000	26	
	GGT = SGGT =		13/10/2000	82	
	GGT = SGGT =		20/10/2000	92	
	GGT = SGGT =		02/11/2000	52	
	SAP = ALP		13/10/2000	151	

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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 159194 Seq: 1 Gender: F

Reported: 10/11/2000 Weight: 57.00 Hospitalisation: Age: 43Y

Onset Date: 13/10/2000 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

ROHYPNOL (Other drug) Reason: Specific disorders of sleep

2.0 Milligram Daily

Batch: Started: L TERM Stopped:

OLANZAPINE (Suspected) Reason: Depression

5.0 Milligram Daily

Batch: Started: 01/08/2000 Stopped: 24/10/2000

Laboratory Investigations:

<u> </u>	y mroonga				
Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP		20/10/2000	157	
	SAP = ALP		02/11/2000	107	

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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 159237
 Seq: 1
 Gender:
 F

 Reported:
 13/11/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 72

Onset Date: 07/09/2000 DOB: 22/11/1927

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle contractions involuntary		Involuntary muscle movements of face and limbs	Patient was hospitalised.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 28/07/2000 Stopped: 12/09/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patint was also taking antenex, betamin, ferro-gradumet, rocaltrol, acimax, multi b. long history of alcohol use.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 159461 Seq: 1 Gender: M

Reported: 22/11/2000 Weight: 76.00 Hospitalisation: Age: 47

Onset Date: 31/10/2000 **DOB**: 02/11/1952

Outcome: Recovered Causality: Causality probable

Reaction Details:

Dueferned Terms	Coverity	Depart Description	Trootmont
Preferred Term	Severity	Report Description	Treatment
Neutropenia			Date of recovery 16/11/00. olanzapine ceased.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

20.0 Milligram Daily

Batch: Started: 06/09/2000 Stopped: 01/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details	
	Neutrophils				Neutrophil count dropprd from 2.17 pre-treatment to 1.58 at 6 weeks. neutrophil count increased after discontinuation of olanzapine.	

Additional Information:

Patient also taking sodium valproate.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 159594 Seq: 1 Gender: M
Reported: 29/11/2000 Weight:

 Hospitalisation:
 Age: 89

 Onset Date: 09/04/2000
 DOB: 15/03/1911

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase in	cr		
Hypertonia			
Neuroleptic malignant syndrome			Paracetamol given. iv hydration. ceased neuroleptic drugs. physiotherapy.

Medicine Details:

Medicine Details.					
PERICYAZINE (Suspected)			Reason:	Otr spec symp psychopathol nec	
	2.5	Milligram	As no	ecessary	
Batch:	Started:			Stopped:	
OLANZAPINE (Suspected)			Reason:	Unspecified psychosis	
Tablet	15.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		11/04/2000	168	
	Creatine		13/04/2000	5001	
	Creatine		14/04/2000	844	
	Creatine		16/04/2000	220	
	Creatine		17/04/2000	258	
	Creatine		21/04/2000	625	
	Creatine		23/04/2000	282	

Additional Information:

Patient also taking aspirin, benztropine, nulax, senocot, temazepam.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 159594 Seq: 1 Gender: M
Reported: 29/11/2000 Weight:

Hospitalisation: Age: 89

Onset Date: 09/04/2000 **DOB**: 15/03/1911

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

PERICYAZINE (Suspected)		Reason: Otr spec symp psychopathol nec
	2.5 Milligram	As necessary
Batch:	Started:	Stopped:
OLANZAPINE (Suspected)		Reason: Unspecified psychosis
Tablet	15.0 Milligram	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		26/04/2000	488	

Additional Information:

Patient also taking aspirin, benztropine, nulax, senocot, temazepam.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 159672
 Seq: 1
 Gender:
 F

 Reported:
 29/11/2000
 Weight:

Hospitalisation: Age: 84

Onset Date: 27/05/2000 **DOB**: 30/06/1915

Outcome: Recovered Causality: Causality probable

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Pyrexia		Tempetatures ranging from 39c to 35.5 c degrees	Patient admitted to hospital, olanzapine ceased. treated with paracetamol.
Blood creatine phosphokinase incr			
Chills			
Hyperhidrosis			

Medicine Details:

 OLANZAPINE (Suspected)
 Reason:
 Unspecified schizophrenia

 Tablet
 10.0 Milligram
 Daily
 Oral

 Batch:
 Started:
 Stopped: 08/06/2000
 2W

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine	< 180			Ck of 218.

Additional Information:

Patient also taking zuclopenthixol, amitriptyline, benztropine, atorvastatin, captopril.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 159707 Seq: 1 Gender: M

Reported: 04/12/2000 Weight: 100.00 Hospitalisation: Age: 47Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Cardiomegaly		La and rv - enlargement.	
	Blood creatine phosphokinase incr		Moderate ck rise.	
	Atrial fibrillation			

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 5.0 Milligram Daily Oral

Batch: Started: 01/01/1998 **Stopped:** 28/11/2000

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

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 159753
 Seq: 1
 Gender: M

 Reported:
 04/12/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 65Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touction Betails.			
Preferred Term	Severity	Report Description	Treatment
Oedema		Body and limb oedema.	
Neuroleptic malignant syndrome			Transferred to the intensive care unit. ventilated.
Respiratory failure			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/10/2000 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1	Report Description	Gender: F Weight: Age: 29Y DOB: Causality: Causality probable		
Severity	Report Description	Age: 29Y DOB:		
Severity	Report Description	DOB:		
Severity	Report Description			
Severity	Report Description	Caucanty: Caucanty propagie		
Severity	Report Description	, , , , , , , , , , , , , , , , , , , ,		
		on Treatment		
		Sodium valproate as prophylaxis.		
40.0 Millio	Reason:			
		Stopped:		
s:				
	Started: 30/06/19	10.0 Milligram Daily Started: 30/06/1999 Sto		

Rep



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 160276 Reported: 22/12/2000 Ospitalisation: Admitted to hospital Onset Date: 20/04/2000 Outcome: Recovered Caction Details: Preferred Term Orug withdrawal syndrome	eq: 1 Severity		Report De	Weig A D Causal	der: F pht: ge: 49 OB: 21/11/1950 lity: Causality possible Treatment
Onset Date: 20/04/2000 Outcome: Recovered Caction Details: Preferred Term rug withdrawal syndrome			Report De	A D Causal	ge: 49 OB: 21/11/1950 lity: Causality possible
Onset Date: 20/04/2000 Outcome: Recovered action Details: Preferred Term rug withdrawal syndrome			Report De	D Causal	OB: 21/11/1950 lity: Causality possible
Outcome: Recovered action Details: Preferred Term rug withdrawal syndrome	Severity		Report De	Causal	lity: Causality possible
Preferred Term rug withdrawal syndrome	Severity		Report De		
Preferred Term rug withdrawal syndrome	Severity		Report De	scription	Treatment
rug withdrawal syndrome	Severity	+	Report De	scription	Treatment
					l
lania					Carbamazepine, olanzapine clonazepam, droperidol.
-					
ledicine Details: OLANZAPINE (Suspected)			Reason:	Unspecifid affective p	sychosis
		Milligram	Daily		
Batch:	Started:		Decem	Stopped:	ovele e die
LITHIUM CARBONATE (Suspected)	1.0	Gram	Reason:	Unspecifid affective p	sycnosis
Batch:	Started:	Gram	Daily	Stopped:	
aboratory Investigations: Date Type Range	Date Tes	sted Re	esult		Details
7,1					

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 160316 Seq: 1 Gender: F
Reported: 22/12/2000 Weight:
Hospitalisation: Age: 48Y

Onset Date: 11/12/2000 DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pallor		Became pale	
Hypoxia		Oxygen saturations dropped to 83%	
Cardiac arrest			
Cardiomyopathy			
Hyperhidrosis			
Sudden death			

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
CIPRAMIL (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

<u> </u>	oratory invocagationor				
Date	Туре	Range	Date Tested	Result	Details
	Pharmacokinetics				Olanzapine plasma levels were 0.2mg/kg & cipramil plasma levels were 1.9mg/kg.

Additional Information:

Patient died 11/12/00.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 160523 Seq: 1 Gender: F

Reported: 11/01/2001 Weight: 89.00 Hospitalisation: Age: 49Y

Onset Date: 17/09/2000 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema		General body oedema	Olanzapine ceased.

Medicine Details:

OLANZAPINE (Suspected) Reason:

10.0 Milligram Daily

Batch: Started: L TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking lithium, epilim, allegron.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 160571
 Seq: 1
 Gender: M

 Reported:
 12/01/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 46Y
Onset Date: 17/10/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction betains:			
Preferred Term	Severity	Report Description	Treatment
			Patient was hospitalised. treated with promethazine oral and calamine lotion. 25.10.00 the rash resolved and zyprexa has continued (dose has increased).

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: 25/09/2000 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking epilim, zactin, paxam, clopixol, temazepam, midazolam and clonazepam.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 161060 Seq: 1 Gender: M
Reported: 31/01/2001 Weight:

Hospitalisation: Age: 19Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient hospitalised	

Medicine Details:

Medicine Details.				
EPILIM (Suspected)		Reason:		
Oral application	0.0		Oral	
Batch:	Started:		Stopped:	
ZYPREXA (Suspected)		Reason:		
Tablet	30.0 Millig	ram Daily	Oral	
Batch:	Started:		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of using illicit drugs. patient has a history of existing cardiac problems.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 161061
 Seq: 1
 Gender: M

 Reported:
 31/01/2001
 Weight:

Hospitalisation: Admitted to hospital **Age**: 81

Onset Date: 17/01/2001 **DOB**: 21/03/1919

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depression		Patient hospitalised	

Medicine Details:

TIMOLOL MALEATE (Other drug)		Reason:
	0.0	
Batch:	Started:	Stopped:
ALBALON (Other drug)		Reason:
	0.0	
Batch:	Started:	Stopped:
LIPEX (Other drug)		Reason: Othr&unspec metabolic diseases
	80.0 Milligram	Daily
Batch:	Started: 05/11/1999	Stopped: CONTIN
FLUOXETINE HYDROCHLORIDE (Sus	pected)	Reason: Depression
Oral application	300.0 Milligram	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Used in ct but not a ct drug.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 161061 Reported: 31/01/2001 Hospitalisation: Admitted to hospi Onset Date: 17/01/2001 Outcome: Unknown Reaction Details:	Seq: 1			
Medicine Details:		Pagan.		
OLANZAPINE (Suspected) Oral application	48.0 Milligram	Reason: Daily	Oral	
Batch:	Started:	Stopp		
Laboratory Investigations:				
Additional Information: Used in ct but not a ct drug.				

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Rep



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 161111
 Seq: 1
 Gender: F

 Reported:
 01/02/2001
 Weight:

Hospitalisation: Age: 33

Onset Date: DOB: 09/08/1967

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cleft lip		Foetal/neonatal.	

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Tablet 10.0 Milligram Daily Oral

Batch: Started: 19/08/2000 Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
Ī	Other data					Uss findings: cleft lip identified on left side, 12/1/01.

Additional Information:

Patient was initially on 7.5mg olanzapine then was increased to 10mg on the 19/8/00, then increased to 12.5mg 4/9/00.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 161119 Seq: 1 Gender: F

Reported: 01/02/2001 **Weight:** 110.00

Hospitalisation: Age: 17

Onset Date: 26/12/2000 **DOB**: 24/06/1983

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Betans.	saction betails:									
Preferred Term	Severity	Report Description	Treatment							
Pyrexia		Fever 39 degrees	Required a visit to doctor.							
Neutropenia										

Medicine Details:

ZYPREXA (Suspected)		Reason:	Schizophrenia	
	20.0 Milligrar	n Daily		
Batch:	Started: 04/12/2000		Stopped:	
SEROQUEL (Suspected)		Reason:	Schizophrenia	
	800.0 Milligrar	n Daily		
Batch:	Started: 28/08/2000		Stopped: 21/12/2000	
CARBAMAZEPINE (Suspected)		Reason:	Other&unspecified epilepsy	
	1.2 Gram	Daily		
Batch:	Started:	L TERM	Stopped: 29/01/2001	
VIGABATRIN (Suspected)		Reason:	Other&unspecified epilepsy	
	2.0 Gram	Daily		
Batch:	Started:	L TERM	Stopped: 19/01/2001	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	(1.7-7)	28/12/2000	1.3	

Additional Information:

Reaction occurred 22 days after commencing zyprexa. patient recovered 24/1/01.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 161120 Seq: 1 Gender: F

Reported: 01/02/2001 Weight: 115.00 Hospitalisation: Age: 59

Onset Date: 06/01/2001 **DOB**: 05/01/1942

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Fever 39 degrees	Required a visit to doctor.
Hepatic function abnormal			

Medicine Details:

Medicine Details.				
TEGRETOL CR (Suspected)		Reason:	Other&unspecified epilepsy	
	400.0 Milligram	Daily		
Batch:	Started: 01/01/1999		Stopped: 11/01/2001	
ZYPREXA (Suspected)		Reason:	Schizophrenia	
	20.0 Milligram	Daily		
Batch:	Started: 20/11/2000		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	(14-51)	13/12/2000	21	
	ALT = SGPT	(14-51)	09/01/2001	298	
	ALT = SGPT	(14-51)	24/01/2001	28	
	AST = SGOT	(15-45)	13/12/2000	11	
	AST = SGOT	(15-45)	09/01/2001	92	
	AST = SGOT	(15-45)	24/01/2001	16	
	Bilirubin	(0-25)	13/12/2000	7	

Additional Information:

Patient was also taking zuclopenthixol depot, metformin, lasix, ramipril. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 161120 Seq: 1 Gender: F

Reported: 01/02/2001 Weight: 115.00 Hospitalisation: Age: 59

Onset Date: 06/01/2001 **DOB**: 05/01/1942

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Modifile Botalies		
TEGRETOL CR (Suspected)		Reason: Other&unspecified epilepsy
	400.0 Milligram	Daily
Batch:	Started: 01/01/1999	Stopped: 11/01/2001
ZYPREXA (Suspected)		Reason: Schizophrenia
	20.0 Milligram	Daily
Batch:	Started: 20/11/2000	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	(0-25)	09/01/2001	16	
	Bilirubin	(0-25)	24/01/2001	9	
	GGT = SGGT =	(0-30)	13/12/2000	56	
	GGT = SGGT =	(0-30)	09/01/2001	626	
	GGT = SGGT =	(0-30)	24/01/2001	188	
	SAP = ALP	(38-1260	13/12/2000	106	
	SAP = ALP	(38-1260	09/01/2001	331	

Additional Information:

Patient was also taking zuclopenthixol depot, metformin, lasix, ramipril. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 161120 Gender: F Seq: 1

Reported: 01/02/2001 Weight: 115.00 Hospitalisation: Age: 59

Onset Date: 06/01/2001 **DOB**: 05/01/1942

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

TEGRETOL CR (Suspected)		Reason:	Other&unspecified epilepsy
	400.0 Milligram	Daily	
Batch:	Started: 01/01/1999		Stopped: 11/01/2001

ZYPREXA (Suspected) Reason: Schizophrenia

> 20.0 Milligram Daily

Batch: Started: 20/11/2000 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	(38-1260	24/01/2001	136	

Additional Information:

Patient was also taking zuclopenthixol depot, metformin, lasix, ramipril. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 161420
 Seq: 1
 Gender:
 F

 Reported:
 12/02/2001
 Weight:

Hospitalisation: Age: 38Y
Onset Date: 31/12/2000 DOB:

Outcome: Death Causality: Causality possible

Reaction Details:

	Cachon Details.			
	Preferred Term	Severity	Report Description	Treatment
Sudden death			Sudden death	
	Weight increased			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

0.0

Batch: Started: L TERM 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 161629 Gender: M Seq: 1 Weight: 92.00 Reported: 16/02/2001

Hospitalisation: Admitted to hospital **Age:** 67

Onset Date: 26/11/2000 **DOB**: 09/02/1933 Causality: Causality probable

Outcome: Not yet recovered

Reaction Details:

deaction Details.						
Preferred Term	Severity	Report Description	Treatment			
Hypertension		Max 181/85.				
Pyrexia		Max 39.7c	Patient was hospitalised. cease olanzapine, supportive measures.			
Cough		Moist cough with nasal congestion.				
Bronchospasm		Scattered diffuse expiratory wheeze.				
Tachycardia		Sinus tachycardia, max pr 119.				
Hypertonia		Stiffness -> leadpipe rigidity.				
Productive cough		Thick yellow sputum produced.				
Blood creatine phosphokinase incr						
Confusional state						

Medicine Details:

OLANZAPINE (Suspected)		Reason:	Unspecified schizophrenia
Oral application	25.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1998		Stopped: 27/11/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		29/11/2000	4988	
	Creatine		11/12/2000	80	

Additional Information:

Patient also taking madopar 125, madopar hbs and sodium valproate. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 161629 Seq: 1 Gender: M

Reported: 16/02/2001 Weight: 92.00
Hospitalisation: Admitted to hospital Age: 67

Onset Date: 26/11/2000 DOB: 09/02/1933

Outcome: Not yet recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

Medicine Details:

OLANZAPINE (Suspected)

Oral application

Started: 01/01/1998

Reason: Unspecified schizophrenia

Oral

Oral

Stopped: 27/11/2000

Laboratory Investigations:

Additional Information:

Patient also taking madopar 125, madopar hbs and sodium valproate. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 161784 Seq: 1 Gender: F

Reported: 21/02/2001 Weight: Hospitalisation: Age:

Onset Date: 31/12/2000 **DOB:**

Outcome: Recovered Causality: Causality probable

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus			
Hyperglycaemia			Required a visit to doctor. olanzapine ceased. change to seroquel. date of recovery: 16/2/2001.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

15.0 Milligram Daily

Batch: Started: 01/10/2000 Stopped: 28/02/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Serum glucose			Bsl 6-8mmol/l, on olanzapine 12-20mmol/l.	

Additional Information:

Patient also taking diamicron, diaformin, lipitor, valium and aropax. - 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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Report Details:

Case Number: 161945

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 26/02/2001		Weight:				
ospitalisation: Hospitalisatio	n prolonged	Age:				
Onset Date:		DOB:				
Outcome: Not yet recov	ered	Causality: Causality possible				
action Details:	1 0 "					
Preferred Term	Severity		escription	Treatment		
ffect lability		Developed a labile m	lood, almost manic.	Hospitalisation has been prolonged. zyprexa ceased and the patient was recommenced on stelazine		
Medicine Details: ZYPREXA (Suspected)		Reason:	Unspecified schizoph	renia		
Oral application	0.0		Oral			
Batch:	Started:		Stopped:	4W		
aboratory Investigation	NS:	D It		D-4-11-		
Date Type	Range Date Teste	ed Result		Details		
Additional Information:						



Report Details:

Case Number: 162457

Reported: 09/03/2001

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight:

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

spitalisation: Admitted to hos	pital		Age: 30Y			
Onset Date:		DOB:				
Outcome: Recovered			Caus	sality: Causality probable		
action Details: Preferred Term	Severity	Papart D	escription	Treatment		
nia	Seventy	Керип	езсприоп	Olanzapine and citalopram ceased. patient was commenced on risperidone and lithium. patient was hospitalised.		
edicine Details:						
ITALOPRAM HYDROBROMIDE (Sus		Reason:				
	0.0					
Batch:	Started:	Bassani	Stopped:			
_ANZAPINE (Suspected)	20.0 Mill	Reason: ligram Dail	v			
Batch:	Started:	ngram Dan	Stopped:			
aboratory Investigations:						
	inge Date Tested	Result		Details		
.1.11(1) 1 . 1 . (1) (1)						
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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 162655 Seq: 1 Gender: M
Reported: 15/03/2001 Weight: 70.00

Hospitalisation: Admitted to hospital Age: 71

Onset Date: 10/03/2001 DOB: 20/03/1929
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening		Reaction was life threatening. patient was hospitalised. treated wirh bromocriptine/dantrolene.

Medicine Details:

EXELON (Suspected) Reason: Presenile dementia 0.0 Batch: Started: S TERM Stopped: 11/03/2001 **ZYPREXA (Suspected)** Reason: Otr spec symp psychopathol nec 2.5 Milligram Daily Batch: Started: 09/03/2001 Stopped: 10/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking prednisolone. onset of rigidity and hyperthermia (t=40 degress c) within hours of single dose of zyprexa.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 162854 Seq: 1 Gender: M

Reported: 16/03/2001 Weight: 65.00 Hospitalisation: Age: 25

Onset Date: 07/03/2001 DOB: 09/09/1975

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria			Required a visit to doctor. date of recovery: 13/3/2001.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Oral application 10.0 Milligram Daily Oral

Batch: Started: 21/02/2001 **Stopped:** 08/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No previous urticaria, no other medications.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 162924 Seq: 1 Gender: F
Reported: 26/03/2001 Weight:

Hospitalisation: Age: 40Y
Onset Date: 01/05/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory failure			

Medicine Details:

Medicine Details.			
LITHIUM CARBONATE (Other drug)		Reason:	
Oral application	1.0 Gram	Daily Oral	
Batch:	Started:	Stopped: 28/01/2001	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1999	Stopped: 16/01/2001	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patients medical history: a heavy smoker, morbid obesity, hypertension, st ress and urge urinary incontinence, hypothyroidism, complex partial seizures, benign intracranial hypertension and bronchial asthma. 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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repo	rt D	etai	ls:
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Case Number: 163242 Seq: 1 Gender: M

Reported: 03/04/2001 Weight: 80.00 Hospitalisation: Age: 69

Onset Date: 15/03/2001 **DOB**: 24/07/1931

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Therapy ceased.

Medicine Details:

OLANZAPINE (Suspected) Reason:

2.5 Milligram Daily

Batch: Started: 06/03/2001 **Stopped:** 15/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 163373
 Seq: 1
 Gender: M

 Reported:
 02/04/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 20Y
Onset Date: 13/03/2001
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.	faction betails.								
Preferred Term	Severity	Report Description	Treatment						
Aplastic anaemia			Patient was hospitalised. zyprexa discontinued. patient is being investigated by an oncologist.						

Medicine Details:

 ZYPREXA (Suspected)
 Reason:
 Unspecified schizophrenia

 Oral application
 0.0
 Oral

 Batch:
 Started: 01/10/2000
 Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

The dose start date for zyprexa is not necessarily accurate but indicates zyprexa was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repo	rt D	etai	ls:
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 Case Number:
 163428
 Seq: 1
 Gender:
 F

 Reported:
 05/04/2001
 Weight:
 92.00

Hospitalisation: Age: 32Y
Onset Date: 22/03/2001
DOB:

Outcome: Recovered with sequelae Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Gravitational oedema			Moduretic 1df mane, zyprexa ceased, seroquel commenced.
Purpura		Purpuric rash on medial aspect of I foot & ankles.	

Medicine Details:

NAPROGESIC (Other drug)		Reason:	
	0.0	As necessary	
Batch:	Started:	Stopped:	
PANADEINE (Other drug)		Reason:	
	0.0	As necessary	
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	Stopped:	
LUVOX (Other drug)		Reason:	
	400.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:				
Case Number: 163428 Reported: 05/04/2001 Hospitalisation: Onset Date: 22/03/2001	Seq: 1		Gender: Weight: Age: DOB:	92.00 32Y
Outcome: Recovered with s	sequelae		Causality:	Causality possible
Reaction Details:				
Medicine Details:				
ZYPREXA (Suspected)	10.0 Milligram	Reason: Daily		
Batch:	Started:	Daily	Stopped:	
Laboratory Investigations:				

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Date Range: 1 Jan 2000 To 31 Dec 2002 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: 163468 Seq: 1 Gender: F

Reported: 29/03/2001 Weight: 63.00
Hospitalisation: Age: 54Y
Onset Date: DOB:

Outcome: Death Causality: Causality possible

Reaction Details:

,	Cachon Details.			
	Preferred Term	Severity	Report Description	Treatment
	Dyspnoea		Breathless.	
	Sudden death			

Medicine Details:

EFEXOR (Suspected) Reason: Depression

300.0 Milligram Daily

Batch: Started: 28/07/1999 Stopped: 15/11/2000

ZYPREXA (Suspected) Reason: Depression

15.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Serum drug level				Blood venlafaxime level = 3.8mg/l (ref <0.5 mg/l)

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:163811Seq: 1Gender: MReported:19/04/2001Weight: 73.00Hospitalisation:Admitted to hospitalAge: 20Y

Onset Date: 13/03/2001 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aplastic anaemia	Severe	Severe aplatic anaemia.	
Pancytopenia			Olanzapine ceased. patient was hospitalised.

Medicine Details:

 OLANZAPINE (Suspected)
 Reason:
 Unspecified schizophrenia

 Tablet
 7.5 Milligram
 Daily
 Oral

 Batch:
 Started: 01/10/2000
 Stopped: 13/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin		24/10/2000	167	
	Haemoglobin		13/03/2001	43	
	Neutrophils		24/10/2000	4.44	
	Neutrophils		13/03/2001	0.36	
	Platelets		24/10/2000	190	
	Platelets		13/03/2001	14	
	White blood cells		24/10/2000	6.9	

Additional Information:

The dose start date is not necessarily accurate but indicates the drug was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:163811Seq: 1Gender: MReported:19/04/2001Weight: 73.00Hospitalisation:Admitted to hospitalAge: 20Y

Onset Date: 13/03/2001 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 7.5 Milligram Daily Oral

Batch: Started: 01/10/2000 Stopped: 13/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells		13/03/2001	25	

Additional Information:

The dose start date is not necessarily accurate but indicates the drug was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 164046 Seq: 1 Gender: M
Reported: 17/04/2001 Weight:

Hospitalisation: Admitted to hospital **Age**: 71

Onset Date: 12/03/2001 DOB: 20/03/1929

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Gait disturbance Hypertonia Neuroleptic malignant syndrome			Patient hospitalised. treated with bromocriptine and dantrolene after the insertion of a nasogastric tube.
Pyrexia			

Medicine Details:

ARICEPT (Other drug)		Reason:		
	10.0 Milligram	Daily		
Batch:	Started: 02/09/1997		Stopped:	
EXELON (Suspected)		Reason:		
Capsule	1.5 Milligram	Daily		Oral
Batch:	Started: 01/03/2001		Stopped:	12/03/2001
ZYPREXA (Suspected)		Reason:	Otr spec symp	psychopathol nec
	5.0 Milligram	Daily		
Batch:	Started: 10/03/2001		Stopped:	10/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatinine		11/03/2001	654	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:164109Seq: 1Gender: UReported:30/04/2001Weight:Hospitalisation:Admitted to hospitalAge:

Onset Date: 18/04/2001 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

٠,	todotion Botanoi			
	Preferred Term	Severity	Report Description	Treatment
	Rhabdomyolysis			Patient was hospitalised, fluids, monitoring. date of recovery: 24/4/2001.

Medicine Details:

SODIUM VALPROATE (Suspected)		Reason: Unspecifid affective psychosis
	1.0 Gram	Daily
Batch:	Started: 01/09/2000	Stopped: 18/04/2001
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia
	10.0 Milligram	Daily
Batch:	Started: 01/09/2000	Stopped: 18/04/2001
SERTRALINE HYDROCHLORIDE (Susp	ected)	Reason: Unspecified schizophrenia
	50.0 Milligram	Daily
Batch:	Started: 01/09/2000	Stopped: 18/04/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start dates for sodium valproate, olanzapine and sertraline are not necessarily accurate but indicates these drugs were started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 164155 Seq: 1 Gender: M
Reported: 02/05/2001 Weight: 90.00
Hospitalisation: Age: 80

Onset Date: 05/04/2001 **DOB**: 21/03/1921

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Hepatic function abnormal			Ceased venlafaxine and olanzapine.

Medicine Details:

ASPIRIN (Other drug)		Reason: Otr&nos disord of heart rhythm
	150.0 Milligram	Daily
Batch:	Started: 01/01/2001	Stopped:
DIGOXIN (Other drug)		Reason: Otr&nos disord of heart rhythm
	125.0 Microgram	Daily
Batch:	Started: 01/01/2001	Stopped:
VENLAFAXINE HYDROCHLORIDE (Suspected)	Reason: Depression
	75.0 Milligram	Daily
Batch:	Started: 30/03/2001	Stopped : 06/04/2001
OLANZAPINE (Suspected)		Reason: Depression
	5.0 Milligram	Daily
Batch:	Started: 30/03/2001	Stopped: 06/04/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		05/04/2001	69	
	AST = SGOT		05/04/2001	72	
	Bilirubin		05/04/2001	38	
	GGT = SGGT =		05/04/2001	263	
	SAP = ALP		05/04/2001	904	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 164175
 Seq: 1
 Gender:
 F

 Reported:
 03/05/2001
 Weight:

Hospitalisation: Age: 52Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Flatulence		Very distended stomach	
Weight increased		Weight gain 3/4 stone.	

Medicine Details:

COGENTIN (Other drug)		Re	ason:		
	3.0	Milligram	Daily		
Batch:	Started:	L TERM	1	Stopped:	
VALIUM (Other drug)		Re	ason:		
	5.0	Milligram	Daily		
Batch:	Started:	L TERM	1	Stopped:	
ZOLOFT (Other drug)		Re	ason:		
ZOLOFT (Other drug)	50.0	Rea Milligram	ason: Daily		
ZOLOFT (Other drug) Batch:	50.0 Started:		Daily	Stopped:	
, ,		Milligram L TERM	Daily	Stopped:	
Batch:	Started:	Milligram L TERM	Daily I	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but indicates the drug was started sometime in the month.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	164175	Seq: 1			Gender:	F
Reported:	03/05/2001				Weight:	
Hospitalisation:					Age:	52Y
Onset Date:					DOB:	
Outcome:	Unknown				Causality:	Causality possible
Reaction Detai	ls:					
Medicine Deta	ails:					
CALTRATE (Other	drug)			Reason:		
		120.0	Milligram	Daily		
Batch:		Started:			Stopped:	
ZYPREXA (Suspec	cted)			Reason:	Unspecified schizophrenia	
		10.0	Milligram	Daily		
Batch:		Started: 01	/08/2000		Stopped:	
1 - 1 4 1	4! 4!					
Laboratory in	vestigations:					
Additional Inf	formation:					
		accurate but ind	licates the dr	ug was sta	rted sometime in the mo	onth.
	,			-		

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 164176 Seq: 1 Gender: F
Reported: 03/05/2001 Weight:
Hospitalisation: Age: 56Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Thirst		For soft drinks	
Increased appetite		For sweet things	
Flatulence		Stomach very distended	
Weight increased		Weight gain from 48kg to 118kg in 2 and 1/2 years	

Medicine Details:

RISPERDAL (Other drug)		Reason:		
	0.0			
Batch:	Started:		Stopped:	
CALCIUM NOS (Other drug)		Reason:		
	1.0 Dos	se Unspecified 1 tim	e	
Batch:	Started:		Stopped:	
BETAMIN (Other drug)		Reason:		
	1.0 Dos	se Unspecified Daily	•	
Batch:	Started:	L TERM	Stopped:	
24,0	Starteu.	LIERIVI	эторреи.	
PREMIA 5 (Other drug)	Started.	Reason:	экорреи.	
			· ·	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but indicates the drug was started sometime in the month patient is an alcoholic, abstinence for years now.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	1641/6	Seq: 1		Gende	
_	03/05/2001			Weight	
ospitalisation:					: 56Y
Onset Date:				DOE	
Outcome:	Unknown			Causality	: Causality possible
eaction Detail	ils:				
Medicine Det	aile				
ZYPREXA (Suspe	alis. cted)		Reason:	Unspecified schizophrer	nia
	, , , , , , , , , , , , , , , , , , ,	15.0 Milligram	Daily	Chiopochiod Comizophilo	
Batch:		Started: 01/04/2000	Daily	Stopped:	
Batcii.		Started: 01/04/2000		эторреи.	
aboratory Ir	vestigations:				
Additional In	formation:				
he dose start dat	e is not necessarily	accurate but indicates the	drug was sta	rted sometime in the r	nonth patient is an alcoholic
he dose start dat	e is not necessarily	accurate but indicates the	drug was sta	rted sometime in the r	nonth patient is an alcoholic
he dose start dat	e is not necessarily	accurate but indicates the	drug was sta	rted sometime in the r	nonth patient is an alcoholic
Additional In The dose start dat abstinence for yea	e is not necessarily	accurate but indicates the	drug was sta	rted sometime in the r	nonth patient is an alcoholic

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number		_						_
			q : 1				Gender	
_	: 03/05/2001	1					Weight:	
ospitalisation							_	: 57Y
Onset Date							DOB	
	Unknown						Causality	: Causality possible
eaction Deta		1 6	Davida i		Dona		a a minutia n	Tractmant
	red Term	3	Severity	04			scription	Treatment
Tatulence Veight increase	vd.				ach distend nt gain 3 st			
Medicine De		rug)			Rea	son:		
		rug)	500.0	Milligra		son: Daily		
Medicine De LITHIUM CARBO Batch:			500.0 Started:	Milligra			Stopped:	
LITHIUM CARBO	NATE (Other d			Milligra	am L TERM		Stopped:	
LITHIUM CARBO Batch:	NATE (Other d		Started:		am L TERM	Daily	Stopped:	
Batch: CELERY (Other o	NATE (Other d		Started:		am L TERM Re a	Daily	Stopped:	
Batch:	NATE (Other d		Started: 2.0 Started:	Dose U	L TERM Rea Jnspecified L TERM	Daily son: Daily son:		
Batch: CELERY (Other of Batch: CIPRAMIL (Other	NATE (Other d		2.0 Started: 30.0		L TERM Rea Jnspecified L TERM	Daily son: Daily	Stopped:	
Batch: CELERY (Other of Batch: CIPRAMIL (Other of Batch:	NATE (Other d		Started: 2.0 Started:	Dose U	L TERM Rea Jnspecified L TERM Rea	Daily son: Daily son: Daily	Stopped:	
Batch: CELERY (Other of Batch: CIPRAMIL (Other	NATE (Other d		2.0 Started: 30.0 Started:	Dose U	L TERM Rea Jnspecified L TERM Rea am	Daily son: Daily son: Daily	Stopped:	а
Batch: CELERY (Other of Batch: CIPRAMIL (Other Batch: Batch:	NATE (Other d		2.0 Started: 30.0 Started: 20.0	Dose U	L TERM Rea Jnspecified L TERM Rea am	Daily son: Daily son: Daily	Stopped: Stopped: Unspecified schizophrenia	а
Batch: CELERY (Other of Batch: CIPRAMIL (Other Batch: ZYPREXA (Suspendent)	NATE (Other d		2.0 Started: 30.0 Started:	Dose U	L TERM Rea Jnspecified L TERM Rea am	Daily son: Daily son: Daily	Stopped:	a
Batch: CELERY (Other of Batch: CIPRAMIL (Other Batch: Batch:	NATE (Other d		2.0 Started: 30.0 Started: 20.0	Dose U Milligra Milligra //09/1999	L TERM Rea Jnspecified L TERM Rea am	Daily son: Daily son: Daily	Stopped: Stopped: Unspecified schizophrenia	

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE, ZYPREXA, Zyprexa IM, Zyprexa Zydis

Report Details:

Case Number: 164357 Gender: F Seq: 1

Reported: 09/05/2001 Weight: 50.00 Hospitalisation: Age: 80

Onset Date: 14/04/2001 **DOB**: 13/06/1920

Outcome: Recovered Causality: Causality probable

Reaction Details:

touction bottom			
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Elevated Ifts with no associated clinical symptoms	Zyprexa ceased.

Medicine Details:

Batch:

PHENERGAN (Other drug) Reason: Premedication

> 20.0 Milligram 1 time

Batch: Started: 21/03/2001 Stopped:

RANITIDINE (Other drug) Reason: Premedication

> 150.0 Milligram 1 time

Started: 21/03/2001 Stopped: Batch:

Started:

NEFAZODONE HYDROCHLORIDE (Other drug) Reason: Depression

> 3.0 Kilogram Daily

> > L TERM

Stopped: COVERSYL (Other drug) Reason:

Essential benign hypertension

6.0 Milligram Daily

Batch: Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		22/02/2001	8	
	ALT = SGPT		14/04/2001	59	
	ALT = SGPT		18/04/2001	720	
	ALT = SGPT		02/05/2001	45	
	ALT = SGPT		19/04/2001	546	
	AST = SGOT		22/02/2001	20	
	AST = SGOT		18/04/2001	453	

Additional Information:

Patient was taking 2.5mg zyprexa from 22/3 - 27/3.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 164357 Seq: 1 Gender: F

Reported: 09/05/2001 Weight: 50.00 Hospitalisation: Age: 80

Onset Date: 14/04/2001 **DOB**: 13/06/1920

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

UREX (Other drug)			Reason:	Congestive heart failure	
	80.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	
LOSEC (Other drug)			Reason:	Peptic ulcer nos w/o ment perf	
	40.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	
ZYPREXA (Suspected)			Reason:	Paranoia	
	5.0	Milligram	Daily		
Batch:	Started: 27	/03/2001		Stopped: 18/04/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT		14/04/2001	90	
	AST = SGOT		19/04/2001	249	
	AST = SGOT		02/05/2001	19	
	Bilirubin		22/02/2001	6	
	Bilirubin		14/04/2001	-	
	Bilirubin		18/04/2001	7	
	Bilirubin		19/04/2001	6	

Additional Information:

Patient was taking 2.5mg zyprexa from 22/3 - 27/3.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 164357 Seq: 1 Gender: F

Reported: 09/05/2001 Weight: 50.00 Hospitalisation: Age: 80

Onset Date: 14/04/2001 **DOB**: 13/06/1920

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

PHENERGAN (Other drug) Reason: Premedication

20.0 Milligram 1 time

Batch: Started: 21/03/2001 Stopped:

RANITIDINE (Other drug) Reason: Premedication

150.0 Milligram 1 time

Batch: Started: 21/03/2001 Stopped:

NEFAZODONE HYDROCHLORIDE (Other drug) Reason: Depression

3.0 Kilogram Daily

Batch: Started: L TERM Stopped:

COVERSYL (Other drug) Reason: Essential benign hypertension

6.0 Milligram Daily

Batch: Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin		02/05/2001	5	
	GGT = SGGT =		22/02/2001	46	
	GGT = SGGT =		14/04/2001	165	
	GGT = SGGT =		19/04/2001	381	
	GGT = SGGT =		02/05/2001	176	
	GGT = SGGT =		18/04/2001	412	
	SAP = ALP		22/02/2001	86	

Additional Information:

Patient was taking 2.5mg zyprexa from 22/3 - 27/3.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 164357 Seq: 1 Gender: F

Reported: 09/05/2001 Weight: 50.00 Hospitalisation: Age: 80

Onset Date: 14/04/2001 **DOB**: 13/06/1920

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

UREX (Other drug)			Reason:	Congestive heart failure	
,	80.0	Milligram	Daily	•	
Batch:	Started:		L TERM	Stopped:	
LOSEC (Other drug)			Reason:	Peptic ulcer nos w/o ment perf	
	40.0	Milligram	Daily		
Batch:	Started:	I	LTERM	Stopped:	
ZYPREXA (Suspected)			Reason:	Paranoia	
	5.0	Milligram	Daily		
Batch:	Started: 27/	03/2001		Stopped: 18/04/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		14/04/2001	158	
	SAP = ALP		18/04/2001	297	
	SAP = ALP		19/04/2001	282	
	SAP = ALP		02/05/2001	153	

Additional Information:

Patient was taking 2.5mg zyprexa from 22/3 - 27/3.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 164436 Seq: 1 Gender: F

Reported: 11/05/2001 Weight: 50.00
Hospitalisation: Admitted to hospital Age: 93

Onset Date: 08/03/2001 **DOB**: 01/08/1907

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state	Ocventy		Patient was hospitalised. stopped olanzapine.

Medicine Details:

RAMIPRIL (Other drug)			Reason:	Essential benign hypertension	ı
	10.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	CONTIN
ATENOLOL (Other drug)			Reason:	Essential benign hypertension	1
	50.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	CONTIN
RANITIDINE (Other drug)			Reason:		
	300.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	CONTIN
OLANZAPINE (Suspected)			Reason:		
	10.0	Milligram	Daily		
Batch:	Started: 07	/03/2001		Stopped: 12/03/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 164438 Seq: 1 Gender: F

Reported: 11/05/2001 Weight: 55.00
Hospitalisation: Admitted to hospital Age: 74

Onset Date: 04/03/2001 **DOB**: 15/01/1927

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Syncope		Found collapsed on floor.	
Coordination abnormal		Loss of balance.	
Confusional state		Rapid deterioration in mental state.	Patient was hospitalised. ceased olanzapine on admission.

Medicine Details:

ASTRIX 100 (Other drug)			Reason:	Chron isch heart dis no hyper	
	100.0	Milligram	Daily		
Batch:	Started:	I	L TERM	Stopped:	CONTIN
ATENOLOL (Other drug)			Reason:	Essential benign hypertension	
	50.0	Milligram	Daily		
Batch:	Started:	I	L TERM	Stopped:	CONTIN
PERINDOPRIL (Other drug)			Reason:	Essential benign hypertension	
	4.0	Milligram	Daily		
Batch:	Started:	I	L TERM	Stopped:	CONTIN
DIGOXIN (Other drug)			Reason:	Otr&nos disord of heart rhythm	1
	125.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

 Case Number:
 164438
 Seq: 1
 Gender:
 F

 Reported:
 11/05/2001
 Weight:
 55.00

Hospitalisation: Admitted to hospital Age: 74

Onset Date: 04/03/2001 **DOB**: 15/01/1927

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ATORVASTATIN (Other drug)			Reason:	Othr&unspec	metabolic dise	ases	
	20.0	Milligram	Daily				
Batch:	Started:	I	L TERM	Stopped:		CONTIN	
FERRO-GRADUMET (Other drug)			Reason:	Anorexia			
	350.0	Milligram	Daily				
Batch:	Started:	I	L TERM	Stopped:		CONTIN	
DOXEPIN HYDROCHLORIDE (Other drug)			Reason:	Specific disord	ders of sleep		
	25.0	Milligram	Daily				
Batch:	Started:	ļ	L TERM	Stopped:		CONTIN	
HALOPERIDOL (Suspected)			Reason:	Hallucinations			
	3.0	Milligram	Daily				
Batch:	Started:		L TERM	Stopped:	02/03/2001		

Laboratory Investigations:

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation: Onset Date: Outcome: Reaction Detai	11/05/2001 Admitted to hospi 04/03/2001 Recovered Is:	Seq: 1				55.00	
Medicine Deta OLANZAPINE (Sus			Reason:	Unspecified ps	vehoeie		
OLANZAPINE (Sus	specieuj	5.0 Milligram	Daily		ychosis		
Batch:		Started: 02/03/2001	Daily	Stopped:	05/03/2001	1	
Laboratory In	vestigations:						
Additional Inf	ormation:						

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 164697
 Seq: 1
 Gender:
 F

 Reported:
 21/05/2001
 Weight:

Hospitalisation: Admitted to hospital **Age**: 48

Onset Date: 30/04/2001 **DOB**: 20/09/1952

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bronchospasm			
Face oedema			
Hypersensitivity			Patient was hospitalised. treated with normal saline iv 2 litres, phenergan 25mg iv, hydrocortisone 100mg iv, valium 5mg oral and commenced on prednisolone 25mg/day orally.
Nausea			
Tongue oedema			
Urticaria			

Medicine Details:

ASPRO (Other drug)		Reason:	Migraine		
Tablet	0.0			Oral	
Batch:	Started: 01/10/1999		Stopped:		CONTIN
ASPIRIN (Other drug)		Reason:	Headache		
Oral application	0.0			Oral	
Batch:	Started: 28/02/2001		Stopped:		CONTIN
PEPCIDINE (Other drug)		Reason:	Heartburn		
Tablet	0.0			Oral	
Batch:	Started: 20/03/2001		Stopped:		CONTIN
MYLANTA (Other drug)		Reason:	Heartburn		
Oral application	0.0			Oral	
Batch:	Started: 14/03/2001		Stopped:	21/03/2001	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Medical history includes major depressive disorder since 1990.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Details	3:
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 Case Number:
 164697
 Seq: 1
 Gender:
 F

 Reported:
 21/05/2001
 Weight:

Hospitalisation: Admitted to hospital **Age**: 48

Onset Date: 30/04/2001 **DOB**: 20/09/1952

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

DYMADON (Other drug)		Reason:	Headache	
Oral application	0.0			Oral
Batch:	Started:		Stopped:	CONTIN
OLANZAPINE (Suspected)		Reason:	Depression	
Tablet	12.0 Milligram	Daily		Oral
Batch:	Started:		Stopped:	
FLUOXETINE HYDROCHLORIDE (S	uspected)	Reason:	Depression	
Tablet	25.0 Milligram	Daily		Oral
Batch:	Started:		Stopped:	

Laboratory Investigations:

Additional Information:

Medical history includes major depressive disorder since 1990.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 164772 Seq: 1 Gender: F

Reported: 21/05/2001 Weight: 81.00 Hospitalisation: Age: 37

Onset Date: 01/05/2001 **DOB**: 21/12/1963

Outcome: Recovered Causality: Causality probable

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Breast enlargement			
Generalised oedema			Date of recovery 15/05/2001. required a visit to doctor.
Pain			

Medicine Details:

IMOVANE (Other drug) Reason: Specific disorders of sleep

15.0 Milligram As necessary

Batch: Started: 01/04/2001 Stopped:

LARGACTIL (Other drug) Reason: Specific disorders of sleep

25.0 Milligram As necessary

Batch: Started: 01/04/2001 Stopped:

EFEXOR (Other drug) Reason: Depression

450.0 Milligram Daily

Batch: Started: 12/09/2000 Stopped:

OLANZAPINE (Suspected) Reason: Hallucinations

20.0 Milligram As necessary

Batch: Started: 14/04/2001 **Stopped:** 07/05/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 164884 Seq: 1 Gender: F

Reported: 28/05/2001 Weight: 30.00 Hospitalisation: Age: 19

Onset Date: 16/02/2001 **DOB**: 11/10/1981

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Olanzapine ceased.

Medicine Details:

OLANZAPINE (Suspected) Reason: Feeding disturbances

Tablet 5.0 Milligram Daily Oral

Batch: Started: 14/02/2001 Stopped: 16/02/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells		09/03/2001	1.4	Lowest wcc 0.6.

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	165098	Seq:	1			Gender:	M	
Reported	: 01/06/200	1				Weight:		
ospitalisation						Age:	30	
Onset Date	:					DOB:	20/12/1970	
Outcome:	Not yet re	covered			C	ausality:	Causality poss	ible
action Deta	ils:							
Prefer	red Term	Sev	verity	Rep	ort Description		Treatmer	nt
omnolence						Req	uired a visit to d	octor.
ledicine De ZYPREXA (Suspe			2.5 Milli		son: Unspecified po	sychosis		
Batch:		Sta	arted:		Stopped:			
aboratory I	nvestigat	ions:						
Date	Туре		Date Tested	Result		Details		
						•		
dditional In	ıformatio	n:						
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Causality: Causality possible

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 165147
 Seq: 1
 Gender: M

 Reported:
 04/06/2001
 Weight: 90.00

Hospitalisation: Age: 49

Onset Date: 29/03/2001 **DOB**: 29/06/1951

Outcome: Not yet recovered

Reaction Details:

touotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			Reduced zyprexa. required a visit to doctor.

Medicine Details:

EFEXOR-XR (Other drug)		Reason: Manic depressive	psycho, depre
	150.0 Milligram	Daily	
Batch:	Started: 01/01/2000	Stopped:	CONTIN
EPILIM (Other drug)		Reason:	
	800.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Manic depressive	psycho, depre
	5.0 Milligram	Daily	
Batch:	Started: 29/03/2001	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The onset date is not necessarily accurate but indicates onset sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 165325 Seq: 1 Gender: F

Reported: 12/06/2001 Weight: 50.00 Hospitalisation: Age: 28

Onset Date: 29/04/2001 **DOB**: 06/03/1973

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Acne		Pimples on face - perioral.	

Medicine Details:

OLANZAPINE (Suspected) Reason: Manic-depression psycho, manic

5.0 Milligram Daily

Batch: **Started**: 27/04/2001 **Stopped**: 01/06/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No other allergies known. never had acne before.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 165645 Seq: 1 Gender: F

Reported: 20/06/2001 Weight:
Hospitalisation: Admitted to hospital Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

ZYPREXA (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Zyprexa was discontinued, the patient was quite unwell and zyprexa was recommenced at 7.5mg/day then increased to 20mg/day and the patient's lfts increased again. patient was also taking sodium valproate.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repor spitalisat	ted: 20/06/2001 ion:			Weight: Age: 63Y			
Onset D	ate:					D	OB:
	me: Not yet reco	vered				Causal	lity: Causality possible
action D	etails: eferred Term	Se	everity	Pen	ort Description		Treatment
lallucination		36	eventy	Пер	on Description		Zyprexa was ceased and
iandomation	•						commenced on modecate.
Dedema pe	ripheral						
	5 4 11						
				Rea	son.		
			0.0	Rea	son:		
	her drug)	s	0.0 started:	Rea	son: Stoppe	ed:	
DIGOXIN (Ot Bato	her drug) :h:	s				ed:	
DIGOXIN (Ot Bato	her drug) :h:	s			Stoppe	ed:	
DIGOXIN (Ot Bato LIPEX (Other Bato	her drug) :h: · drug) :h:		tarted:	Rea	Stoppe son: Stoppe		
DIGOXIN (Ot Batc LIPEX (Other Batc PRAMIN (Other	her drug) ch: r drug) ch:		0.0	Rea	Stoppe son:	ed:	
Bato PRAMIN (Other Table	her drug) ch: r drug) ch: ner drug)	S	0.0 started:	Rea	Stoppe son: Stoppe son:	e d: Oral	
DIGOXIN (Ot Bato LIPEX (Other Bato PRAMIN (Other Table Bato	her drug) ch: r drug) ch: ner drug) et ch:	S	0.0	Rea Rea	Stoppe son: Stoppe son: Stoppe	od: Oral	
Bato LIPEX (Other Bato PRAMIN (Other Table Bato ZYPREXA (S	her drug) ch: r drug) ch: ner drug) ct ch: uspected)	S	0.0 started: 0.0 started: 0.0 started:	Rea Rea Rea	Stoppe son: Stoppe son: Stoppe son: Schizophre	Oral enia	
Bato LIPEX (Other Bato PRAMIN (Other Table ZYPREXA (S	her drug) ch: r drug) ch: ner drug) ct ch: uspected)	S S	0.0 started: 0.0 started: 5.0 Millig	Rea Rea Rea	Stoppe son: Stoppe son: Stoppe Daily	Oral ed: Oral Oral Oral	
Bato PRAMIN (Other Table Bato ZYPREXA (S Table Bato	ther drug) th: r drug) th: ner drug) et th: uspected) et	S S	0.0 started: 0.0 started: 0.0 started:	Rea Rea Rea	Stoppe son: Stoppe son: Stoppe son: Schizophre	Oral ed: Oral Oral Oral	
Bato PRAMIN (Otr Table Bato ZYPREXA (S Table	her drug) ch: r drug) ch: ner drug) ct ch: uspected)	S S	0.0 started: 0.0 started: 5.0 Millig	Rea Rea Rea	Stoppe son: Stoppe son: Stoppe Daily	Oral ed: Oral enia Oral ed:	Details

The dose start date is not necesarily accurate but indicates zyprexa was started sometime in the month.

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: 25/06/2001 espitalisation:	Seq: 1			
spitalisation:			Gender	
			Weight	
			_	: 55Y
Onset Date: 28/08/1999			DOE	
Outcome: Unknown			Causanty	: Causality possible
action Details: Preferred Term	Severity	Report Desc	rintion	Treatment
emor	- 1	Hand tremors		enztropine and multivitam
edicine Details: YPREXA (Suspected)			nspecified schizophren	ia
Batch:	10.0 N Started: 11/03	Milligram Daily	Stopped:	CONTIN
aboratory Investigations: Date Type Ra	: ange Date Teste	d Result	Det	

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 165877
 Seq: 1
 Gender:
 M

 Reported:
 27/06/2001
 Weight:
 109.00

Hospitalisation: Age: 42

Onset Date: 03/05/2001 **DOB:** 26/08/1958

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Weight increased		Significant weight gain, about 20-30kg.	
	Diabetes mellitus			Required a visit to doctor.

Medicine Details:

PRAVASTATIN SODIUM (Other drug)		Reason: Othr&unspec metabolic diseases
	40.0 Milligram	Daily
Batch:	Started:	Stopped: 16/05/2001
GEMFIBROZIL (Other drug)		Reason: Othr&unspec metabolic diseases
	1.2 Gram	Daily
Batch:	Started:	Stopped: 11/04/2001
OMEPRAZOLE (Other drug)		Reason:
	20.0 Milligram	Daily
Batch:	Started:	Stopped: CONTIN
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia
	15.0 Milligram	Daily
Batch:	Started: 01/04/2000	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				3.5.01 glucose fasting 16.5, hbaic 11%.

Additional Information:

The dose start date for olanzapine is not necessarily accurate but indicates the drug was started sometime in the month. sequelae: commencement of oral hypoglycaemics, bsl/diet monitorying. patient history: comorbid hyperlipidaemia, hypertension and pud.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 165956 Seq: 1 Gender: M

Reported: 29/06/2001 Weight:
Hospitalisation: Age: 20

Onset Date: 28/05/2001 **DOB**: 26/07/1980

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis			Date of recovery 10/05/2001.

Medicine Details:

Medicine Details.				
EPILIM (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	1.4 Gra	am Daily	Oral	
Batch:	Started:		Stopped: 01/05/2001	
ZYPREXA (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	10.0 Mil	ligram Daily	Oral	
Batch:	Started:		Stopped: 01/05/2001	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose stop date for the drugs epilim and zyprexa is not necessarily accuate but indicates the drugs were started sometime in the year. patient has a history of iv amphetamine use.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 166032
 Seq: 1
 Gender:
 F

 Reported:
 02/07/2001
 Weight:

Hospitalisation: Age: 53

Onset Date: 19/11/2000 **DOB**: 19/05/1947

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Olanzapine ceased.

Medicine Details:

CELECOXIB (Other drug)		Reason:	Unspecified arthritis	
	300.0 Milligram	Daily		
Batch:	Started:		Stopped:	CONTIN
RANITIDINE (Other drug)		Reason:		
	300.0 Milligram	Daily		
Batch:	Started:		Stopped:	CONTIN
OLANZAPINE (Suspected)		Reason:	Unspecified schizophrenia	l
	7.5 Milligram	Daily		
Batch:	Started: 22/06/2000		Stopped: 01/12/2000)
VENLAFAXINE HYDROCHLORIDE	(Suspected)	Reason:	Depression	
	75.0 Milligram	Daily		
Batch:	Started: 01/05/2000		Stopped: 01/12/2000)

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		10/05/2000	3.64	
	Neutrophils		19/11/2000	0.9	
	Neutrophils		01/12/2000	1.25	
	Neutrophils		18/12/2000	2.76	
	Neutrophils		13/12/2000	1.58	
	Neutrophils		04/12/2000	1.69	
	White blood cells		10/05/2000	5.58	

Additional Information:

The dose start dates for venlafaxine and valproate are not necessarily accurate but indicate the drugs were started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 166032
 Seq: 1
 Gender:
 F

 Reported:
 02/07/2001
 Weight:

Hospitalisation: Age: 53

Onset Date: 19/11/2000 **DOB**: 19/05/1947

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

SODIUM VALPROATE (Suspected) Reason:

1.0 Gram Daily

Batch: Started: 01/05/2000 **Stopped:** 01/12/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells		19/11/2000	3.40	
	White blood cells		01/12/2000	3.21	
	White blood cells		04/12/2000	4.10	
	White blood cells		13/12/2000	3.90	
	White blood cells		18/12/2000	4.98	

Additional Information:

The dose start dates for venlafaxine and valproate are not necessarily accurate but indicate the drugs were started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 166126
 Seq: 1
 Gender: M

 Reported:
 04/07/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 65Y
Onset Date: 28/03/2001
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arthralgia			
Blood creatine phosphokinase incr			
Confusional state			
Constipation			
Dementia			
Hepatic function abnormal			
Pyrexia			Olanzapine ceased and admitted to hospital
Weight decreased			

Medicine Details:

OLANZAPINE (Suspected)Reason:Unspecified schizophreniaTablet15.0 MilligramDailyOralBatch:Started: 05/03/2001Stopped: 28/05/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset for the reaction is not necessarily accurate but indicates onset sometime in the month. the dose stop date for olanzapine is also not necessarily accurate but indicates that olanzapine was ceased sometime in may 2001.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 166264
 Seq: 1
 Gender: F

 Reported:
 06/07/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 43Y
Onset Date: 28/12/2000 DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia			The patient presented to hospital where she later died.
Confusional state			
Convulsion			
Coordination abnormal			
Dizziness			
Hypertension			
Hyponatraemia			
Polydipsia			

Medicine Details:

Medicine Details.				
OLANZAPINE (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	10.0 Mi	illigram Daily	Oral	
Batch:	Started: 30/08/	2000	Stopped: 28/12/2000	
COVERSYL (Suspected)		Reason:	Essential benign hypertension	
	6.0 Mi	illigram Daily	,	
Batch:	Started:	L TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine Serum drug level		08/12/2000		On 8/12/00, olanzapine blood leverls were 0.24 and haloperidol <0.007.
	Sodium		08/12/2000	98	

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dates of administration for olanzapine are also not necessarily accurate but indicate starting and stopping in the dates indicated.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 166393
 Seq: 1
 Gender: M

 Reported:
 13/07/2001
 Weight:

Hospitalisation: Age: 16

Onset Date: 25/05/2001 **DOB**: 27/02/1985

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Dotano						
Preferred Term	Severity	Report Description	Treatment			
Priapism			Olanzapine dose reduced over 1 week ceased 20/6/01. required a visit to doctor.			

Medicine Details:

TEGRETOL (Other drug)		Reason:		
	0.0			
Batch:	Started: 01/01/1995		Stopped:	
RITALIN (Other drug)	Reason			
	0.0			
Batch:	Started: 01/01/1995		Stopped:	
MELLERIL (Other drug)		Reason:		
	0.0			
Batch:	Started: 01/01/1995		Stopped:	
AURORIX (Other drug)		Reason:		
	0.0			
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 22/6/01. the dose start date is not necessarily accurate but indicates olanzapine was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Repor	rt De	tails:
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 Case Number:
 166393
 Seq: 1
 Gender: M

 Reported:
 13/07/2001
 Weight:

Hospitalisation: Age: 16

Onset Date: 25/05/2001 **DOB**: 27/02/1985

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

EPILIM (Other drug) Reason: Other&unspecified epilepsy

1.0 Dose Unspecified Daily

Batch: Started: 01/01/1995 Stopped: CONTIN

OLANZAPINE (Suspected) Reason: Unspecified psychosis

2.5 Milligram Daily

Batch: Started: 01/08/2000 Stopped: 20/06/2001

Laboratory Investigations:

Additional Information:

Patient recovered 22/6/01. the dose start date is not necessarily accurate but indicates olanzapine was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 166489
 Seq: 1
 Gender:
 F

 Reported:
 17/07/2001
 Weight:

Hospitalisation: Age: 50

Onset Date: 18/05/2001 **DOB**: 10/09/1950

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.				
Preferred Term	Severity Report Description		Treatment	
Dystonia		Dystonic reaction		
Hypertonia			Given benztropine. ceased metoclopramide, haloperidol and olanzapine.	

Medicine Details:

CIPROFLOXACIN (Other drug)		Reason:	
	600.0 Milligram	Daily	
Batch:	Started: 15/05/2001	Stopped: 23/05/2001	
TRAMADOL HYDROCHLORIDE (Other of	drug)	Reason: Pain	
	400.0 Milligram	Daily	

Batch: Started: 17/05/2001 Stopped:

SORBILAX (Other drug) Reason:

40.0 Millilitre Daily

Batch: Started: 13/05/2001 Stopped:

COLOXYL WITH SENNA (Other drug) Reason:

2.0 Dose Unspecified Daily

Batch: Started: 13/05/2001 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 166489
 Seq: 1
 Gender:
 F

 Reported:
 17/07/2001
 Weight:

Hospitalisation: Age: 50

Onset Date: 18/05/2001 DOB: 10/09/1950
Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

FLUCLOXACILLIN SODIUM (Other drug)		Reason:	
Injection	4.0 Gram	Daily	Intravenous
Batch:	Started: 15/05/2001	Stopped:	23/05/2001
METOCLOPRAMIDE HYDROCHLORIDE (Se	uspected)	Reason:	
Injection	30.0 Milligram	Daily	Intravenous
Batch:	Started: 15/05/2001	Stopped:	18/05/2001
HALOPERIDOL (Suspected)		Reason: Anxiety neuro	sis
	10.0 Milligram	Daily	
Batch:	Started: 17/05/2001	Stopped:	18/05/2001
OLANZAPINE (Suspected)		Reason: Anxiety neuro	sis
	5.0 Milligram	Daily	
Batch:	Started: 18/05/2001	Stopped:	18/05/2001

Laboratory Investigations:

Additional Information:

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Report Details:

Case Number: 166702

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 23/07/2 lospitalisation: Admitt Onset Date:		Weight: Age: DOB:					
Outcome: Not ye eaction Details:	recovered				Causality: Causality possible		
Preferred Term	n S	everity	Rep	ort Description	Treatment		
Hyponatraemia Polydipsia					Hospitalised		
Medicine Details:							
ZYPREXA (Suspected)				ason:			
Batch:		20.0 Millio Started:	gram	Daily Stopped:			
Laboratory Investi <u>c</u>	aations:						
Date Type	Range	Date Tested	Result		Details		
Additional Informa	ion:						
port Run: 04/06/2007 04:5	6PM Database: p	usime02		ADRS004	Page 255 of 440		



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report De	4 • • •							
-, •	taiis:							
Case Numb	er: 166703	Seq:	1			Ge	nder: M	
Report	ed: 23/07/200	01		Weight:				
lospitalisati	on: Admitted	to hospital					Age:	
Onset Da						ĺ	DOB:	
Outcor	ne: Not yet re	ecovered			Causality: Causality possible			y possible
eaction De	etails:							
Pre	ferred Term	Se	everity	Repo	rt Des	scription	Tre	eatment
Hyponatraen	nia						Admitted to he reduced.	nospital. zyprexa
Medicine I				Reas	on:			
			0.0	Reas	on:			
Medicine I COGENTIN (C Batcl	ther drug)	Si	0.0 tarted:	Reas	on:	Stopped:		
COGENTIN (C	ther drug)		tarted:	Reas		Stopped:		
COGENTIN (C Batcl INDAPAMIDE	other drug) n: HEMIHYDRATE	(Suspected)	tarted: 0.0					
Batcl	other drug) n: HEMIHYDRATE n:	(Suspected)	tarted:	Reas	on:	Stopped:		
Batcl	other drug) n: HEMIHYDRATE	(Suspected)	0.0		on:			
Batcl UNDAPAMIDE Batcl QUINAPRIL H	other drug) 1: HEMIHYDRATE 1: YDROCHLORIDI	(Suspected) St	0.0 tarted:	Reas	on:	Stopped:		
Batcl UNDAPAMIDE Batcl QUINAPRIL H	other drug) 1: HEMIHYDRATE 1: YDROCHLORIDI 1:	(Suspected) St	0.0	Reas Reas	on: on:	Stopped:	phronia	
Batcl INDAPAMIDE Batcl QUINAPRIL H Batcl	other drug) I: HEMIHYDRATE I: YDROCHLORIDI I: I: I: I: I: I: I: I: I:	(Suspected) St	0.0 tarted: 0.0 tarted:	Reas Reas Reas	son:	Stopped: Stopped: Unspecified schizo		
Batcl INDAPAMIDE Batcl QUINAPRIL H Batcl ZYPREXA (Su	other drug) 1: HEMIHYDRATE 1: YDROCHLORIDI 1: spected)	(Suspected) St E (Suspected) St	tarted: 0.0 tarted: 0.0 tarted: 10.0 Millig	Reas Reas Reas	on: on:	Stopped: Stopped: Unspecified schizop	I	·IN
Batcl INDAPAMIDE Batcl QUINAPRIL H Batcl ZYPREXA (Su Table Batcl	other drug) 1: HEMIHYDRATE 1: YDROCHLORIDI 1: Ispected)	(Suspected) St E (Suspected) St	0.0 tarted: 0.0 tarted:	Reas Reas Reas	son:	Stopped: Stopped: Unspecified schizo		TIN
Batcl INDAPAMIDE Batcl QUINAPRIL H Batcl ZYPREXA (Su Table Batcl	other drug) 1: HEMIHYDRATE 1: YDROCHLORIDI 1: spected)	(Suspected) St E (Suspected) St	tarted: 0.0 tarted: 0.0 tarted: 10.0 Millig	Reas Reas Reas	son:	Stopped: Stopped: Unspecified schizop	I	TIN .

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 166705
 Seq: 1
 Gender: F

 Reported:
 23/07/2001
 Weight:

Hospitalisation: Admitted to hospital **Age**: 62

Onset Date: **DOB**: 22/08/1938

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion botano.								
Preferred Term	Severity	Report Description	Treatment					
Apathy		Indifferent face						
Agitation			Patient admitted to hosptial					

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
VALIUM (Other drug)		Reason: Otr spec symp psychopathol nec	
	15.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Anxiety neurosis	
	10.0 Milligram	Daily	
Batch:	Started: 18/12/2000	Stopped: 16/06/2001	
XANAX (Suspected)		Reason: Specific disorders of sleep	
	1.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also developed bizaar repetitive movements.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation: Onset Date: Outcome: Reaction Detai	23/07/2001 Admitted to hospit Unknown Is:	Seq: 1				
Medicine Deta			D	Damasaisa		_
AROPAX (Suspect	ea)	40.0 Milliaram	Reason:	Depression		
Batch:		40.0 Milligram Started: 17/11/2000	Daily	Stopped:	CONTIN	
- Duton:		Cturtou. 1771172000		оторроц.	OCIVIIIV	_
Laboratory In	vestigations:					
Additional Inf Patient also develo	iormation: oped bizaar repetitive	e movements.				

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 166869
 Seq: 1
 Gender: M

 Reported:
 25/07/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 26

Onset Date: 16/07/2001 **DOB**: 12/06/1975

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Details.			
	Preferred Term	Severity	Report Description	Treatment
	Leukopenia			Chlorpromazine discontinued.
	Neutropenia			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

30.0 Milligram Daily

Batch: Started: Stopped:

LARGACTIL (Suspected) Reason: Unspecified psychosis

400.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient recovered on the 24/7/2001.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 166890
 Seq: 1
 Gender:
 F

 Reported:
 30/07/2001
 Weight:

Hospitalisation: Age: 78

Onset Date: 12/06/2001 **DOB**: 09/11/1922

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Betails.			
Preferred Term	Severity	Report Description	Treatment
Bradycardia			
Syncope			Monitor, iv fluid, reduce dosage. date of recovery 12/06/2001.
Ventricular tachycardia			

Medicine Details:

OLANZAPINE (Suspected) Reason: Depression

 Tablet
 5.0 Milligram
 Daily
 Oral

 Batch:
 Started: 06/06/2001
 Stopped: 21/06/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Olanzapine was also taken at 2.5mg/daily 19/06/2001.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 167341
 Seq: 1
 Gender: M

 Reported:
 08/08/2001
 Weight:
 95.00

Hospitalisation: Age: 30Y
Onset Date: 14/04/2001
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Required Specialist Consultation		Nil.

Medicine Details:

TEMAZE (Other drug)		Reason: Specific disorders of sleep
	20.0 Milligram	As necessary
Batch:	Started: 18/01/2001	Stopped:
LARGACTIL (Other drug)		Reason: Otr spec symp psychopathol nec
	25.0 Milligram	As necessary
Batch:	Started: 19/02/2001	Stopped:
AROPAX (Other drug)		Reason: Depression
	60.0 Milligram	Daily
Batch:	Started: 18/01/2001	Stopped:
ZYPREXA (Suspected)		Reason: Unspecified psychosis
	7.5 Milligram	Daily
Batch:	Started: 09/03/2001	Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 168090
 Seq: 1
 Gender: M

 Reported:
 03/09/2001
 Weight:

Hospitalisation: Admitted to hospital **Age**: 42

Onset Date: **DOB**: 14/06/1959

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus			Patient required urgent hospitalisation to stabilise.

Medicine Details:

ZYPREXA (Suspected)			Reason:	Unspecified schizophrenia
	20.0	Milligram	Daily	
Batch:	Started:		L TERM	Stopped:
AVAPRO (Suspected)			Reason:	Essential benign hypertension

150.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No family history of diabetes.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Gender: F Case Number: 168373 Seq: 1

Reported: 12/09/2001 Weight: **Hospitalisation: Age:** 76Y Onset Date: 07/08/2001 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

٠,	todotion Botanoi			
	Preferred Term	Severity	Report Description	Treatment
	Hepatic function abnormal			Admitted to the psychiatric hospital. zyprexa and claratyne discontinued.

Medicine Details:			
ZYPREXA (Suspected)		Reason:	
	0.0		
Batch:	Started: 04/07/2001	Stopped:	10/08/2001
CLARATYNE (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 03/08/2001	Stopped:	10/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		07/08/2001	143	
	GGT = SGGT =		07/08/2001	283	
	SAP = ALP		07/08/2001	198	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 168425
 Seq: 1
 Gender:
 F

 Reported:
 14/09/2001
 Weight:

Hospitalisation: Age: 46Y
Onset Date: 22/08/2001
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Castion Betailer			
Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus			Date of recovery 24/08/01. given metformin, glimepiride, insulin actrapid.

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug) Reason:

50.0 Milligram As necessary

Batch: Started: Stopped:

SALBUTAMOL (Other drug) Reason: Asthma

Inhalation 2.0 Dose Unspecified As necessary Inhalation

Batch: Started: Stopped:

CITALOPRAM HYDROBROMIDE (Other drug) Reason: Depression

40.0 Milligram Daily

Batch: Started: Stopped:

SODIUM VALPROATE (Other drug) Reason: Other&unspecified epilepsy

2.4 Gram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose		22/08/2001	37.3	
	Serum glucose		23/08/2001	25	

Additional Information:

Niddm normally controlled on diet alone.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Details:
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 Case Number:
 168425
 Seq: 1
 Gender:
 F

 Reported:
 14/09/2001
 Weight:

Hospitalisation: Age: 46Y
Onset Date: 22/08/2001
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

CARBAMAZEPINE (Other drug)			Reason:	Other&unspecified epilepsy
	200.0	Milligram	Daily	
Batch:	Started:			Stopped:
ATORVASTATIN (Other drug)			Reason:	Othr&unspec metabolic diseases
	80.0	Milligram	Daily	
Batch:	Started:			Stopped:
QUINAPRIL HYDROCHLORIDE (Other drug	j)		Reason:	Essential benign hypertension
	10.0	Milligram	Daily	
Batch:	Started:			Stopped:
OLANZAPINE (Suspected)			Reason:	
	10.0	Milligram	Daily	
Batch:	Started:			Stopped: 24/08/2001

Laboratory Investigations:

Additional Information:

Niddm normally controlled on diet alone.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 168455 Seq: 1 Gender: M
Reported: 17/09/2001 Weight: 75.00
Hospitalisation: Age: 32

Onset Date: 28/02/2001 **DOB:** 08/02/1969

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Life threatening	Dilated cardiomyopathy with severe I.v.dysfunction	
Cardiac failure	Life threatening	Life threatening.	
Mitral valve incompetence			
Pericardial effusion			
Pulmonary hypertension			

Medicine Details:

OLANZAPINE (Suspected)			Reason:			
	0.0					
Batch:	Started: 01	/08/2000		Stopped:	05/04/2001	
FLUOXETINE HYDROCHLORIDE (Suspecte	ed)		Reason:			
	20.0	Milligram	Daily			
Batch:	Started:			Stopped:		CONTIN
BENZTROPINE MESYLATE (Suspected)			Reason:			
	2.0	Milligram	Daily			
Batch:	Started:			Stopped:		CONTIN
LITHIUM CARBONATE (Suspected)			Reason:			
	900.0	Milligram	Daily			
Batch:	Started:			Stopped:		CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Coronary				Normal coronary arteries on angiography. echocardiogram showed marked dilatation of all chambers with severely impaired systolic function.

Additional Information:

Mild improvement on aggressive treatment for ccf but still has severe left ventricular dysfunction. the dose start date for the drug olanzapine is not necessarily accurate but indicates the drug was started sometime in the month. the date of onset is not necessarily accurate but indicates onset sometime in the month. there is a strong family history of coronary artery disease and cardiomyopathy

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DOB: 08/02/1969

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	port	Det	tail	s:

 Case Number:
 168455
 Seq: 1
 Gender: M

 Reported:
 17/09/2001
 Weight:
 75.00

Hospitalisation: Age: 32

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Onset Date: 28/02/2001

Medicine Details:

OLANZAPINE (Suspected)			Reason:			
	0.0					
Batch:	Batch: Started: 01/08/2000			Stopped: 05/0	4/2001	
FLUOXETINE HYDROCHLORIDE (Suspecte	ed)		Reason:			
	20.0	Milligram	Daily			
Batch:	Started:			Stopped:	CONTIN	
BENZTROPINE MESYLATE (Suspected)			Reason:			
	2.0	Milligram	Daily			
Batch:	Started:			Stopped:	CONTIN	
LITHIUM CARBONATE (Suspected)			Reason:			
	900.0	Milligram	Daily			
Batch:	Started:			Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Echocardiography report 13/2/02: all chambers are markedly dilated. there is moderate to severe impairment of Iv systolic function. the right ventricle is also hypokinetic. pulmonary artery systolic pressure is estimated to be 51mmhg there is a small pericardial effusion. conclusion: 1.dilatation of all heart chambers with moderate to sever impairment of left ventricular systolic

Additional Information:

Mild improvement on aggressive treatment for ccf but still has severe left ventricular dysfunction. the dose start date for the drug olanzapine is not necessarily accurate but indicates the drug was started sometime in the month. the date of onset is not necessarily accurate but indicates onset sometime in the month. there is a strong family history of coronary artery disease and cardiomyopathy

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DOB: 08/02/1969

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 168455
 Seq: 1
 Gender:
 M

 Reported:
 17/09/2001
 Weight:
 75.00

Hospitalisation: Age: 32

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Onset Date: 28/02/2001

Medicine Details:

OLANZAPINE (Suspected)			Reason:			ļ
	0.0					ļ
Batch:	Started: 01/08	/2000		Stopped: 05/04/2	2001	
FLUOXETINE HYDROCHLORIDE (Suspect	ed)		Reason:			
	20.0 M	lilligram	Daily			
Batch:	Started:			Stopped:	CONTIN	
BENZTROPINE MESYLATE (Suspected)			Reason:			
	2.0 M	lilligram	Daily			
Batch:	Started:			Stopped:	CONTIN	
LITHIUM CARBONATE (Suspected)			Reason:			
	900.0 M	lilligram	Daily			
Batch:	Started:			Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Function. 2. moderate mitral regurgitation. 3. moderate pulmonary hypertension 4. tiny pericardial effusion.

Additional Information:

Mild improvement on aggressive treatment for ccf but still has severe left ventricular dysfunction. the dose start date for the drug olanzapine is not necessarily accurate but indicates the drug was started sometime in the month. the date of onset is not necessarily accurate but indicates onset sometime in the month. there is a strong family history of coronary artery disease and cardiomyopathy

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 168534
 Seq: 1
 Gender:
 F

 Reported:
 19/09/2001
 Weight:

Hospitalisation: Admitted to hospital
Onset Date:

Onset Date:

DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder			Patient was hospitalised.

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified schizophreniaTablet2.5 MilligramDailyOral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient history: a fear of "taking too many medications". the patient had previously been treated with olazapine 20mg/day and the dose was slowly titrated down to a maintenance dose of 5mg/day. the patient psychiatric condition was stable at this dose for a long time, but the patient was requesting a further dose reduction to 2.5mg/day.

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Report Details:

Case Number: 168627

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 24/0	9/2001				Weig	ght:		
ospitalisation: Adm	itted to hospital				A	Age : 22Y		
Onset Date:					D	OB:		
Outcome: Unkr	iown				Causa	lity: Causality possible		
action Details:								
Preferred Te	rm S	Severity	Rep	ort Desc	cription	Treatment		
ardiac failure								
erotonin syndrome						Patient hospitalised		
<u>ledicine Details:</u>								
ZYPREXA (Suspected)				ason:				
		10.0 Mil	ligram	Daily				
Batch:		Started:			Stopped:			
OVAN (Suspected)				ason:				
		60.0 Mil	ligram	Daily				
Batch:		Started:			Stopped:			
.aboratory Invest	i gations: Range	Date Tested	Result	T		Details		
Date Type	Kange	Date Tested	Result			Details		
dditional Inform	ation:							
oort Run: 04/06/2007 04	l:56PM Database:	pusime02		ADRS004		Page 270 of 440		



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 168707
 Seq: 1
 Gender: M

 Reported:
 27/09/2001
 Weight:

Hospitalisation: Age: 16

Onset Date: 07/09/2001 **DOB**: 08/12/1984

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
C-reactive protein increased		C-reactive protein increased	
Pyrexia		Spiking fevers.	
Cardiac enzymes increased			
Fatigue			
Influenza like illness			
Malaise			
Myocarditis			Clozaril ceased.

Medicine Details:

OLANZAPINE (Suspected)		Reason:		
	0.0			
Batch:	Started: 16/11/2000	Sto	ppped: 11/09/2001	
ALCOHOL (Suspected)		Reason:		
	0.0			
Batch:	Started:	Sto	ppped:	
CLOZARIL (Suspected)		Reason: Unspe	cified schizophrenia	
Tablet	250.0 Milligram	Daily	Oral	
Batch:	Started: 23/08/2001	Sto	pped: 06/09/2001	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	C-Reactive Protein		07/09/2001	-	
	C-Reactive Protein		08/09/2001	106	
	C-Reactive Protein		18/09/2001	5.1	
	C-Reactive Protein		10/09/2001	88	
	C-Reactive Protein		20/09/2001	5.2	
	Creatine		07/09/2001	684	
	Creatine		08/09/2001	684	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 168707
 Seq: 1
 Gender: M

 Reported:
 27/09/2001
 Weight:

Hospitalisation: Age: 16

Onset Date: 07/09/2001 **DOB**: 08/12/1984

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected) Reason:

0.0

Batch: Started: 16/11/2000 **Stopped:** 11/09/2001

ALCOHOL (Suspected) Reason:

0.0

Batch: Started: Stopped:

CLOZARIL (Suspected) Reason: Unspecified schizophrenia

Tablet 250.0 Milligram Daily Oral

Batch: Started: 23/08/2001 **Stopped:** 06/09/2001

Laboratory Investigations:

etails
ed normal left ventricular size an ling profile, no resting regional tion fraction 73%.
tion fraction 73 %.
jec

Additional Information:

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Weight:

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:		
Case Number: 168707	Seq: 1	Gender: M

Hospitalisation: Age: 16

Onset Date: 07/09/2001 DOB: 08/12/1984

Outcome: Unknown Causality: Causality possible

Reaction Details:

Reported: 27/09/2001

Medicine Details:

OLANZAPINE (Suspected) Reason:

0.0

Batch: Started: 16/11/2000 **Stopped:** 11/09/2001

ALCOHOL (Suspected) Reason:

0.0

Batch: Started: Stopped:

CLOZARIL (Suspected) Reason: Unspecified schizophrenia

 Tablet
 250.0 Milligram
 Daily
 Oral

 Batch:
 Started: 23/08/2001
 Stopped: 06/09/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Troponin		08/09/2001	0.95	
	Troponin		10/09/2001	-	
	Troponin		18/09/2001	-	
	Troponin		20/09/2001	-	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Details:
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 Case Number:
 168800
 Seq: 1
 Gender:
 F

 Reported:
 02/10/2001
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Agitation neonatal			
Somnolence			Required a visit to doctor.

Medicine Details:

OLANZAPINE (Suspected) Reason:

Oral application 2.5 Milligram Daily Breast milk transfer

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Breastfeeding mother with bipolar disorder, recently commenced olanzapine- sliding scale dose from 2.5mg to 10mg daily. has noticed 7 month old male baby becomes sleepy on low dose and agitated on high dose.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 168805
 Seq: 1
 Gender:
 F

 Reported:
 04/10/2001
 Weight:

Hospitalisation: Admitted to hospital **Age**: 60

Onset Date: 19/09/2001 **DOB**: 28/07/1941

Outcome: Recovered Causality: Causality possible

Reaction Details:

cuotion betails:						
Severity	Report Description	Treatment				
	Eosinophil counts decreased.					
		Stopped epilim, efexor, zyprexa, rocephin iv 2gm commenced, changed psychotics to serenace 2.5mg bd then increase to 5mg.				
	Severity	· · · · · · · · · · · · · · · · · · ·				

Medicine Details:

WARFARIN SODIUM (Other drug)			Reason:	
	3.0	Milligram	Daily	
Batch:	Started:			Stopped:
EFEXOR-XR (Suspected)			Reason:	Unspecified psychosis
	75.0	Milligram	Daily	
Batch:	Started:			Stopped: 19/09/2001
EPILIM (Suspected)			Reason:	Other&unspecified epilepsy
	600.0	Milligram	Daily	
Batch:	Started:			Stopped: 19/09/2001
ZYPREXA (Suspected)			Reason:	Unspecified psychosis
	10.0	Milligram	Daily	
Batch:	Started:			Stopped: 19/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 26/9/01.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detail	04/10/2001 Admitted to hospir 19/09/2001 Recovered Is:	Seq: 1				
TARGOCID (Suspe				Reason:	Cellul&absc otr,mult&nos	sites
TARCOOLD (Guspe	otou,		400.0 Milligram	Daily	Condidado ou , manarios	ones
Batch:		Star	ted: 11/09/2001	,	Stopped:	
Laboratory In	vestigations:					
Additional Inf Patient recovered 2						

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Report Details:

Case Number: 168902

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 02/10/2		Weight:				
lospitalisation: Admitte			Age : 65Y			
Onset Date:					DOB:	
Outcome: Recove	red			Cau	sality: Causality possible	
eaction Details:		1				
Preferred Term Hypotension	S	everity	Report	Description	Treatment Patient was hsopitalised.	
71		,				
Medicine Details: ZYPREXA (Suspected)			Reaso	า.		
ZTI REXA (Ouspecteu)		0.0	Rousoi			
Batch:	5	Started:		Stopped:	CONTIN	
aboratory Investig	Range	Date Tested	Result		Details	
	1					
Additional Informat	ion:					
port Run : 04/06/2007 04:56	6PM Database: p	ousime02	ADF	RS004	Page 277 of 440	



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 168947
 Seq: 1
 Gender: M

 Reported:
 05/10/2001
 Weight:

Hospitalisation: Age: 69

Onset Date: 20/04/2001 DOB: 29/09/1931

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

LIPITOR (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
NOTEN (Other drug)		Reason:	
	12.5 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
WARFARIN SODIUM (Other drug)		Reason:	
	4.5 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
ZOLOFT (Suspected)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started: 01/04/2001	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT				Alt - 272.
	AST = SGOT				Ast - 84.
	GGT = SGGT =				Ggt - 210.

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:			
Case Number: 168947 Reported: 05/10/2001 Hospitalisation: Onset Date: 20/04/2001 Outcome: Recovered Reaction Details:	Seq: 1		
Medicine Details: OLANZAPINE (Suspected)	2.5 Milligram	Reason: Unspecified psychosis Daily	
Batch:	Started: 03/04/2001	Stopped:	CONTIN
Laboratory Investigations:			
Additional Information:			

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 169095 Seq: 1 Gender: M

Reported: 10/10/2001 Weight: 95.00 Hospitalisation: Age: 49

Onset Date: 27/08/2001 **DOB**: 13/04/1952

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

OLANZAPINE (Suspected) Reason: Depression

10.0 Milligram Daily

Batch: Started: 21/08/2001 Stopped: 27/08/2001

DIAZEPAM (Suspected) Reason: Depression

30.0 Milligram Daily

Batch: Started: 21/08/2001 Stopped: 27/08/2001

QUILONUM SR (Suspected) Reason: Depression

3.0 Dose Unspecified Daily

Batch: Started: 10/05/2001 Stopped:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason: Depression

75.0 Milligram Daily

Batch: Started: 25/08/2001 **Stopped:** 27/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		27/08/2001	646	
	AST = SGOT		27/08/2001	249	
	Albumin		27/08/2001	35	
	Bilirubin		27/08/2001	12	
	GGT = SGGT =		27/08/2001	277	
	GGT = SGGT =		27/08/2001	277	
	Protein		27/08/2001	73	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 169095 Seq: 1 Gender: M

Reported: 10/10/2001 Weight: 95.00 Hospitalisation: Age: 49

Onset Date: 27/08/2001 **DOB**: 13/04/1952

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected) Reason: Depression

10.0 Milligram Daily

Batch: Started: 21/08/2001 Stopped: 27/08/2001

DIAZEPAM (Suspected) Reason: Depression

30.0 Milligram Daily

Batch: Started: 21/08/2001 Stopped: 27/08/2001

QUILONUM SR (Suspected) Reason: Depression

3.0 Dose Unspecified Daily

Batch: Started: 10/05/2001 Stopped:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason: Depression

75.0 Milligram Daily

Batch: Started: 25/08/2001 **Stopped:** 27/08/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP		27/08/2001	198	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 169384 Seq: 1 Gender: F

Reported: 26/10/2001 Weight: 84.00 Hospitalisation: Age: 44

Onset Date: 23/10/2001 DOB: 12/05/1957

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Details.				
Preferred Term	Severity	Report Description	Treatment	l
Convulsion			Date of recovery 23.10.01. treated with midazolam and pentothal.	

Medicine Details:

OLANZAPINE (Suspected) Reason: Depression

10.0 Milligram Daily

Batch: Started: S TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Prolonged fit on ect.

Report Run: 04/06/2007 04:56PM Database: pusime02 ADRS004 Page 282 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 169494 Seq: 1 Gender: F

Reported: 29/10/2001 Weight: 50.00 Hospitalisation: Age: 51

Onset Date: 12/10/2001 **DOB**: 23/03/1950

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

Medicine Details.				
EPILIM (Suspected)		Reason:		
Oral Liquid	37.5 Millilitre	Daily	Oral	
Batch:	Started: 04/07/2001	s	Stopped:	
ZYPREXA (Suspected)		Reason:		
	5.0 Milligram	Daily		
Batch:	Started: 04/07/2001	S	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		12/10/2001	1.7	

Additional Information:

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Report Details:

Case Number: 169539

Reported: 02/11/2001

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight:

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Onset Date: Outcome: Not yet recovered seation Details: Preferred Term Severity Report Description Treatment Depression Increased appetite Weight increased Medicine Details: LITHIUM CARBONATE (Other drug) Reason: Batch: Started: Stopped: SERTRALINE HYDROCHLORIDE (Other drug) Reason: 200.0 Milligram Daily Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped: DAILY DEtailS	łospitalisati	on:						Age : 28
Preferred Term Severity Report Description Treatment Depression Increased appetite Weight increased Medicine Details: LITHIUM CARBONATE (Other drug) Batch: Started: Stopped: SERTRALINE HYDROCHLORIDE (Other drug) Batch: Started: Stopped: SCANZAPINE (Suspected) Part of Milligram Daily Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis Daily Batch: Started: Stopped: Consider the proper of the proper of the part of the proper of the prope	Onset Da	ate:					I	DOB: 25/05/1973
Preferred Term Severity Report Description Treatment Depression Increased appetite Weight increased Medicine Details: LITHIUM CARBONATE (Other drug) Batch: Started: Started: Stopped: SERTRALINE HYDROCHLORIDE (Other drug) Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped:	Outcor	ne: Not yet re	covered				Caus	ality: Causality possible
Depression ncreased appetite Meight increased Medicine Details: Lithium Carbonate (Other drug) Batch: Started: Stopped: SERTRALINE HYDROCHLORIDE (Other drug) Batch: Started: Stopped: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped:			•					
Medicine Details: LITHIUM CARBONATE (Other drug) Batch: Started: Stopped: SERTRALINE HYDROCHLORIDE (Other drug) Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped:	Pre	eferred Term	S	Severity		Report De	scription	Treatment
Medicine Details: LITHIUM CARBONATE (Other drug) Batch: Started: Stopped: SERTRALINE HYDROCHLORIDE (Other drug) Batch: Started: Stopped: COLANZAPINE (Suspected) Batch: Started: Stopped: OLANZAPINE (Suspected) Batch: Started: Stopped: COLANZAPINE (Suspected) Batch: Started: Stopped:								
Medicine Details: LITHIUM CARBONATE (Other drug) Batch: Started: 200.0 Milligram Batch: Started: Stopped: COLANZAPINE (Suspected) Batch: Started: Stopped: Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Stopped: Stopped: Stopped: Colanzapine (Suspected) Reason: Unspecified psychosis Daily Batch: Started: Stopped:	ncreased ap	petite						Olanzapine ceased, required a
Batch: Started: Stopped: Batch: Started: Stopped: 200.0 Milligram Daily Batch: Started: Stopped: CLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped: Stopped: Stopped: Aboratory Investigations:	Veight incre	ased						
Reason: Daily Batch: Started: Stopped:								
Reason: Daily Stopped: St								
Reason: Daily Batch: Started: Stopped:								
Reason: Daily Stopped: St								
Reason: Daily Batch: Started: Stopped:	ladiaina l	Dotoilo						
Batch: Started: Stopped: SERTRALINE HYDROCHLORIDE (Other drug) Reason: 200.0 Milligram Daily Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped:			drug)			Reason:		
SERTRALINE HYDROCHLORIDE (Other drug) 200.0 Milligram Daily Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped: Aboratory Investigations:		·	. ,	1.8	Gram	Daily		
Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped: aboratory Investigations:	Batcl	h:	;	Started:			Stopped:	
Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: Unspecified psychosis 20.0 Milligram Daily Batch: Started: Stopped: aboratory Investigations:	SERTRALINE	HYDROCHLORIC	DE (Other drug)		Reason:		
OLANZAPINE (Suspected) 20.0 Milligram Daily Batch: Started: Stopped: aboratory Investigations:				200.0 N	1illigram	Daily		
20.0 Milligram Daily Batch: Started: Stopped: aboratory Investigations:	Batcl	h:	!	Started:			Stopped:	
Batch: Started: Stopped: aboratory Investigations:	OLANZAPINE	(Suspected)				Reason:	Unspecified psycho	osis
aboratory Investigations:				20.0 N	1illigram	Daily		
	Batcl	h:	,	Started:			Stopped:	
	.aborator	y Investigat	ions:					
				Date Tested	d Res	ult		Details
	dditional	l Informatio	n·					
additional Information:	Muulliolla	i iiiioiiiialioi	11.					
Additional Information:								
Additional Information:								
Additional Information:								
dditional Information:								
dditional Information:	ort Run : 04/0	06/2007 04:56PM	Ո Database: լ	ousime02		ADRS00	04	Page 284 of 440
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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

eport Details:			_	
ase Number: 170006	•	Gender: F		
Reported: 12/11/20	001		Weig	
ospitalisation:				\ge : 45
Onset Date: 08/07/20				OB : 03/10/1955
Outcome: Not yet	recovered		Causa	lity: Causality certain
action Details:				
Preferred Term	Severity	•	escription	Treatment
eight increased		22kg in 7 weeks.		
rug withdrawal syndrom atigue	ie			
ledicine Details: AURORIX (Other drug)		Reason:	Depression	
URORIX (Other drug)	0.0 Started:	Reason:		
AURORIX (Other drug) Batch:	0.0 Started:		Depression Stopped:	
AURORIX (Other drug) Batch:	Started:	Reason:		
URORIX (Other drug) Batch:			Stopped:	
AURORIX (Other drug) Batch: UVOX (Other drug) Batch:	Started: 0.0 Started:			
AURORIX (Other drug) Batch: LUVOX (Other drug) Batch:	Started: 0.0 Started:	Reason:	Stopped:	
AURORIX (Other drug) Batch: UVOX (Other drug) Batch:	Started: 0.0 Started: ATE (Other drug)	Reason:	Stopped:	
Batch: Batch: LUVOX (Other drug) Batch: DEXAMPHETAMINE SULPHA	0.0 Started: ATE (Other drug) 0.0	Reason:	Stopped:	
Batch: LUVOX (Other drug) Batch: Batch: Batch:	0.0 Started: ATE (Other drug) 0.0	Reason: Reason:	Stopped:	
AURORIX (Other drug) Batch: LUVOX (Other drug) Batch: DEXAMPHETAMINE SULPHA	Started: 0.0 Started: ATE (Other drug) 0.0 Started:	Reason: Reason:	Stopped:	
Batch: Batch: Batch: Batch: DEXAMPHETAMINE SULPHA Batch: BUSPAR (Other drug) Batch:	Started: 0.0 Started: ATE (Other drug) 0.0 Started: 0.0 Started:	Reason: Reason:	Stopped: Stopped:	
Batch: Batch: Batch: Batch: Batch: Batch: Batch: Batch: Batch:	Started: 0.0 Started: ATE (Other drug) 0.0 Started: 0.0 Started:	Reason: Reason:	Stopped: Stopped: Stopped:	Details

Additional Information:

The second time this has happened upon taking zyprexa. removing zyprexa - chemistry falls apart.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Detail	s:				
lospitalisation: Onset Date:	12/11/2001	Seq: 1			
eaction Detai				-	·
Medicine Det					
EPILIM (Other drug	g)	0.0	Reason:		
Batch:		0.0 Started:		Stopped:	
MINOMYCIN (Other	r drug)		Reason:		
		0.0			
Batch: ZYPREXA (Suspec	cted)	Started:	Reason:	Stopped:	
		0.0			
Batch:		Started:		Stopped:	
Laboratory In	vestigations:				

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Report Details:

Case Number: 170147

Reported: 22/11/2001

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Weight:

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Olisel Da	on: Admitted to ate: 07/11/200					Age: 72Y DOB:
	ne: Not yet red				Cau	sality: Causality possible
action De	=	overed			Odd	santy: Gausanty possible
	ferred Term	S	everity	Repo	ort Description	Treatment
Coma				·	·	Patient was hospitalised overnight.
liosis						
ledicine [Details: AZIDE (Other drug	<u> </u>		Rea	son:	
3ENDKOPLU/	AZIDE (Other drug	1)	0.0	Nea	son.	
Batch	ո։	;	Started:		Stopped:	CONTIN
TOLBUTAMID	E (Other drug)			Rea	son:	
			0.0			
Batch			Started:		Stopped:	CONTIN
DILANTIN (Ot	her drug)		0.0	Rea	son:	
Batch	n:	;	Started:		Stopped:	CONTIN
	FORTE (Other dru		, , , , , , , , , , , , , , , , , , ,	Rea		00111111
			0.0			
Batch	ո։		Started:		Stopped:	CONTIN
	v Investigati	ons:				
ahorator		<u>0113.</u>				
aboratory Date	Туре	Range	Date Tested	Result		Details



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:			
Case Number: 170147 Reported: 22/11/2001 Hospitalisation: Admitted to hospi Onset Date: 07/11/2001 Outcome: Not yet recovered Reaction Details:		Gender: Weight: Age: DOB: Causality:	72Y
Medicine Details:			
ZYPREXA (Suspected)	0.0	Reason:	
Batch:	Started: 07/11/2001	Stopped:	CONTIN
Laboratory Investigations:			
Additional Information:			

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report De	etail	s:								
Case Numl	ber:	170200	Se	eq: 1					Gende	er: M
Repor	ted:	23/11/200)1						Weigh	t:
lospitalisati	ion:								Ag	e: 83Y
Onset D	ate:	09/05/200)1						DO	B:
Outco	me:	Not yet re	ecovered					С	ausalit	y: Causality possible
eaction D										
Pre	eferre	ed Term		Severity		Repo	ort De	scription		Treatment
Agitation										
Paranoia									1	Sinemet dose decreased.
Psychotic dis	sorde	er								
Medicine	Dot	aile:								
TEMAZEPAN						Rea	son:			
Table				10.0	Mill	igram	Daily		Oral	
Batc	:h:			Started:				Stopped:		CONTIN
SINEMET (Su	ıspec	ted)				Rea	son:	Paralysis agita	ins	
Table	et			1.0	Dos	se Unspecified	Daily		Oral	
Batc	:h:			Started:				Stopped:	10/05/20	001
PERGOLIDE	(Susp	ected)				Rea	son:	Paralysis agita	ins	
Table	et			3.0	Dos	se Unspecified	Daily		Oral	
Batc	:h:			Started: 04	/05/2	001		Stopped:	07/05/20	001
OLANZAPINE	E (Sus	spected)				Rea	son:			
Table	et			2.5	Mill	igram	Daily		Oral	
Batc	:h:			Started:				Stopped:	10/05/20	001
_aborator	v In	vestigat	ions:							
Date	<i>y</i>	Туре	Range	Date Tes	ted	Result			De	etails
A alalist - ·	4	: 								
Additiona	ı ınt	ormatio	n:							

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 170291 Seq: 1 Gender: F

Reported: 26/11/2001 Weight:
Hospitalisation: Age: 16

Onset Date: 11/09/2001 **DOB**: 16/12/1984

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Ceased olanzapine.

Medicine Details:

OLANZAPINE (Suspected) Reason:

5.0 Milligram Daily

Batch: Started: 01/05/2000 **Stopped:** 11/09/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but indicates olanzapine was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:	Rei	port	Deta	ils:
-----------------	-----	------	------	------

 Case Number:
 170378
 Seq: 1
 Gender:
 F

 Reported:
 27/11/2001
 Weight:

Hospitalisation:
Onset Date: 02/11/2001
Age: 40Y
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Convulsion			
Syncope			

Medicine Details:

DEPO-PROVERA (Other drug)		Reason:
	0.0	
Batch:	Started:	Stopped:
ALCOHOL (Suspected)		Reason:
	0.0	
Batch:	Started:	Stopped:
LUVOX (Suspected)		Reason: Depression
	100.0 Milligram	Daily
Batch:	Started: 01/10/2001	Stopped: 12/11/2001
ZYPREXA (Suspected)		Reason:
	10.0 Milligram	Daily
Batch:	Started: 01/10/2001	Stopped: 02/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start dates for luvox and zyprexa are not necessarily accurate but indicates the drugs were started sometime in the month. no patient history of seizures.

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Date Range: 1 Jan 2000 To 31 Dec 2002 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: 170472 Seq: 1 Gender: F

Reported: 26/11/2001 Weight:
Hospitalisation: Admitted to hospital Age: 36

Onset Date: 02/01/2001 DOB: 24/08/1964

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			Patient was hospitalised.

Medicine Details:

Medicine Details.				
OLANZAPINE (Suspected)		Reason: Depre	ession	
Capsule	6.0 Milligram	Daily	Oral	
Batch:	Started: 05/12/2000	S	topped:	
FLUOXETINE HYDROCHLORIDE (S	uspected)	Reason: Depre	ession	
Capsule	50.0 Milligram	Daily	Oral	
Batch:	Started: 05/12/2000	S	topped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 04:56PM Database: pusime02 ADRS004 Page 292 of 440



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	170473	Seq:	1			Gend	er: F		
Reported:	26/11/200	1			Weight:				
Hospitalisation:	Admitted t	to hospital			Age : 37				
-	Date: 01/11/2001				DOB: 24/08/1964				
Outcome:	Not vet re	covered			С		ty: Causality possible		
Reaction Deta	-						,		
	ed Term	Se	everity	Report De	escription		Treatment		
Coma					200				
Suicide attempt							Patient admitted to intensive care unit. intubated, monitored, nasogastric tube and charcoal. olanzapine and fluoxetine discontinued.		
Suicide attempt									
Medicine Det									
OLANZAPINE (Su	spected)			Reason:	Depression				
	Capsule 0.0					Oral			
Batch:			tarted:		Stopped:	05/11/2	2001		
FLUOXETINE HYD	ROCHLORID	E (Suspected)		Reason:	Depression				
Capsule			0.0			Oral			
Batch:		S	tarted:		Stopped:	05/11/2	2001		
Laboratory Ir									
Date	Туре	Range	Date Tested	Result		D	etails		
Additional In	formatio	n:							

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 170550
 Seq: 1
 Gender:
 F

 Reported:
 30/11/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 85

Onset Date: 28/11/2001 **DOB**: 17/10/1916

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation			Patient was hospitalised. zyprexa stopped.
Dehydration			
Somnolence			

Medicine Details:

ZYPREXA (Suspected) Reason: Otr spec symp psychopathol nec

 Tablet
 5.0 Milligram
 Daily
 Oral

 Batch:
 Started: 27/04/2001
 Stopped: 27/11/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The onset date is not necessaily accurate but indicates onset was sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 170615
 Seq: 1
 Gender: M

 Reported:
 30/11/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 77
Onset Date: DOB: 06/08/1924

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Dotano			
Preferred Term	Severity	Report Description	Treatment
Diarrhoea		•	Patient was hospitalised. zyorexia was ceased.
Purpura			

Medicine Details:

MADOPAR (Other drug)		Reason:	
Oral application	2.5 Milligram	Daily	Oral
Batch:	Started: 05/09/2001	Stopped:	07/11/2001
ZYPREXA (Suspected)		Reason: Hallucinations	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started: 05/09/2001	Stopped:	07/11/2001
FLORINEF (Suspected)		Reason: Essential beni	gn hypertension
Oral application	200.0 Microgram	Daily	Oral
Batch:	Started: 01/10/2001	Stopped:	CONTIN
CARDIPRIN 100 (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but indicates florinef was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 170850
 Seq: 1
 Gender:
 F

 Reported:
 05/12/2001
 Weight:
 90.00

Hospitalisation: Age: 22

Onset Date: DOB: 17/03/1979

Outcome: Unknown Causality: Causality possible

Reaction Details:

Severity	Report Description	Treatment
		Ceased zyprexia and switched to seroquel. required a visit to doctor.

Medicine Details:

ANAFRANIL (Other drug)		Reason:		
	25.0 Milligram	Daily		
Batch:	Started: 06/01/1998		Stopped:	01/08/2001
AROPAX (Other drug)		Reason:		
	20.0 Milligram	Daily		
Batch:	Started: 08/08/2001		Stopped:	
ZYPREXA (Suspected)		Reason:		
	10.0 Milligram	Daily		
Batch:	Started: 24/03/2001		Stopped:	19/10/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Cpk increased to 313 u/l (<150)

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 170968 Seq: 1 Gender: F

Reported: 10/12/2001 Weight: 111.00 Hospitalisation: Age: 17

Onset Date: 12/07/2001 **DOB**: 20/10/1983

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Cogwheel rigidity, dribbling, slow shuffling gait.	Stelazine ceased. date of recovery 18.7.01.

Medicine Details:

modicino Botano.			
EPILIM (Other drug)		Reason:	
Tablet	800.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
EFEXOR (Other drug)		Reason:	
	150.0 Milligram	Daily	
Batch:	Started:	Stopped:	
INDERAL (Other drug)		Reason: Migraine	
	20.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily Oral	
Batch:	Started: 01/05/2001	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start dates for zyprexia and stelazine are not necessarily accurate but indicates the drug was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Detail	S:					
Case Number:	170968	Seq: 1			Gender:	F
	10/12/2001	•			Weight:	
lospitalisation:					Age:	
Onset Date:	12/07/2001				_	20/10/1983
	Not yet recovered	4				Causality possible
eaction Detai		4			Causanty.	Causanty possible
eaction Detai	13.					
Medicine Det	aile					
STELAZINE (Susp				Reason:		
` .	•		20.0 Milligram	Daily		
Batch:		Start	ted: 28/07/2000	,	Stopped:	
Laboratory In	vestigations:					
•	•					
Additional In	formation:					
The dose start date	es lot zvorexia and s	stelazine	are not necessari	ly accurate but	indicates the drug wa	s started sometime in the
The dose start dat month.	es for Zyprexia and s	stelazine	are not necessari	ly accurate but	indicates the drug wa	s started sometime in the
The dose start date month.	es for zyprexia and s	stelazine	are not necessari	ly accurate but	indicates the drug wa	s started sometime in the

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 171134
 Seq: 1
 Gender: M

 Reported:
 17/12/2001
 Weight:

Hospitalisation: Age: 21

Onset Date: 19/11/2001 **DOB**: 14/11/1980

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Betails.	cuotion Details.									
Preferred Term	Severity	Report Description	Treatment							
Blood amylase increased										
Hypertriglyceridaemia										
Pancreatitis										

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 20.0 Milligram Daily Oral

Batch: Started: 01/01/1999 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Triglyceride			Triglycerides were above the normal limits.	

Additional Information:

The dose start date is not accurate but indicates the drug was started sometim e in the year.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	oa	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 171516
 Seq: 1
 Gender: M

 Reported:
 02/01/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 80Y
Onset Date: DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

todotion Botanor								
Preferred Term	Severity	Report Description	Treatment					
Aggression			Patient was hospitalised, olanzapine was ceased.					
Coma								
Neuroleptic malignant syndrome								

Medicine Details:

OLANZAPINE (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: 01/07/2001 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but indicates olanazapine was started sometime in the month. pateint died.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 171673
 Seq: 1
 Gender:
 F

 Reported:
 02/01/2002
 Weight:

Hospitalisation: Age: 27

Onset Date: 06/12/2001 DOB: 22/10/1974
Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment						
	Dizziness									
,	Somnolence			Lowered dosage.						

Medicine Details:

OLANZAPINE (Suspected) Reason: Hallucinations

10.0 Milligram Daily

Batch: Started: 12/07/2001 Stopped: 12/11/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Stopped drug after a few days and restarted on 10mg - again sedated and some dizziness at times.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 171854
 Seq: 1
 Gender:
 F

 Reported:
 15/01/2002
 Weight:
 60.00

Hospitalisation: Age: 74Y
Onset Date: 22/12/2001
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Hypertonia			
Hypotension			
Neuroleptic malignant syndrome			
Pyrexia			
Tremor			

Medicine Details:

 OLANZAPINE (Suspected)
 Reason:

 Tablet
 10.0 Milligram
 Daily
 Oral

 Batch:
 Started:
 L TERM
 Stopped:
 22/12/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Ck increased to 4000.

Additional Information:

Patient history of coad.

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Case Number: 172067

Reported: 17/01/2002

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 60.00

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

ospitalisation: Hospitalisa	tion prolonged		Age : 66			
Onset Date:			D	DOB : 19/05/1935		
Outcome: Recovered			Causa	lity: Causality probable		
action Details:				1		
Preferred Term	Severity	Report	t Description	Treatment		
inary retention				Olanzapine ceased and risperidone commenced. prolonged hospitalisation by 7-10 days.		
edicine Details:						
ARACETAMOL (Other drug)		Reaso	on:			
ν, σ,	0.0					
Batch:	Started:		Stopped:			
_ANZAPINE (Suspected)		Reaso	n:			
	2.5 Mil	ligram Γ	Daily			
Batch:	Started: 10/12/2	2001	Stopped: 03/01	/2002		
aboratory Investigation	ons:					
Date Type	Range Date Tested	Result		Details		
dditional Information	:					
ort Run: 04/06/2007 04:56PM	Database: pusime02	AD	RS004	Page 303 of 440		



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Detail	s:
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Case Number:172159Seq: 1Gender: MReported:24/01/2002Weight: 69.00Hospitalisation:Admitted to hospitalAge: 32

Onset Date: 17/01/2002 DOB: 26/11/1969

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Convulsion			Treated with diazepam 2.5mg prn. patient was hospitalised.
	Drug withdrawal syndrome			

Medicine Details:

CLOZARIL (Other drug)		Reason:	
	0.0		
Batch:	Started: 04/01/2002		Stopped:
PULMICORT TURBUHALER (Other drug)		Reason:	
	1.6 Milligram	Daily	
Batch:	Started:		Stopped:
LOSEC (Other drug)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:		Stopped:
OLANZAPINE (Suspected)		Reason:	
	0.0		
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:		
Case Number: 172190	Seq: 1	Gender: M
Reported: 25/01/2002		Weight:

Hospitalisation: Age: 72Y
Onset Date: 03/09/2001
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			

Medicine Details:

TEMAZEPAM (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	CONTIN
VENLAFAXINE HYDROCHLORIDE (O	ther drug)	Reason:	
	0.0		
Batch:	Started:	Stopped:	
PARACETAMOL (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	CONTIN
ZYPREXA (Suspected)		Reason: Unspecified ps	sychosis
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 01/09/2001	Stopped:	28/09/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start and stop dates for olanzapine are not necessarily accurate but indicate the drug was started and stopped sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 172292 Gender: F Seq: 1

Weight: 60.00 Reported: 29/01/2002 Hospitalisation: **Age:** 30

Onset Date: DOB: 21/11/1971

Causality: Causality possible Outcome: Not yet recovered

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Paraesthesia		Strange sensation runing down I side of back.	

Medicine Details:

AURORIX (Other drug)		Reason:	Depression
	900.0 Milligram	Daily	•
Batch:	Started: 09/09/1999		Stopped:

ZYPREXA (Suspected) Reason: Schizophrenia

> 10.0 Milligram Daily

Batch: Started: 01/10/2001 Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient only noticed this reaction since increasing zyprexia from 5mg to 10mg daily, the dose start date is not necessarily accurate but indicates zyprexia was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Preferred Term Seviabetes mellitus edicine Details: MICROGYNON 50 (Other drug) Batch: Sta	verity 0.0	Report Do	Causali escription	
Pepitalisation: Onset Date: 04/02/2002 Outcome: Unknown action Details: Preferred Term Severabetes mellitus Pedicine Details: MICROGYNON 50 (Other drug) Batch: Sta	0.0		Ag DC Causali escription	ge: 40 OB: 08/04/1961 ity: Causality possible
Outcome: Unknown action Details: Preferred Term Sevabetes mellitus edicine Details: MICROGYNON 50 (Other drug) Batch: Sta	0.0		Causali escription	ty: Causality possible
Preferred Term Seviabetes mellitus Iedicine Details: MICROGYNON 50 (Other drug) Batch: Sta	0.0		escription	
ledicine Details: MICROGYNON 50 (Other drug) Batch: Sta	0.0			Treatment
ledicine Details: MICROGYNON 50 (Other drug) Batch: Sta	0.0			Treatment
Medicine Details: MICROGYNON 50 (Other drug) Batch: Sta		Reason:		
MICROGYNON 50 (Other drug) Batch: Sta		Reason:		
MICROGYNON 50 (Other drug) Batch: Sta		Reason:		
MICROGYNON 50 (Other drug) Batch: Sta		Reason:		
Batch: Sta		Reason.	Contracontion	
			Contraception	
	arted:		Stopped:	
		Reason:		
	2.0 Milligram	As n	ecessary	
Batch: Sta	arted:		Stopped:	
OXAZEPAM (Other drug)		Reason:		
	0.0	As n	ecessary	
	arted:		Stopped:	
VALIUM (Other drug)		Reason:		
	0.0	As n	ecessary	
Batch: Sta	arted:		Stopped:	
aboratory Investigations:				
Date Type Range	Date Tested F	Result	D	etails

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

		Seq: 1	Gender:	
Reported:	06/02/2002		Weight:	
ospitalisation:			Age:	
Onset Date:				08/04/1961
Outcome:			Causality:	Causality possible
action Detai	ils:			
ladiaina Dat	-!!			
ledicine Det			Reason: Depression	
Altor Ax (ouspect	ieu,	20.0 Milligram	2 times	
Batch:		Started:	Stopped:	
		Starteu.	Stopped.	
7YPRFYA (Suena)	rtad)			
ZYPREXA (Suspe	cted)	10.0 Milligram	Reason: Unspecified schizophrenia	
	cted)	10.0 Milligram	Reason: Unspecified schizophrenia 1 time	
ZYPREXA (Susped	cted)	10.0 Milligram Started:	Reason: Unspecified schizophrenia	
	cted)		Reason: Unspecified schizophrenia 1 time	
	cted)		Reason: Unspecified schizophrenia 1 time	
	cted)		Reason: Unspecified schizophrenia 1 time	
	cted)		Reason: Unspecified schizophrenia 1 time	
	cted)		Reason: Unspecified schizophrenia 1 time	
Batch:		Started:	Reason: Unspecified schizophrenia 1 time	
Batch:	eted)	Started:	Reason: Unspecified schizophrenia 1 time	
Batch:		Started:	Reason: Unspecified schizophrenia 1 time	
Batch:		Started:	Reason: Unspecified schizophrenia 1 time	
Batch:		Started:	Reason: Unspecified schizophrenia 1 time	
Batch:		Started:	Reason: Unspecified schizophrenia 1 time	
Batch:		Started:	Reason: Unspecified schizophrenia 1 time	
Batch:		Started:	Reason: Unspecified schizophrenia 1 time	
Batch:		Started:	Reason: Unspecified schizophrenia 1 time	
Batch:	vestigations	Started:	Reason: Unspecified schizophrenia 1 time	
Batch:	vestigations	Started:	Reason: Unspecified schizophrenia 1 time	
Batch:	vestigations	Started:	Reason: Unspecified schizophrenia 1 time	
Batch:	vestigations	Started:	Reason: Unspecified schizophrenia 1 time	
Batch:	vestigations	Started:	Reason: Unspecified schizophrenia 1 time	

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Hospitalisation Onset Da	ed: 06/02/200 on: ite: ne: Unknown	Seq:	1		W	ender: M /eight: Age: DOB: sality: Causality po	ssible
	ferred Term	Se	verity	Repo	ort Description	Treatm	ent
Syncope							
Medicine D	N otails:						
OLANZAPINE				Rea	son:		
			0.0				
Batch			tarted:		Stopped:		
LITHIUM CAR	BONATE (Suspe	cted)		Rea	son:		
Batch	_	04	0.0		Stopped:		
	•	•					
	/ Investigat						
Date	Туре	Range	Date Tested	Result		Details	
Additional	Informatio	n:					

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 172442 Seq: 1 Gender: M

Reported: 06/02/2002 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 99U
Onset Date: 28/12/2001
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

Medicine Details:

Medicine Details.		
MELLERIL (Interaction)		Reason: Unspecified schizophrenia
	0.0	Oral
Batch:	Started:	Stopped:
OLANZAPINE (Interaction)		Reason:
	0.0	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

180454 is a duplicate.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Re	por	t De	tai	s:
----	-----	------	-----	----

Case Number: 172450 Seq: 1 Gender: M

Reported: 05/02/2002 Weight: 78.00 Hospitalisation: Age: 46

Onset Date: 23/01/2002 DOB: 15/06/1955

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Rash erythematous		Red blotches	Olanzapine ceased.
	Oedema peripheral			

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 16/01/2002 **Stopped:** 26/01/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 172641
 Seq: 1
 Gender:
 F

 Reported:
 13/02/2002
 Weight:

Hospitalisation: Age: 44

Onset Date: 22/04/2001 **DOB**: 27/12/1956

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	toaction Botaile.				
	Preferred Term	Severity	Report Description	Treatment	ĺ
	Delirium				l
	Leukopenia				l
	Neutropenia			Quetiapine ceased.	ı

Medicine Details:

PREMIA 5 (Other drug)		Reason: Menopausal symptoms	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ASPIRIN (Other drug)		Reason:	
	600.0 Milligram	Daily	
Batch:	Started:	Stopped:	
LORAZEPAM (Suspected)		Reason:	
	2.5 Milligram	As necessary	
Batch:	Started: 19/04/2001	Stopped:	
SEROQUEL (Suspected)		Reason: Unspecified schizophreni	а
	300.0 Milligram	Daily	
Batch:	Started:	Stopped:	2W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		22/04/2001	2.46	
	Neutrophils		23/04/2001	1.9	
	White blood cells		22/04/2001	4.14	
	White blood cells		23/04/2001	3.27	

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: 13/02/2002 Weight: Age: 44			q: 1			Gender	• •
Dobus 22/04/2001		3/02/2002				Weight:	
Outcome: Unknown action Details: Causality: Causality possible	ospitalisation:					Age:	44
Action Details: Color Details Details							
Company						Causality	: Causality possible
DLANZAPINE (Suspected) 20.0 Milligram Daily Batch: Started: 21/04/2001 Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) 20.0 Milligram Daily Batch: Started: Started: Stopped: 18/04/2001 VENLAFAXINE HYDROCHLORIDE (Suspected) 300.0 Milligram Daily	action Details	:					
DLANZAPINE (Suspected) 20.0 Milligram Daily Batch: Started: 21/04/2001 Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) 20.0 Milligram Daily Batch: Started: Started: Stopped: 18/04/2001 VENLAFAXINE HYDROCHLORIDE (Suspected) 300.0 Milligram Daily							
DLANZAPINE (Suspected) 20.0 Milligram Daily Batch: Started: 21/04/2001 Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) 20.0 Milligram Daily Batch: Started: Started: Stopped: 18/04/2001 VENLAFAXINE HYDROCHLORIDE (Suspected) 300.0 Milligram Daily							
DLANZAPINE (Suspected) 20.0 Milligram Daily Batch: Started: 21/04/2001 Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) 20.0 Milligram Daily Batch: Started: Started: Stopped: 18/04/2001 VENLAFAXINE HYDROCHLORIDE (Suspected) 300.0 Milligram Daily							
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Batch: Started: 21/04/2001 Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: Stopped: 18/04/2001 VENLAFAXINE HYDROCHLORIDE (Suspected) Reason: 300.0 Milligram Daily					Possoni		
Batch: Started: 21/04/2001 Stopped: ZUCLOPENTHIXOL ACETATE (Suspected) Reason: 20.0 Milligram Daily Batch: Started: Stopped: 18/04/2001 VENLAFAXINE HYDROCHLORIDE (Suspected) Reason: 300.0 Milligram Daily	OLANZAPINE (SUSPE	cted)	20.0	Milliaram			
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Batch: Started: Stopped: 18/04/2001 VENLAFAXINE HYDROCHLORIDE (Suspected) Reason: 300.0 Milligram Daily		CETATE (Supposted)	Started: 21/	/U4/2UUT	Passari	Stopped:	
Batch: Started: Stopped: 18/04/2001 VENLAFAXINE HYDROCHLORIDE (Suspected) Reason: 300.0 Milligram Daily	LUULUPEN I MIXUL A	toe raile (Suspected)	20.0	Milligram			
VENLAFAXINE HYDROCHLORIDE (Suspected) Reason: 300.0 Milligram Daily				wwwyraili	Dally	Stonned: 18/04/200	1
300.0 Milligram Daily	Ratch:		Juitu.			510pped. 10/04/200	1
		OCHLORIDE (Suspect			Reason:		
		OCHLORIDE (Suspect	ed)	Milligram			
	VENLAFAXINE HYDR	OCHLORIDE (Suspect	ed) 300.0	Milligram		Stopped: 20/04/200	1
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	VENLAFAXINE HYDR	COCHLORIDE (Suspect	ed) 300.0	Milligram		Stopped : 20/04/200	1
	VENLAFAXINE HYDR Batch:		ed) 300.0	Milligram		Stopped : 20/04/200	1
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aboratory Investigations:	VENLAFAXINE HYDR Batch:		ed) 300.0	Milligram		Stopped : 20/04/200	1
aboratory Investigations:	VENLAFAXINE HYDR Batch:		ed) 300.0	Milligram		Stopped : 20/04/200	1
aboratory Investigations:	VENLAFAXINE HYDR Batch:		ed) 300.0	Milligram		Stopped: 20/04/200	1
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aboratory Investigations:	VENLAFAXINE HYDR Batch:		ed) 300.0	Milligram		Stopped: 20/04/200	1
	Batch: -aboratory Inve	estigations:	ed) 300.0	Milligram		Stopped: 20/04/200	1
aboratory Investigations: dditional Information:	Batch: -aboratory Inve	estigations:	ed) 300.0	Milligram		Stopped: 20/04/200	1
	Batch: -aboratory Inve	estigations:	ed) 300.0	Milligram		Stopped: 20/04/200	1
	Batch: -aboratory Inve	estigations:	ed) 300.0	Milligram		Stopped: 20/04/200	1
	VENLAFAXINE HYDR Batch: _aboratory Inve	estigations:	ed) 300.0	Milligram		Stopped: 20/04/200	1

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details: Gender: M Case Number: 172737 Seq: 1 Reported: 13/02/2002 Weight: Hospitalisation: Age: 59 Onset Date: 18/03/2001 DOB: 02/06/1941 Outcome: Recovered Causality: Causality possible Reaction Details: Preferred Term Severity Report Description Treatment Blood creatine phosphokinase incr Confusional state Dyspnoea Hyperhidrosis Hyperreflexia Hypertonia Hypokalaemia Hyponatraemia Muscle twitching Neuroleptic malignant syndrome Hold lithium, olanzapine, paroxetine. strict fluid restriction/balance **Medicine Details: TEMAZEPAM** (Other drug) Reason: 0.0 Batch: Started: Stopped: NITRAZEPAM (Other drug) Reason: 0.0 Started: Stopped: Batch: **ASPIRIN** (Other drug) Reason: 0.0 Started: Batch: Stopped: FOLIC ACID (Other drug) Reason: 0.0 Batch: Started: Stopped: **Laboratory Investigations:** Date Date Tested Result Details Type Range Biochemistry Ck - 8403, ldh - 350 Electrolytes Sodium - 116, potassium - 2.6 **Additional Information:** Other reaction - rhabdomyolisis.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	172737	Seq: 1			Gender:	M
Reported:	13/02/2002				Weight:	
Hospitalisation:					Age:	59
Onset Date:	18/03/2001					02/06/1941
Outcome:	Recovered				Causality:	Causality possible
Reaction Detail	s:					
Medicine Deta	ils:					
ATORVASTATIN (O	ther drug)			Reason:		
		0.0				
Batch:		Started:			Stopped:	
METOPROLOL TAR	RTRATE (Other drug)		Reason:		
		0.0				
Batch:		Started:			Stopped:	
LITHIUM CARBONA	ATE (Suspected)			Reason:		
		0.0				
Batch:		Started:			Stopped:	15M
OLANZAPINE (Sus	pected)			Reason:		
		10.0	Milligram	Daily		
Batch:		Started:			Stopped:	15M
l abayataw day	.aatimatiama.					
Laboratory Inv	vestigations:					
Additional Info	ormation:					
Other reaction - rha	bdomyolisis.					

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1	Weight Age DOE	
		6M
	pected) 20.0 Milligram Started:	Weight Age DOE Causality pected) Reason: 20.0 Milligram Daily Started: Stopped:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 172742 Seq: 1 Gender: M
Reported: 13/02/2002 Weight:

Hospitalisation: Age: 71

Onset Date: DOB: 24/11/1930

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Hypertonia Leukocytosis Neuroleptic malignant syndrome			Stop pericyazine and olanzapine, also atorvastatin. supportive therapy (parace tamol, rehydration with iv fluids) given. later given levodopa/benserazide.
Pyrexia			

Medicine Details:

PANADEINE FORTE (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ROFECOXIB (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
WARFARIN SODIUM (Other drug)		Reason: Otr&nos disord of heart rhythm	
	8.0 Milligram	Daily	
Batch:	Started:	Stopped:	
DIGOXIN (Other drug)		Reason: Otr&nos disord of heart rhythm	
	250.0 Microgram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		02/10/2001	658	
	Creatine		03/10/2001	1749	
	Creatine		05/10/2001	465	
	Creatine		04/10/2001	753	
	Creatine		16/10/2001	2244	
	Creatine		17/10/2001	1309	
	Creatine		20/10/2001	325	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 172742
 Seq: 1
 Gender: M

 Reported:
 13/02/2002
 Weight:

Hospitalisation: Age: 71

Onset Date: **DOB**: 24/11/1930

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

PERINDOPRIL (Other drug)		Reason: Chron isch heart dis no hyper	
	2.0 Milligram	Daily	
Batch:	Started:	Stopped:	
FRUSEMIDE (Other drug)		Reason: Essential benign hypertension	
	40.0 Milligram	Daily	
Batch:	Started:	Stopped:	
PERICYAZINE (Suspected)		Reason: Presenile dementia	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Nervousness	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	19D

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		26/10/2001	35	
	Creatine		22/10/2001	98	
	Creatine		19/10/2001	693	
	Creatine		16/10/2001	1990	
	White blood cells		18/10/2001	18.3	
	White blood cells		19/10/2001	16.8	
	White blood cells		20/10/2001	14.9	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 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:
 172742
 Seq: 1
 Gender: M

 Reported:
 13/02/2002
 Weight:

Hospitalisation: Age: 71

Onset Date: DOB: 24/11/1930
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ATORVASTATIN (Suspected) Reason: Othr&unspec metabolic diseases

10.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells		21/10/2001	16.9	
	White blood cells		22/10/2001	18.6	
	White blood cells		23/10/2001	12.8	
	White blood cells		26/10/2001	9.11	
	White blood cells		30/10/2001	12.8	
	White blood cells		31/10/2001	9.20	
	White blood cells		01/11/2001	9.31	

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Nun	nber:	172742	Sed	q: 1			Gender: M
-		13/02/2002	2				Weight:
lospitalisa	tion:						Age : 71
Onset	Date:						DOB : 24/11/1930
Outco	ome:	Not yet red	covered				Causality: Causality possible
eaction I	Detai	ls:					
Medicine	Deta	ails:					
		E (Other dru	g)		Rea	son:	
				0.0			
Bat	ch:			Started:			Stopped:
ROFECOXII	3 (Othe	r drug)			Rea	son:	
				0.0			
Bat	ch:			Started:			Stopped:
WARFARIN	SODIU	M (Other dru	g)		Rea	son:	Otr&nos disord of heart rhythm
				8.0 Millio	gram	Daily	
Bat	ch:			Started:			Stopped:
DIGOXIN (C	ther dr	ug)			Rea	son:	Otr&nos disord of heart rhythm
				250.0 Micr	ogram	Daily	
Bat	ch:			Started:			Stopped:
<u>Laborato</u>							
Date		Туре	Range	Date Tested	Result		Details
	White	blood cells		02/11/2001	8.07		
	White	blood cells		02/11/2001	8.07		
Addition	al Inf	ormation	1:				

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Case Number: 172742

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Reported: 13/02/2002				Weight:	
ospitalisation:				Age: 71	
Onset Date:				DOB: 24/	11/1930
Outcome: Not yet recovered				Causality: Ca	usality possible
action Details:					
Andinina Dataila.					
Medicine Details: PERINDOPRIL (Other drug)			Reason:	Chron isch heart dis no hyper	
r Elandor ME (other drug)	20	Milligram	Daily	Official four fleat die fie flyper	
Batch:	Started:	wiiiigi airi	Buny	Stopped:	
FRUSEMIDE (Other drug)			Reason:	Essential benign hypertension	
	40.0	Milligram	Daily		
Batch:	Started:	9	24,	Stopped:	
PERICYAZINE (Suspected)			Reason:	Presenile dementia	
(10.0	Milligram	Daily		
Batch:	Started:	Ü	·	Stopped:	
OLANZAPINE (Suspected)			Reason:	Nervousness	
	5.0	Milligram	Daily		
Batch:	Started:	Ü	·	Stopped:	19D
				··	
aboratory Investigations:					
Additional Information:					
Additional information:					

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:					
Case Number: 1727 Reported: 13/0 Hospitalisation: Onset Date: Outcome: Not	2/2002				
Medicine Details:	cted)		Reason:	Othr&unspec metabolic dis	seases
Batch:	1 Started	10.0 Milligram I:	Daily	Stopped:	
Laboratory Inves	tigations:				
Additional Inform	ation:				

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 172752 Seq: 1 Gender: M
Reported: 13/02/2002 Weight:

Hospitalisation: Admitted to hospital **Age**: 71

Onset Date: 14/03/2001 DOB: 07/07/1929

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Tonic/clonic seizure	
Blood creatine phosphokinase incr			
Confusional state			
Dyskinesia			
Hypertonia			
Hyponatraemia			
Neuroleptic malignant syndrome			Patient was admitted to icu, given benztropine 2mg but no effect, olanzapine ceased, saline given and fluid restriction.
Pyrexia			

Medicine Details:

Medicine Details.				
BENZTROPINE MESYLATE (Other drug)			Reason:	Disturbance of coordination
	2.0	Milligram	As	necessary
Batch:	Started:		L TERM	Stopped:
SULFASALAZINE (Other drug)			Reason:	Regional enteritis
	1.5	Gram	Dai	ily
Batch:	Started:		L TERM	Stopped:
STELAZINE (Suspected)			Reason:	Unspecified psychosis
	5.0	Milligram	Dai	ily
Batch:	Started:		L TERM	Stopped:
OLANZAPINE (Suspected)			Reason:	Schizophrenia
	10.0	Milligram	Dai	ily
Batch:	Started:		S TERM	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		16/03/2001	10,780	
	Creatine		17/03/2001	6840	

Additional Information:

Patient had stanage movements lip-smacking, constant swallowing, neck extension, ocular movements.



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 172752
 Seq: 1
 Gender: M

 Reported:
 13/02/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 71

Onset Date: 14/03/2001 **DOB**: 07/07/1929

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia			

Medicine Details:

BENZTROPINE MESYLATE (Other drug)			Reason:	Disturbance of coordination
	2.0	Milligram	As ne	ecessary
Batch:	Started:		L TERM	Stopped:
SULFASALAZINE (Other drug)			Reason:	Regional enteritis
	1.5	Gram	Daily	
Batch:	Started:		L TERM	Stopped:
STELAZINE (Suspected)			Reason:	Unspecified psychosis
	5.0	Milligram	Daily	
Batch:	Started:		L TERM	Stopped:
OLANZAPINE (Suspected)			Reason:	Schizophrenia
	10.0	Milligram	Daily	
Batch:	Started:		STERM	Stopped:

Laboratory Investigations:

Additional Information:

Patient had stanage movements lip-smacking, constant swallowing, neck extension, ocular movements.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:172793Seq: 1Gender: MReported:15/02/2002Weight: 60.00Hospitalisation:Admitted to hospitalAge: 79

Onset Date: 01/02/2002 **DOB**: 03/05/1922

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Spiking temps.	
Blood creatine phosphokinase incr			
Bradykinesia			Patient was hospitalised given 3 doses of ceftriaxone 1gm daily. ceased olanzapine.
Hypertonia			
Leukocytosis			
Neuroleptic malignant syndrome			

Medicine Details:

Miculcine Details.					
LITHIUM CARBONATE (Suspected)			Reason:	Unspecifid affective psychosic	S
	500.0	Milligram	Daily		
Batch:	Started:			Stopped:	CONTIN
OLANZAPINE (Suspected)			Reason:	Unspecified psychosis	
	15.0	Milligram	Daily		
Batch:	Started:			Stopped: 02/02/2002	

Laboratory Investigations:

<u> </u>	i ji iii tootiga				
Date	Туре	Range	Date Tested	Result	Details
	Creatine		01/02/2002	835	
	White blood cells		01/02/2002	26.6	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 172970
 Seq: 1
 Gender:
 F

 Reported:
 20/02/2002
 Weight:

Hospitalisation:
Onset Date: 20/11/2001
Age: 67Y
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Involuntary wrist, arm and leg movements.	

Medicine Details:

FRUSEMIDE (Other drug)		Reason:	Edema and dr	opsy	
Tablet	80.0 Milligram	Daily		Oral	
Batch:	Started:		Stopped:	17/11/2001	
SALBUTAMOL (Other drug)		Reason:	Pain		
	1.2 Milligram	Daily			
Batch:	Started:		Stopped:		CONTIN
DEXTROPROPOXYPHENE HYDROCHLORII	DE (Other drug)	Reason:	Pain		
Capsule	600.0 Milligram	Daily		Oral	
Batch:	Started:		Stopped:		CONTIN
PARACETAMOL (Other drug)		Reason:	Pain		
Tablet	6.0 Gram	Daily		Oral	
Batch:	Started:		Stopped:		CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Progressively becoming worse (flick of hand, kick of leg and shake of entire body whilst resting in bed).

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Rep	oort	Deta	ils:
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 Case Number:
 172970
 Seq: 1
 Gender:
 F

 Reported:
 20/02/2002
 Weight:

Hospitalisation:
Onset Date: 20/11/2001
Age: 67Y
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

SIMVASTATIN (Other drug)			Reason:	Othr&unspec me	tabolic diseases	
Tablet	80.0	Milligram	Daily	C)ral	
Batch:	Started:			Stopped:	CONTI	N
FLUTICASONE PROPIONATE (Other drug)			Reason:			
Inhalation	1.0	Milligram	Daily	Ir	nhalation	
Batch:	Started:			Stopped:	CONTI	N
OLANZAPINE (Suspected)			Reason:			
Tablet	5.0	Milligram	Daily	C)ral	
Batch:	Started:			Stopped:	CONTI	N

Laboratory Investigations:

Additional Information:

Progressively becoming worse (flick of hand, kick of leg and shake of entire body whilst resting in bed).

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:173089Seq: 1Gender: MReported:25/02/2002Weight: 75.00Hospitalisation:Admitted to hospitalAge: 42

Onset Date: 17/02/2002 DOB: 24/08/1959

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope	Life threatening		Patient admitted to icu for airway protection and haemofiltration. given bromocriptine 5mg tds. zyprexa, largactil, anafranil and xanax ceased. transferred to renal ward for continuing dialysis and management of renal function.
Hypertonia Blood creatine phosphokinase incr		Severe rigidity.	

Medicine Details:

XANAX (Suspected)		Reason: Obsessive compulsive neurosis
	0.5 Milligram	As necessary
Batch:	Started:	Stopped : 18/02/2002
ZYPREXA (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	Stopped: 18/02/2002
LARGACTIL (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	Stopped: 18/02/2002
ANAFRANIL (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	Stopped: 18/02/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		17/02/2002	130536	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:173089Seq: 1Gender: MReported:25/02/2002Weight: 75.00Hospitalisation:Admitted to hospitalAge: 42

Onset Date: 17/02/2002 **DOB:** 24/08/1959

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touction Dotumor			
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening		
Neuropathy peripheral	Life threatening		
Renal impairment	Life threatening		
Rhabdomyolysis	Life threatening		
Tremor			

Medicine Details:

XANAX (Suspected)		Reason: Obsessive compulsive neurosis
	0.5 Milligram	As necessary
Batch:	Started:	Stopped: 18/02/2002
ZYPREXA (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	Stopped: 18/02/2002
LARGACTIL (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	Stopped: 18/02/2002
ANAFRANIL (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	Stopped: 18/02/2002

Laboratory Investigations:

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 173133
 Seq: 1
 Gender: M

 Reported:
 26/02/2002
 Weight:

Hospitalisation:
Onset Date: 07/12/2001
Age: 29Y
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	toaction Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Leukopenia			
	Neutropenia			

Medicine Details:

DIAZEPAM (Other drug)			Reason:			
Tablet	5.0	Milligram	As necess	sary	Oral	
Batch:	Started: 02/	12/2001		Stopped:		CONTIN
TEMAZEPAM (Other drug)			Reason:			
Tablet	10.0	Milligram	Monthly		Oral	
Batch:	Started:			Stopped:		
OLANZAPINE (Suspected)			Reason:			
Tablet	5.0	Milligram	Daily		Oral	
Batch:	Started: 04/	12/2001		Stopped:	06/12/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Monocytes		02/12/2001	0.3	
	Monocytes		07/12/2001	0.1	
	Monocytes		08/12/2001	0.1	
	Monocytes		10/12/2001	0.2	
	Neutrophils		02/12/2001	4.8	
	Neutrophils		07/12/2001	1.3	
	Neutrophils		08/12/2001	2.6	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 173133
 Seq: 1
 Gender: M

 Reported:
 26/02/2002
 Weight:

Hospitalisation: Age: 29Y

Onset Date: 07/12/2001 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started: 02/12/2001	Stopped:	CONTIN
TEMAZEPAM (Other drug)		Reason:	
Tablet	10.0 Milligram	Monthly	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 04/12/2001	Stopped:	06/12/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		10/12/2001	1.3	
	White blood cells		02/12/2001	6.8	
	White blood cells		07/12/2001	4.8	
	White blood cells		08/12/2001	2.6	
	White blood cells		10/12/2001	3.1	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:173278Seq: 1Gender:FReported:01/03/2002Weight:98.00Hospitalisation:Admitted to hospitalAge: 43Y

Onset Date: 24/01/2002 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Decreased bp.	
Blood creatine phosphokinase incr		Elevated ck.	
Anuria		Not passing urine.	
Dyspnoea			
Generalised oedema			Patient was hospitalised. medication was reviewed and some withdrawn with polypharmacy being the major factor.
Peripheral ischaemia			

Medicine Details:

DERALIN (Other drug)		Reason:	Anxiety neuros	sis
Tablet	40.0 Milligram	Daily		Oral
Batch:	Started: 24/01/2002		Stopped:	CONTIN
DERALIN (Suspected)		Reason:	Anxiety neuros	sis
Tablet	80.0 Milligram	Daily		Oral
Batch:	Started: 17/01/2002		Stopped:	24/01/2002
CIPRAMIL (Suspected)		Reason:	Depression	
Tablet	40.0 Milligram	Daily		Oral
Batch:	Started: 17/01/2002		Stopped:	24/01/2002
PAXAM (Suspected)		Reason:	Other disturba	nce of sensation
Tablet	4.0 Milligram	Daily		Oral
Batch:	Started: 17/01/2002		Stopped:	24/01/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Detai	ls:
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Case Number:173278Seq: 1Gender:FReported:01/03/2002Weight:98.00Hospitalisation:Admitted to hospitalAge: 43Y

Onset Date: 24/01/2002 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

PAXAM (Suspected)		Reason:	Other disturba	nce of sensation
Tablet	2.0 Milligram	Daily		Oral
Batch:	Started: 24/01/2002		Stopped:	24/01/2002
NEURONTIN (Suspected)		Reason:		
Capsule	1.8 Gram	Daily		Oral
Batch:	Started: 21/01/2002		Stopped:	24/01/2002
NEURONTIN (Suspected)		Reason:		
Capsule	300.0 Milligram	Daily		Oral
Batch:	Started: 24/01/2002		Stopped:	28/01/2002
DROLEPTAN (Suspected)		Reason:	Otr spec symp	psychopathol nec
Injection	5.0 Milligram	Daily		Intravenous
Batch:	Started: 17/01/2002		Stopped:	26/01/2002

Laboratory Investigations:

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: 01/03/2002 Weight: 98.00 Ralisation: Admitted to hospital neet Date: 24/01/2002 DOB: Outcome: Recovered Causality: Causality possible of Details: Cine Details: EXA (Suspected) Reason: Unspecified schizophrenia Daily Oral Batch: Started: 15/01/2002 Stopped: 24/01/2002 PQUEL (Suspected) Reason: Unspecified schizophrenia Daily Oral	ort Details:					
Causality Caus	Number: 173278 Reported: 01/03/2002	·			Weight:	98.00
Causality: Causality possible ion Details: Causality: Causality possible Causality: Caus		ospital			_	43Y
icine Details: Reason: Unspecified schizophrenia Oral application 20.0 Milligram Daily Oral Batch: Started: 15/01/2002 Stopped: 24/01/2002 DQUEL (Suspected) Reason: Unspecified schizophrenia Oral application 20.0 Milligram Daily Oral Stopped: 24/01/2002 DQUEL (Suspected) Reason: Unspecified schizophrenia Tablet 400.0 Milligram Daily Oral Batch: Started: 21/01/2002 Stopped: 24/01/2002 ENACE (Suspected) Reason: Unspecified psychosis Tablet 10.0 Milligram Daily Oral				С		Causality possible
Reason: Unspecified schizophrenia Oral application 20.0 Milligram Daily Oral Batch: Started: 15/01/2002 Stopped: 24/01/2002 POUBL (Suspected) Reason: Unspecified schizophrenia Tablet 400.0 Milligram Daily Oral Batch: Started: 21/01/2002 Stopped: 24/01/2002 Batch: Started: 21/01/2002 Stopped: 24/01/2002 ENACE (Suspected) Reason: Unspecified psychosis Tablet 10.0 Milligram Daily Oral	ion Details:					, ,
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Batch: Started: 21/01/2002 Stopped: 24/01/2002 NACE (Suspected) Reason: Unspecified psychosis Tablet 10.0 Milligram Daily Oral			24,	Stopped:	24/01/2002	!
Tablet 10.0 Milligram Daily Oral	Batch:					
Tablet 10.0 Milligram Daily Oral	Batch: DQUEL (Suspected)	Started: 15/01/2002	Reason:		chizophrenia	
	Batch: DQUEL (Suspected) Tablet	Started: 15/01/2002 400.0 Milligram	Reason:	Unspecified so	chizophrenia Oral	
	Batch: DQUEL (Suspected) Tablet Batch:	Started: 15/01/2002 400.0 Milligram	Reason: Daily	Unspecified so	chizophrenia Oral 24/01/2002	
Batch : Started : 21/01/2002 Stopped : 24/01/2002	Batch: DQUEL (Suspected) Tablet Batch: ENACE (Suspected)	Started: 15/01/2002 400.0 Milligram Started: 21/01/2002	Reason: Daily Reason:	Unspecified so	chizophrenia Oral 24/01/2002 sychosis	
	Batch: QUEL (Suspected) Tablet Batch: NACE (Suspected)	Started: 15/01/2002 400.0 Milligram Started: 21/01/2002	Reason: Daily Reason:	Stopped: Unspecified ps	chizophrenia Oral 24/01/2002 sychosis Oral	:
ratory Investigations:	Batch: DQUEL (Suspected) Tablet Batch: ENACE (Suspected) Tablet Batch:	Started: 15/01/2002 400.0 Milligram Started: 21/01/2002 10.0 Milligram Started: 21/01/2002	Reason: Daily Reason:	Stopped: Unspecified ps	chizophrenia Oral 24/01/2002 sychosis Oral	:
oratory Investigations:	Batch: DQUEL (Suspected) Tablet Batch: ENACE (Suspected) Tablet Batch:	Started: 15/01/2002 400.0 Milligram Started: 21/01/2002 10.0 Milligram Started: 21/01/2002	Reason: Daily Reason:	Stopped: Unspecified ps	chizophrenia Oral 24/01/2002 sychosis Oral	:
pratory Investigations:	Batch: DQUEL (Suspected) Tablet Batch: ENACE (Suspected) Tablet Batch:	Started: 15/01/2002 400.0 Milligram Started: 21/01/2002 10.0 Milligram Started: 21/01/2002	Reason: Daily Reason:	Stopped: Unspecified ps	chizophrenia Oral 24/01/2002 sychosis Oral	:
oratory Investigations:	Batch: DQUEL (Suspected) Tablet Batch: ENACE (Suspected) Tablet Batch:	Started: 15/01/2002 400.0 Milligram Started: 21/01/2002 10.0 Milligram Started: 21/01/2002	Reason: Daily Reason:	Stopped: Unspecified ps	chizophrenia Oral 24/01/2002 sychosis Oral	:
oratory Investigations:	Batch: DQUEL (Suspected) Tablet Batch: ENACE (Suspected) Tablet Batch:	Started: 15/01/2002 400.0 Milligram Started: 21/01/2002 10.0 Milligram Started: 21/01/2002	Reason: Daily Reason:	Stopped: Unspecified ps	chizophrenia Oral 24/01/2002 sychosis Oral	:
oratory Investigations:	Batch: DQUEL (Suspected) Tablet Batch: ENACE (Suspected) Tablet Batch:	Started: 15/01/2002 400.0 Milligram Started: 21/01/2002 10.0 Milligram Started: 21/01/2002	Reason: Daily Reason:	Stopped: Unspecified ps	chizophrenia Oral 24/01/2002 sychosis Oral	:
oratory Investigations:	Batch: DQUEL (Suspected) Tablet Batch: ENACE (Suspected) Tablet Batch:	Started: 15/01/2002 400.0 Milligram Started: 21/01/2002 10.0 Milligram Started: 21/01/2002	Reason: Daily Reason:	Stopped: Unspecified ps	chizophrenia Oral 24/01/2002 sychosis Oral	:
oratory Investigations:	Batch: DQUEL (Suspected) Tablet Batch: ENACE (Suspected) Tablet Batch:	Started: 15/01/2002 400.0 Milligram Started: 21/01/2002 10.0 Milligram Started: 21/01/2002	Reason: Daily Reason:	Stopped: Unspecified ps	chizophrenia Oral 24/01/2002 sychosis Oral	:
	Batch: DQUEL (Suspected) Tablet Batch: ENACE (Suspected) Tablet Batch:	Started: 15/01/2002 400.0 Milligram Started: 21/01/2002 10.0 Milligram Started: 21/01/2002	Reason: Daily Reason:	Stopped: Unspecified ps	chizophrenia Oral 24/01/2002 sychosis Oral	:
	Batch: DQUEL (Suspected) Tablet Batch: ENACE (Suspected) Tablet Batch:	Started: 15/01/2002 400.0 Milligram Started: 21/01/2002 10.0 Milligram Started: 21/01/2002	Reason: Daily Reason:	Stopped: Unspecified ps	chizophrenia Oral 24/01/2002 sychosis Oral	:
oratory Investigations:	Batch: DQUEL (Suspected) Tablet Batch: ENACE (Suspected) Tablet Batch:	Started: 15/01/2002 400.0 Milligram Started: 21/01/2002 10.0 Milligram Started: 21/01/2002	Reason: Daily Reason:	Stopped: Unspecified ps	chizophrenia Oral 24/01/2002 sychosis Oral	:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

ase miiiiii	ber: 173315	OHIL	: 1				Gende	r: M
	ted: 04/03/200	Seq:						: 60.00
ospitalisati		_					_	e: AD
-	ate: 25/02/200	2					DOE	
	me: Recovered					C		: Causality possible
action D		u					uuoumi	7. Guddanty poddibio
	eferred Term	Se	everity	Repo	ort Des	scription		Treatment
holinergic				- 1			lv	v atropine. date of recove
							2	8/02/02.
odioino	Dotaile							
				Rea	son:			
BETOPTIC (C	Other drug)		0.0	Rea	son:		Ophthaln	nic
BETOPTIC (C Eye [Other drug) Orops	s	0.0 Started:	Rea	son:	Stopped:	Ophthaln	nic
BETOPTIC (C Eye [Batc	Other drug) Orops h:	s	0.0 Started:		son:	Stopped:	Ophthaln	nic
BETOPTIC (C Eye [Batc	Other drug) Orops h:	s				Stopped:	Ophthaln	nic
BETOPTIC (C Eye [Batc	Other drug) Drops h: ther drug)		Started:			Stopped:	Ophthaln	nic
BETOPTIC (C Eye [Batc XALATAN (O Batc	Other drug) Drops h: ther drug)		Started: 0.0	Rea			Ophthaln	nic
Batc XALATAN (O Batc	Other drug) Drops h: ther drug)		Started: 0.0	Rea Rea	son:		Ophthaln	nic
BETOPTIC (C Eye [Batc (ALATAN (O Batc	Other drug) Orops h: ther drug) h: E (Suspected)	s	0.0 Started:	Rea Rea	son:		Ophthaln	nic
BETOPTIC (C Eye [Batc KALATAN (O Batc DLANZAPINE Batc	Other drug) Orops h: ther drug) h: E (Suspected)	s	0.0 Started: 2.5 Milli	Rea Rea gram	son:	Stopped:		nic
BETOPTIC (C Eye [Batc XALATAN (O Batc OLANZAPINE	Other drug) Orops h: ther drug) h: E (Suspected)	s	0.0 Started: 2.5 Milli	Rea Rea gram	son: son: Daily	Stopped:		nic
BETOPTIC (C Eye [Batc (ALATAN (O Batc DLANZAPINE Batc	Other drug) Drops h: Ither drug) h: E (Suspected) h: Ispected)	s	0.0 Started: 2.5 Milli	Rea gram Rea gram	son: Son: Daily son:	Stopped:	sychosis	
BETOPTIC (C Eye [Batc (ALATAN (O Batc DLANZAPINE Batc ARICEPT (Su	Other drug) Orops h: ther drug) h: E (Suspected) h: uspected)	s s	0.0 Started: 2.5 Milli Started: 10.0 Milli	Rea gram Rea gram	son: Son: Daily son:	Stopped: Stopped: Unspecified ps	sychosis	
BETOPTIC (C Eye [Batc KALATAN (O Batc DLANZAPINE Batc ARICEPT (Su	Other drug) Drops h: Ither drug) h: E (Suspected) h: Ispected)	s s	0.0 Started: 2.5 Milli Started: 10.0 Milli	Rea gram Rea gram	son: Son: Daily son:	Stopped: Stopped: Unspecified ps	sychosis 25/02/20	

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Age: 20

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:					
Case Number: 173379	Seq: 1	Gender: F			
Reported: 04/03/2002		Weight: 60.00			

Onset Date: DOB: 29/01/1982

Outcome: Recovered Causality: Causality possible

Reaction Details:

Hospitalisation:

eaction Details.							
Preferred Term	Severity	Report Description	Treatment				
Gravitational oedema							
Rash maculo-papular			Required a visit to doctor. date of recovery 22.2.02.				

Medicine Details:

EPILIM (Suspected)		Reason:	Otr&unspec alcoholic psychosis	
	1.2 Gram	Daily		
Batch:	Started: 05/02/2002		Stopped:	
OLANZAPINE (Suspected)		Reason:	Otr&unspec alcoholic psychosis	
	2.5 Milligram	Daily		
Batch:	Started: 25/01/2002		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Det	tails:				
Case Numb Report Hospitalisatio Onset Da Outcon	er: 173393 ed: 06/03/200 on: ate: 05/01/200 ne: Not yet re	2		Weig A D	der: F jht: ge: 47 OB: 26/12/1954 lity: Causality possible
Reaction De	etails: ferred Term	Coverity	Donort D		Trootmont
Rash	ierrea Term	Severity	Rash on face and up	escription	Treatment Required a visit to doctor.
Medicine I		100.0	Reason: Milligram Dail <u>'</u>	Depression /	
Batch	:	Started:		Stopped:	
ZYPREXA (Su	spected)		Reason:	Depression	
		10.0	Milligram Daily	1	
Batch	ı:	Started:		Stopped:	
Laboratory Date	/ Investigat	ions: Range Date Test	ed Result	ı	Details
Additional	Informatio	n:	1		

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	etails:					
Case Num	ber: 173528	Seq: 1		Gen	der: M	
Repor	rted: 11/03/2002	•	Weight: 70.00			
ospitalisat	ion:			A	ge: AD	
-	Date: 06/12/2001				OB:	
Outco	me: Recovered			Causa	lity: Causality probable	
eaction D	etails:					
	eferred Term	Severity	Report	Description	Treatment	
Blood creati	ne phosphokinase	e incr		·		
	rotein increased					
Myalgia					Required a visit to doctor.	
					cease zyprexa. date of recovery: 6/3/2002.	
Medicine	Details:					
COVERSYL	(Other drug)		Reaso	n: Acute myocard infarc	no hypert	
		8.0	Milligram D	aily		
Bato	ch:	Started:		Stopped:		
MAXOR (Oth	ner drug)		Reaso	n: Other diseases of es	phagus	
		20.0	Milligram D	aily		
Bato	ch:	Started:		Stopped:		
ASTRIX 100	(Other drug)		Reaso	n: Acute myocard infarc	no hypert	
ASTRIX 100	(Other drug)		Reaso Dose Unspecified D	-	no hypert	
ASTRIX 100 Bato				-	,no hypert	
Bato	ch:	1.0		Stopped:		
	ch:	1.0	Dose Unspecified D	Stopped:		
Bato	ch: Suspected)	1.0 Started:	Dose Unspecified D	Stopped:	renia	
Bato ZYPREXA (S Bato	ch: Suspected) ch:	1.0 Started: 0.0 Started:	Dose Unspecified D	Stopped: n: Unspecified schizoph	renia	
Bato ZYPREXA (S Bato	ch: Suspected)	1.0 Started: 0.0 Started:	Dose Unspecified D	Stopped: n: Unspecified schizoph Stopped: 27/02	renia	

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Gender: F Case Number: 173812 Seq: 1

Reported: 22/03/2002 Weight: 109.00 Hospitalisation: **Age:** 35

Onset Date: 01/02/2002 **DOB:** 18/08/1966

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Dyskinesia of tongue and jaw.	Zyprexa ceased. replaced with guetiapine. date of recovery 20/03/2002. required a visit to doctor.

Medicine Details:

Ī	EFEXOR-XR (Other drug)		Reason:	Depression
		450.0 Milligram	Daily	•
l	Batch:	Started: 13/03/2000		Stopped:

XENICAL (Other drug) Reason: Obesity othr than endoc origin

3.0 Dose Unspecified Daily

Batch: Started: L TERM Stopped:

CELEBREX (Other drug) Reason: Unspecified arthritis

400.0 Milligram Daily

Batch: L TERM Started: Stopped:

ZYPREXA (Suspected) Reason: Unspecified psychosis

> 20.0 Milligram Daily

Batch: Started: L TERM Stopped: 01/03/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:173818Seq: 1Gender:MReported:22/03/2002Weight:0.00Hospitalisation:Admitted to hospitalAge: 25Y

Onset Date: DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Cuction Betails.			
Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Caused or prolonged inpatient hospitalisation	Shortness of breath and pulmonary fibrosis.	Antibiotics and required long-term arthificial ventilation.
Pulmonary fibrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified schizophrenia10.0MilligramDailyOral

Batch: Started: 01/01/2001 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Relevant medical history - drug abuse, aggression and a smoker. the dose starte date is not accurate but indicates the drug olanzapine was started sometime in the year.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 174005 Seq: 1 Gender: M

Reported: 27/03/2002 Weight: 70.00 Hospitalisation: Age: 19

Onset Date: 27/02/2002 DOB: 23/07/1982

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			Required a visit to doctor and monitoring

Medicine Details:

CARBAMAZEPINE (Suspected) Reason: Unspecified psychosis

600.0 Milligram Daily

Batch: Started: 13/02/2002 Stopped:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

20.0 Milligram Daily

Batch: Started: 31/01/2002 Stopped:

Laboratory Investigations:

<u> Laborator</u>	y ilivostigat				
Date	Туре	Range	Date Tested	Result	Details
F	Platelets		27/02/2002	107	
F	Platelets		04/03/2002	197	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 174151 Seq: 1 Gender: M

Reported: 02/04/2002 Weight: 98.00 Hospitalisation: Age: 63

Onset Date: 31/12/1998 **DOB**: 29/10/1935

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Skin odour abnormal			Zyprexa ceased.

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: Started: Stopped: 28/04/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.

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Report Details:

Case Number: 174182

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

enitalication:	04/04/200)2						Weight	t: 120.00	
lospitalisation:							Age	e : 54		
Onset Date: 14/02/2002							DOE	3 : 19/07/1947		
Outcome: N	lot yet re	covered					С	ausality	y: Causality poss	ible
action Details								1		
Preferred	l Term	S	Severity		Repo	ort Desc	cription		Treatmer	nt
iabetes mellitus										
alaise										
olyuria										
nirst				<u></u>				<u> </u>	Required a visit to d	octor.
edicine Deta										
EFEXOR (Other drug	3)					son:				
				Milligra	am	Daily				
Batch:			Started:				Stopped:			
/IOXX (Other drug)						son:				
				Milligra	am	Daily				
Batch:			Started:				Stopped:			
ZESTRIL (Other drug	g)					son:				
			10.0	Milligra	am	Daily				
Batch:			Started:				Stopped:			
YPREXA (Suspecte	∌d)					son:				
			10.0	Milligra	am	Daily				
			Started: 14/	12/200	1		Stopped:	15/02/20	002	
Batch:										
	estigat									
aboratory Inv	restigat		Date Test	ed	Result			Det	tails	

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 174396
 Seq: 1
 Gender: M

 Reported:
 03/04/2002
 Weight:

Hospitalisation: Age: 45Y
Onset Date: DOB:

Outcome: Death Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

FLUANXOL (Other drug)		Reason: Schizo	phrenia	
(0.0			
Batch:	Started:	Sto	opped:	CONTIN
ALCOHOL (Suspected)		Reason:		
	0.0			
Batch:	Started:	Sto	opped:	
ZYPREXA (Suspected)		Reason: Schizo	phrenia	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/2001	Sto	opped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient was drunk and arrested. whilst in police custody the patient died. the dose start date is not necessarily accurate but indicates zyprex was started sometime in the year. autopsy results: restricted airways, cardiac event, schizophrenia, intoxicatio n and alcohol. date of death ??-december 2000. cause of death - uncertain.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 174676 Seq: 1 Gender: M

Reported: 17/04/2002 Weight:
Hospitalisation: Age: 75Y

Onset Date: 22/12/2001 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			Decreased dose of citalopram, karvea ceased, olanzapine decreased.

Medicine Details:

ISOPTIN (Other drug)	Re	eason:		
	240.0 Milligram	Daily		
Batch:	Started: 26/11/2001	Stopped:	CONTIN	
ACIMAX (Other drug)	Re	eason:		
Tablet	2.0 Dose Unspecified	d Daily O	ral	
Batch:	Started:	Stopped:	CONTIN	
STILNOX (Other drug)	Re	eason:		
Tablet	1.0 Dose Unspecified	d Daily O	ral	
Batch:	Started:	Stopped:	CONTIN	
OLANZAPINE (Suspected)	Re	eason:		
	5.0 Milligram	Daily		
Batch:	Started:	Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 25/12/01.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: ospitalisation: Onset Date:		Seq: 1				Gender:		
Onset Date:						Weight:		
						Age:	75Y	
Outcome	22/12/2001					DOB:		
Outcome.	Recovered				С	ausality:	Causality possib	le
action Detail	s:							
ledicine Deta	ils:							
	ROBROMIDE (Suspec	ted)		Reason:	Depression			
		40.0	Milligram	Daily				
Batch:		Started: 28	3/11/2001		Stopped:			
KARVEA (Suspecte	;d)			Reason:				
		300.0	Milligram	Daily				
Batch:		Started:			Stopped:	24/12/2001		
aboratory Inv	/estigations:							
aboratory Inv	/estigations:							
aboratory Inv	/estigations:							
aboratory Inv	/estigations:							
aboratory Inv	/estigations:							
aboratory Inv	estigations:							
aboratory Inv	estigations:							
aboratory Inv	vestigations:							
dditional Info	ormation:							
dditional Info	ormation:							
aboratory Inv	ormation:							
dditional Info	ormation:							

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DOB: 20/01/1948

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 174728
 Seq: 1
 Gender: M

 Reported:
 22/04/2002
 Weight:
 69.00

Hospitalisation: Age: 54

Outcome: Recovered Causality: Causality probable

Reaction Details:

Onset Date: 08/03/2002

todetion betails.			
Preferred Term	Severity	Report Description	Treatment
Eosinophilia			
Jaundice			Required a visit to doctor. olanzapine ceased. date of recovery: 16/4/2002.
Nausea			
Rash			

Medicine Details:

OLANZAPINE (Suspected) Reason: Depression

15.0 Milligram Daily

Batch: Started: 30/01/2002 Stopped: 07/03/2002

Laboratory Investigations:

Laborato	ry inivestigat				
Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		08/03/2002	380	
	AST = SGOT		08/03/2002	141	
	Bilirubin		08/03/2002	50	
	Eosinophils		08/03/2002	6.3	
	GGT = SGGT =		08/03/2002	907	
	SAP = ALP		08/03/2002	1605	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 174730
 Seq: 1
 Gender: M

 Reported:
 22/04/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 65Y
Onset Date: 18/09/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term Severity Report Describeration Blood pressure of 90/65.	ription I Treatment
Blood pressure of 30/30.	Patient was hospitalised. required intravenous rehydration. zyprexa ceased and risperidone commenced.

Medicine Details:

SERENACE (Other drug)			Reason:	Unspecified psychosis	
Oral application	5.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	23Y
AMYLOBARBITONE (Other drug)			Reason:	Other&unspecified epilepsy	
Tablet	60.0	Milligram	Daily	Oral	
Batch:	Started:		L TERM	Stopped:	CONTIN
DILANTIN (Other drug)			Reason:	Other&unspecified epilepsy	
Oral application	300.0	Milligram	Daily	Oral	
Batch:	Started:		L TERM	Stopped:	CONTIN
OROXINE (Other drug)			Reason:	Myxedema	
Tablet	0.1	Milligram	Daily	Oral	
Batch:	Started:		L TERM	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

ase Number: 17 Reported: 22		Seq:	1					Gender: Weight:	M
spitalisation: A	dmitted to hospita	al						Age: DOB:	65Y
Outcome: R							C	ausality:	Causality possible
action Details	:								
ledicine Detail	s:								
UREX (Other drug)					Reas	on:	Congestive he	art failure	
Tablet				Milligram		Daily		Oral	
Batch:		Sta	40.0 rted:	Milligram	L TERM		Stopped:		CONTIN
Batch:)	Sta	rted:		L TERM		Stopped: Congestive her	art failure	CONTIN
Batch: SLOW-K (Other drug) Tablet)	Sta	rted:	Milligram Gram	Reas		Congestive he		
Batch: SLOW-K (Other drug) Tablet Batch:			rted:		Reas	son: Daily		art failure	CONTIN
Batch: SLOW-K (Other drug) Tablet Batch: COGENTIN (Other drug)			1.2	Gram	Reas L TERM Reas	on: Daily on:	Congestive he	art failure Oral	
Batch: SLOW-K (Other drug) Tablet Batch:		Sta	1.2 rted: 2.0		Reas L TERM Reas	son: Daily	Congestive he	art failure	CONTIN
Batch: SLOW-K (Other drug) Tablet Batch: COGENTIN (Other dru Tablet Batch:	ug)	Sta	1.2	Gram	Reas L TERM Reas	on: Daily on:	Stopped:	art failure Oral Oral	
Batch: SLOW-K (Other drug) Tablet Batch: COGENTIN (Other drug) Tablet Batch:	ug)	Sta	1.2 rted: 2.0 rted:	Gram Milligram	Reas L TERM Reas	on: Daily on: Daily son:	Congestive he	art failure Oral Oral	CONTIN
Batch: SLOW-K (Other drug) Tablet Batch: COGENTIN (Other dru Tablet Batch:	ug)	Sta	1.2 rted: 2.0 rted:	Gram	Reas L TERM Reas L TERM	Daily Son: Daily Daily	Stopped:	art failure Oral Oral	CONTIN

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 174776 Seq: 1 Gender: F

Reported: 23/04/2002 Weight: 85.00 Hospitalisation: Age: 54

Onset Date: 20/03/2002 **DOB**: 29/08/1947

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Dyspnoea			
Face oedema			Required a visit to doctor. date of recovery: 25/3/2002.
Pruritus			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: Started: 11/03/2002 Stopped: 25/03/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Started small dose zyprexa on 11/2/2002, reaction after drug titrated to 10mg.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 175310
 Seq: 1
 Gender: M

 Reported:
 10/05/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 20
Onset Date: 12/02/2002 DOB: 07/03/1981

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			
Cough			
Dyspnoea			
Pneumonia	Life threatening		Prologation of hospitalisation.treated with perindopril 8mg. not yet recovered.
Sepsis			
Syncope			

Medicine Details:

Miculcine Details.			
OLANZAPINE (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 10/08/2001	Stopped:	05/02/2002
ZUCLOPENTHIXOL ACETATE (Suspected	i)	Reason: Unspecified s	chizophrenia
Injection	50.0 Milligram	Daily	Intramuscular
Batch:	Started: 27/08/2001	Stopped:	05/02/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		11/02/2002	202	
	Electrocardiograph				Echocardiogram was performed showing global moderate to severe left and right ventricular dysfunction with mild dilatation. from this investigation a diagnosis of cardiomyopathy was made.
	Electrocardiograph				Chest x ray showed bronchopneumonia - 12/02/02
	Other data				Echocardiogram / I & r ventricular dysfunction & mild dilatation.

Additional Information:

Marajuana and amphetamine abuse.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 175310
 Seq: 1
 Gender: M

 Reported:
 10/05/2002
 Weight:

Hospitalisation: Admitted to hospital **Age**: 20

Onset Date: 12/02/2002 **DOB**: 07/03/1981

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.			
OLANZAPINE (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 10/08/2001	Stopped:	05/02/2002
ZUCLOPENTHIXOL ACETATE (Suspected	(k	Reason: Unspecified so	chizophrenia
Injection	50.0 Milligram	Daily	Intramuscular
Batch:	Started: 27/08/2001	Stopped:	05/02/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Radiololgy				X ray, bronchopneumonia
	SAP = ALP		11/02/2002	115	

Additional Information:

Marajuana and amphetamine abuse.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 175330
 Seq: 1
 Gender:
 F

 Reported:
 08/05/2002
 Weight:

Hospitalisation: Age: 19

Onset Date: 28/02/2002 DOB: 15/05/1982

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caction betains.				
Preferred Term	Severity	Report Description	Treatment	
Galactorrhoea			Required to visit a doctor.therapy changed to clozapine.	

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram Daily

Batch: Started: 26/11/2001 Stopped: 15/04/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 175421 Seq: 1 Gender: F

Reported: 10/05/2002 Weight: 67.00 Hospitalisation: Age: 33

Onset Date: 01/05/2002 DOB: 13/12/1968
Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Eczema		Fine eczematous rash.	
Arthralgia			
Increased appetite			Required a visit to doctor.
Weight increased			

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

5.0 Milligram Daily

Batch: Started: 19/04/2002 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Rash on shoulder and areas where clothes rub (eg bra-line). same reactions when using olanzapine march-june 2001.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Onset Date: Outcome: Not yet recove	ered			ender: U eight: Age: DOB: sality: Causality possible
leaction Details:	Carravit.	Danast	December	Tooloo
Preferred Term Albuminuria Hypoproteinaemia Nephrotic syndrome	Severity	Кероп	Description	Treatment Olanzapine and flupenthixol were ceased.
Medicine Details:				
OLANZAPINE (Suspected)		Reason	1:	
	30.0 M	lilligram D	aily	
Batch:	Started:		Stopped:	
FLUPENTHIXOL DECANOATE (Sus	pected) 60.0 M	Reasor Iilligram D	n: aily	
Batch:	Started:		Stopped:	
	S: Range Date Tested			Details
Biochemistry			oumin 25. protein in urir	_
Immunology		Po	sitive antinuclear antibo	ody.
Additional Information:				

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:175692Seq: 1Gender: FReported:27/05/2002Weight:Hospitalisation:Age:

Onset Date:
Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

•	toaction Botanoi				
	Preferred Term	Severity	Report Description	Treatment	
	Hepatic function abnormal				

Medicine Details:

ZOLOFT (Other drug)		Reason:	Depression	
Tablet	50.0 Milligram	Daily		Oral
Batch:	Started: 25/05/1999		Stopped:	06/09/2000
MOCLOBEMIDE (Other drug)		Reason:		
Oral application	900.0 Milligram	Daily		Oral
Batch:	Started: 06/09/2000		Stopped:	05/09/2001
OLANZAPINE (Suspected)		Reason:	Unspecified so	chizophrenia
Tablet	15.0 Milligram	Daily		Oral
Batch:	Started: 25/05/1999		Stopped:	20/05/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT				Alt 131.
	GGT = SGGT =		13/04/2002	71	
	GGT = SGGT =		13/04/2002	131	
	GGT = SGGT =		13/04/2002	133	
	GGT = SGGT =		15/05/2002	138	
	GGT = SGGT =		15/05/2002	125	

Additional Information:

The date of onset is not accurate but indicates onset sometime in the year. the dose start date for olanzapine is not necessarily accurate but indicates the drug was started sometime in the month.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Reported: pitalisation:	0010=10000	Seq: 1		Geno	
spitalisation:	29/05/2002			Weig	
-					ge: 30
Onset Date:		. al			OB : 04/04/1972
	Not yet recovere	ea		Causai	ity: Causality possible
action Detai	ils: ed Term	Severity	Rer	port Description	Treatment
yskinesia		Coverity	110	7010 Bedonption	Trodinone
ledicine Det BRICANYL (Other				ason: Asthma	
Inhalation		2.0	Dose Unspecified		tion
Batch:		Started:		Stopped:	CONTIN
AMLODIPINE (Oth	er drug)			ason: Essential benign hype	ertension
			Milligram	Daily	
Batch:		Started:		Stopped:	CONTIN
	HALER NOS (Other o			ason: Asthma	
Inhalation			Dose Unspecified	-	
Patch:		Started:		Stopped:	CONTIN
Batch:				ason:	
	ected)		Milligram	Fortnightly	
CLOPIXOL (Suspe	ected)		Ü	a	CONTINU
	ected)	300.0 Started:		Stopped:	CONTIN
CLOPIXOL (Suspe		Started:		Stopped:	CONTIN
CLOPIXOL (Suspe	nvestigațions:	Started:		_	CONTIN

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details	s:					
Hospitalisation: Onset Date:	29/05/2002 Not yet recovered	Seq: 1				
Madiaina Data	.:l					
Medicine Deta				Reason:	Schizophrenia	
,	,		7.5 Milligram	Daily	·	
Batch:		Started	:		Stopped:	CONTIN
Laboratory In	vestigations:					
Additional Inf	ormation:					
•			•			

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 175736
 Seq: 1
 Gender: M

 Reported:
 29/05/2002
 Weight:

Hospitalisation: Age: 64

Onset Date: 28/11/2001 DOB: 05/05/1937
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botanoi						
Preferred Term	Severity	Report Description	Treatment			
Leukopenia	Life threatening					
Neutropenia	Life threatening		Sodiumvalproate and aspirin stopped.			
Pancytopenia						
Thrombocytopenia						

Medicine Details:

CARDIZEM (Other drug)		Reason: Essential benign hypertension	
	180.0 Milligram	Daily	
Batch:	Started:	Stopped:	
COVERSYL (Other drug)		Reason: Essential benign hypertension	
	6.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ASPIRIN (Suspected)		Reason: Transient cereb isch no hypert	
	300.0 Milligram	Daily	
Batch:	Started: 23/11/2001	Stopped: 27/11/2001	
EPILIM (Suspected)		Reason:	
	1.4 Gram	Daily	
Batch:	Started: 23/11/2001	Stopped: 28/11/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haemoglobin		28/11/2001	120	
	Haemoglobin		29/11/2001	117	
	Haemoglobin		30/11/2001	116	
	Lymphocytes		28/11/2001	0.56	
	Lymphocytes		30/11/2001	0.66	
	Lymphocytes		29/11/2001	0.79	
	Monocytes		28/11/2001	101	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 175736
 Seq: 1
 Gender: M

 Reported:
 29/05/2002
 Weight:

Hospitalisation: Age: 64

Onset Date: 28/11/2001 **DOB**: 05/05/1937

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected) Reason: Schizophrenia

10.0 Milligram Daily

Batch: Started: 23/11/2001 Stopped:

Laboratory Investigations:

	, , , , , , , , , , , , , , , , , , , 				
Date	Туре	Range	Date Tested	Result	Details
	Monocytes		30/11/2001	101	
	Monocytes		29/11/2001	101	
	Neutrophils		28/11/2001	1.68	
	Neutrophils		29/11/2001	1.28	
	Neutrophils		30/11/2001	1.89	
	Platelets		28/11/2001	96	
	Platelets		29/11/2001	78	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 175736
 Seq: 1
 Gender: M

 Reported:
 29/05/2002
 Weight:

Hospitalisation: Age: 64

Onset Date: 28/11/2001 **DOB**: 05/05/1937

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

CARDIZEM (Other drug)

	180.0 Milligram	Daily	
Batch:	Started:	Stopped:	
COVERSYL (Other drug)		Reason: Essential benign hypertension	
	6.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ASPIRIN (Suspected)		Reason: Transient cereb isch no hypert	
	300.0 Milligram	Daily	
Batch:	Started: 23/11/2001	Stopped: 27/11/2001	

Reason:

Essential benign hypertension

EPILIM (Suspected) Reason:

1.4 Gram Daily

Batch: **Started**: 23/11/2001 **Stopped**: 28/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets		30/11/2001	85	
	Red blood cells		28/11/2001	3.64	
	Red blood cells		29/11/2001	3.50	
	Red blood cells		30/11/2001	3.50	
	White blood cells		28/11/2001	2.6	
	White blood cells		29/11/2001	2.5	
	White blood cells		30/11/2001	2.9	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:				
Case Number: 175736 Reported: 29/05/2002 Hospitalisation: Onset Date: 28/11/2001 Outcome: Not yet recovered Reaction Details:	Seq: 1	,	Gender: M Weight: Age: 64 DOB: 05/05/1937 ausality: Causality possible	è
Medicine Details: OLANZAPINE (Suspected)		Reason: Schizophrenia		
CENTER INE (Guspecteu)	10.0 Milligram	Daily		
Batch:	Started: 23/11/2001	Stopped:		
Laboratory Investigations:				
Additional Information:				

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 175843
 Seq: 1
 Gender: M

 Reported:
 30/05/2002
 Weight:

Hospitalisation: Age: 21Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

caction Details.			
Preferred Term	Severity	Report Description	Treatment
Fatigue			
Weight increased			

Medicine Details:

OLANZAPINE (Suspected) Reason:

0.0

Batch: Started: 01/05/2000 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Serum drug level				Serum lithium was 1.0.

Additional Information:

The dose start date for olanzapine is not necessarily accurate but indicates the drug was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 176060
 Seq: 1
 Gender:
 F

 Reported:
 06/06/2002
 Weight:

Hospitalisation: Age: 77

Onset Date: 10/05/2002 DOB: 18/09/1924

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Needing to move her feet constantly.	Ceased olanzapine.

Medicine Details:

ZOPICLONE (Other drug)		Reason:		
	15.0 Milli	gram As no	ecessary	
Batch:	Started:		Stopped:	
OROXINE (Other drug)		Reason:	Myxedema	
Oral application	200.0 Milli	gram Daily	Oral	
Batch:	Started:		Stopped:	
ASPIRIN (Other drug)		Reason:		
Oral application	100.0 Milli	gram Daily	Oral	
Batch:	Started:		Stopped:	
SALAZOPYRIN (Other drug)		Reason:	Gastroenteritis and colitis	
Oral application	2.0 Gra	m Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but indicates olanzapine was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

_			
Dan	∩rt	Detai	
Ven	UIL	DELAI	113.

 Case Number:
 176060
 Seq: 1
 Gender:
 F

 Reported:
 06/06/2002
 Weight:

Hospitalisation: Age: 77

Onset Date: 10/05/2002 **DOB:** 18/09/1924

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

Micalcinic Details.				
COLOXYL WITH SENNA (Other drug)			Reason:	Constipation
Oral application	2.0	Dose Unspec	ified Daily	y Oral
Batch:	Started:			Stopped:
OLANZAPINE (Suspected)			Reason:	Unspecified psychosis
	2.5	Milligram	Daily	/
Batch:	Started: 01/	01/2002		Stopped: 10/05/2002

Laboratory Investigations:

Additional Information:

The dose start date is not necessarily accurate but indicates olanzapine was started sometime in the month.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

case Number:	. 1/6284	Seq:	1				Gende	er: M	
Reported	: 14/06/200	2					Weigh	t:	
pitalisation:	Hospitalis	ation prolonge	ed				Age	e: 75Y	
Onset Date	:						DO	B:	
Outcome:	Unknown					C	ausalit	y: Causality po	ossible
ction Deta	ıils:								
Prefer	red Term	Se	verity	Repo	ort Des	scription		Treatn	nent
rapyramidal	disorder						(Olanzapine was	ceased.
edicine De ENTOLIN (Other			0.0	Rea	son:				
Batch:		St	arted:			Stopped:			
TROVENT (Other	er drug)			Rea	son:	•			
			0.0						
Batch:		St	arted:			Stopped:			
YPREXA (Suspe	ected)			Rea	son:	Delirium			
Tablet			7.5 Milli	gram	Daily		Oral		
Batch:		St	arted:			Stopped:			
aboratory l	nvestigat ^{Type}	ions: Range	Date Tested	Result			De	tails	
Additional In	ıformatioı	n:							
ort Run: 04/06/20	007 04:57PN	I Database: pu	usime02		ADRS004	4		Page 36	36 of 44

Rep



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 176285 Gender: M Seq: 1 Reported: 14/06/2002 Weight:

Hospitalisation: Admitted to hospital **Age:** 18

Onset Date: 11/05/2002 **DOB:** 17/04/1984 Causality: Causality probable

Outcome: Not yet recovered

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Diarrhoea			
Hepatic function abnormal			
Vomiting			Patient was admitted to hospital and treated with iv
			fluids, stemetil. discontinued
			zyprexa.

Medicine Details:

ZYPREXA (Suspected)		Reason:	Unspecified psychosis
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 22/10/2001		Stopped: 24/05/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		21/05/2002	225	
	ALT = SGPT		28/05/2002	11	
	GGT = SGGT =		21/05/2002	758	
	GGT = SGGT =		28/05/2002	270	
	GGT = SGGT =		28/05/2002	63	
	Neutrophils		21/05/2002	13.7	
	SAP = ALP		21/05/2002	172	

Additional Information:

The onset date is not necessarily accurate but indicates onset was sometime in the month, the dose start and stop dates are not necessarily accuarte but indicates zyprexa was started and stopped sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 176285
 Seq: 1
 Gender: M

 Reported:
 14/06/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 18

Onset Date: 11/05/2002 DOB: 17/04/1984

Outcome: Not yet recovered Causality: Causality probable

Reaction Details:

Medicine Details:

 ZYPREXA (Suspected)
 Reason:
 Unspecified psychosis

 Tablet
 10.0 Milligram
 Daily
 Oral

 Batch:
 Started: 22/10/2001
 Stopped: 24/05/2002

Laboratory Investigations:

Laborato						
Date	Туре	Range	Date Tested	Result	Details	
	SAP = ALP		28/05/2002	119		
	White blood cells		21/05/2002	15.9		

Additional Information:

The onset date is not necessarily accurate but indicates onset was sometime in the month. the dose start and stop dates are not necessarily accurate but indicates zyprexa was started and stopped sometime in the month.

Report Run: 04/06/2007 04:57PM Database: pusime02 ADRS004 Page 368 of 440



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 176528
 Seq: 1
 Gender: F

 Reported:
 17/06/2002
 Weight:

Hospitalisation: Age: 60Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

detion betails.						
Preferred Term	Severity	Report Description	Treatment			
Dystonia		Jaw stiffness.				
Dysarthria		Slurred speech.				
Chest pain						
Dizziness						
Face oedema						

Medicine Details:

Medicine Details.				
DIAZEPAM (Other drug)	her drug) Reason:			
	0.0	As necessary		
Batch:	Started: 29/11/2001	Stopped:	CONTIN	
ZYPREXA (Suspected)				
	5.0 Milligram	Daily		
Batch:	Started: 01/11/2001	Stopped: 29/11/2	2001	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for zyprexa is not necessarily accurate but indicates the drug was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 176546 Seq: 1 Gender: F
Reported: 26/06/2002 Weight:
Hospitalisation: Admitted to hospital Age: 48Y

Onset Date: 01/12/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chills		·	
Dizziness			
Fatigue			Patient was hospitalised. all drugs ceased. date o recovery january 2001.
Hepatitis			
Jaundice			
Nausea			

Medicine Details:

OLANZAPINE (Suspected)		Reason: Depression
(****)	5.0 Milligram	As necessary
Batch:	Started:	Stopped: 07/12/2000
RIFAMPICIN (Suspected)		Reason: Pulmonary tuberculosis
	600.0 Milligram	Daily
Batch:	Started: 01/05/2000	Stopped: 07/12/2000
ISONIAZID (Suspected)		Reason: Pulmonary tuberculosis
	300.0 Milligram	Daily
Batch:	Started: 01/05/2000	Stopped: 07/12/2000
PYRIDOXINE HYDROCHLORIDE (S	uspected)	Reason: Pulmonary tuberculosis
	50.0 Milligram	Daily
Batch:	Started: 01/05/2000	Stopped: 07/12/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		07/12/2000	1094	
	ALT = SGPT		13/12/2000	1804	
	ALT = SGPT		20/12/2000	910	
	ALT = SGPT		31/01/2001	55	
	Bilirubin		07/12/2000	168	
	Bilirubin		13/12/2000	150	
	Bilirubin		31/01/2001	10	

Additional Information:

The dose start dates for rifampicin, isoniazid, pyridoxine, premarin and zantac are not necessarily accurate but indicates the drugs were started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 176546 Seq: 1 Gender: F

Reported: 26/06/2002 Weight:
Hospitalisation: Admitted to hospital Age: 48Y
Onset Date: 01/12/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

PREMARIN (Suspected) Reason: Menopausal symptoms

625.0 Microgram Daily

Batch: Started: 01/10/2000 Stopped: 07/12/2000

ZANTAC (Suspected) Reason:

300.0 Milligram Daily

Batch: Started: 01/11/2000 Stopped: 07/12/2000

Laboratory Investigations:

<u>Laborato</u>	i y iii vootiga				
Date	Туре	Range	Date Tested	Result	Details
	Bilirubin		20/12/2000	44	
	GGT = SGGT =		07/12/2000	664	
	GGT = SGGT =		13/12/2000	615	
	GGT = SGGT =		31/01/2001	150	
	GGT = SGGT =		20/12/2000	631	
	SAP = ALP		07/12/2000	233	
	SAP = ALP		13/12/2000	208	

Additional Information:

The dose start dates for rifampicin, isoniazid, pyridoxine, premarin and zantac are not necessarily accurate but indicates the drugs were started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 176546
 Seq: 1
 Gender:
 F

 Reported:
 26/06/2002
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 01/12/2000
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		Reason: Depression
	5.0 Milligram	As necessary
Batch:	Started:	Stopped: 07/12/2000
RIFAMPICIN (Suspected)		Reason: Pulmonary tuberculosis
	600.0 Milligram	Daily
Batch:	Started: 01/05/2000	Stopped: 07/12/2000
ISONIAZID (Suspected)		Reason: Pulmonary tuberculosis
	300.0 Milligram	Daily
Batch:	Started: 01/05/2000	Stopped: 07/12/2000
PYRIDOXINE HYDROCHLORIDE (S	uspected)	Reason: Pulmonary tuberculosis
	50.0 Milligram	Daily
Batch:	Started: 01/05/2000	Stopped: 07/12/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP		20/12/2000	176	
	SAP = ALP		31/01/2001	80	

Additional Information:

The dose start dates for rifampicin, isoniazid, pyridoxine, premarin and zantac are not necessarily accurate but indicates the drugs were started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 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:
 176546
 Seq: 1
 Gender:
 F

 Reported:
 26/06/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 48Y
Onset Date: 01/12/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

modicino Dotanoi				
PREMARIN (Suspected)		Reason:	Menopausal symptoms	
	625.0 Microgram	Daily		
Batch:	Started: 01/10/2000		Stopped: 07/12/2000	
ZANTAC (Suspected)		Reason:		
	300.0 Milligram	Daily		
Batch:	Started: 01/11/2000		Stopped: 07/12/2000	

Laboratory Investigations:

Additional Information:

The dose start dates for rifampicin, isoniazid, pyridoxine, premarin and zantac are not necessarily accurate but indicates the drugs were started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 176587 Seq: 1 Gender: F

Reported: 26/06/2002 Weight: 73.00 Hospitalisation: Age: 34Y

Onset Date: 08/09/2000 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia			Olanzapine was ceased. clozapine started.

Medicine Details:

Medicine Details.						
LITHIUM CARBONATE (Other drug)			Reason:	Unspecified ps	sychosis	
Tablet	1.0	Gram	Daily		Oral	
Batch:	Started:		L TERM	Stopped:		
OLANZAPINE (Suspected)			Reason:	Unspecified ps	sychosis	
Tablet	30.0	Milligram	Daily		Oral	
Batch:	Started: 01/	06/2000		Stopped:	17/01/2001	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

34 year old lady has a long history of schizophrenia. the dose start date for olanzapine is not necessarily accurate but indicates that the drug was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 176618
 Seq: 1
 Gender: M

 Reported:
 24/06/2002
 Weight:

Hospitalisation: Age: 18

Onset Date: 28/05/2002 **DOB**: 27/07/1983

Outcome: Unknown Causality: Causality possible

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Chest pain			
Chills			
Lipase increased			
Pancreatitis			Clozaril discontinued.
Vomiting			

Medicine Details:

CHLORPROMAZINE HYDROCHLOR	RIDE (Other drug)	Reason:			
	0.0				
Batch:	Started:	Stopped:			
NICOTINE (Other drug)		Reason:			
	0.0				
Batch:	Started:	Stopped : 10/05/2002			
OLANZAPINE (Suspected)		Reason:			
	0.0				
Batch:	Started:	Stopped: 17/05/2002			
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia			
Tablet	400.0 Milligram	Daily Oral			
Batch:	Started: 01/05/2002	Stopped: 21/05/2002			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Amylase		17/05/2002	NORMAL	
	lipase	30 - 290	17/05/2002	2307	

Additional Information:

The date of onset is not necessarily accurte but indicates onset sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 176867 Seq: 1 Gender: M

Reported: 05/07/2002 Weight: 89.00 Hospitalisation: Age: 23

Onset Date: 25/06/2002 **DOB**: 03/04/1979

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Neutropenia	Life threatening		Ceased olanzapine and sodium valproate. patient recovered 2/7/02.

Medicine Details:

vieuicine Delans.						
BENZOYL PEROXIDE (Other drug)			Reason:			
Ointment	0.0			Topical		
Batch:	Started:			Stopped:		CONTIN
MINOCYCLINE HYDROCHLORIDE (Other drug)			Reason:	Other acne of	sebaceous gland	ds
	100.0	Milligram	Daily			
Batch:	Started:			Stopped:		CONTIN
OLANZAPINE (Suspected)			Reason:			
Tablet	30.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:	25/06/2002	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		25/06/2002	1.4	
	White blood cells		25/06/2002	2.8	

Additional Information:

Patient was also using clindatech.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 176916 Seq: 1 Gender: M

Reported: 08/07/2002 Weight: 58.00 Hospitalisation: Age: 75

Onset Date: DOB: 14/07/1926

Outcome: Recovered Causality: Causality possible

Reaction Details:

caction betails.			
Preferred Term	Severity	Report Description	Treatment
Rash			Patient required a vist to doctor. patient was treated with steroids.

Medicine Details:

COLOXYL WITH SENNA (Other drug)		Reason:		
	2.0 Dose Unspec	ified As necessary		
Batch:	Started:	Stopped:		
PARACETAMOL (Other drug)	Reason:			
	2.0 Dose Unspec	ified As necessary		
Batch:	Started:	Stopped:		
OLANZAPINE (Suspected)		Reason: Unspecified psychosis		
	10.0 Milligram	Daily		
Batch:	Started: 01/01/1999	Stopped: 01/03/2002		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Had skin biopsies to exclude other causes since he had actually been on drug long term. the dose start dates are not necessarily accurate but indicates olanzapine was started and stopped sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

s:				
176922	Seq: 1		Gender:	F
	•		Weight:	
	orolonaed		=	16Y
	- congre		_	
Not yet recover	ed			Causality possible
	ou		oudounty.	Guddanty possible
	Severity	Report Descr	intion	Treatment
	Governy	report 2000.	.p.uom	Trodanone
emia			Pa	tient was hospitalised.
				mont was noophaneed.
	20.0 N	Milligram Daily	Oral	
	Started:		Stopped:	
vestigations	:			
	inge Date Teste	d Result	Deta	ils
		d Result	Deta	ls
i .	05/07/2002 Hospitalisation	O5/07/2002 Hospitalisation prolonged Not yet recovered ils: ed Term Severity emia d ails: cted)	Hospitalisation prolonged Not yet recovered ils: ed Term Severity Report Descremia emia ed ails: cted) Reason: Un 20.0 Milligram Daily	Meight: Hospitalisation prolonged Not yet recovered Causality: ils: ed Term Severity Report Description emia d ails: cted) Reason: Unspecified psychosis 20.0 Milligram Daily Oral

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 176926
 Seq: 1
 Gender:
 F

 Reported:
 05/07/2002
 Weight:

Hospitalisation: Hospitalisation prolonged Age: 19Y

Onset Date: 01/01/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

caction betails.							
Preferred Term	Severity	Report Description	Treatment				
Galactorrhoea							
Hyperprolactinaemia			Prolonged hospital stay. zyprexa ceased.				

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

Tablet 20.0 Milligram Daily Oral

Batch: Started: 01/01/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the year. the dose start date is not necessarily accurate but indicates zyprexa was started sometime in the year.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 177015 Seq: 1 Gender: M
Reported: 05/12/2001 Weight:

Hospitalisation: Age: 47

Onset Date: 09/08/2001 **DOB**: 05/01/1954

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	toaction Botaile.			
	Preferred Term	Severity	Report Description	Treatment
	Hepatic function abnormal			
	Hepatic steatosis			
	Hepatomegaly			

Medicine Details:

Medicine Details.				
FLUOXETINE HYDROCHLORIDE (Suspected	d)		Reason:	Depression
Oral application	25.0	Milligram	Daily	y Oral
Batch:	Started:			Stopped:
OLANZAPINE (Suspected)			Reason:	Depression
Tablet	6.0	Milligram	Daily	y Oral
Batch:	Started:			Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		10/01/2001	45	
	ALT = SGPT		29/06/2001	101	
	AST = SGOT		29/06/2001	41	
	GGT = SGGT =		10/01/2001	152	
	GGT = SGGT =		12/01/2001	140	
	GGT = SGGT =		29/06/2001	129	

Additional Information:

Used in ct but no a ct drug.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Rep	ort D)etai	ls:
-----	-------	-------	-----

 Case Number:
 177015
 Seq: 1
 Gender: M

 Reported:
 05/12/2001
 Weight:

Hospitalisation: Age: 47

Onset Date: 09/08/2001 DOB: 05/01/1954
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

MEGICINE Details.					
FLUOXETINE HYDROCHLORIDE (Suspec	cted)		Reason:	Depression	
Oral application	25.0	Milligram	Daily	y Oral	
Batch:	Started:			Stopped:	
OLANZAPINE (Suspected)			Reason:	Depression	
Tablet	6.0	Milligram	Daily	y Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				9.8.01 - upper abdominal ultrasound whowing an enlarged liver with fatty infiltration. computerised tomography scan shows fatty liver.

Additional Information:

Used in ct but no a ct drug.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 17733 Reported: 22/07/ ospitalisation: Onset Date: 08/07/ Outcome: Recov	2002	j: 1		C	Gender: F Weight: Age: 75 DOB: 13/10/1926 Causality: Causality possible
eaction Details: Preferred Tern	n S	Severity	Repo	ort Description	Treatment
Delirium Confusional state		-	Acute delerium.	<u></u>	Date of recovery: 17/7/02.
Medicine Details: ASPIRIN (Other drug)		150.0 M	Rea : Willigram	son: Daily	
Batch:	:	Started:	······g. •····	Stopped:	CONTIN
CYPROTERONE ACETATE	(Other drug)		Rea	son:	
		300.0 N	Milligram	Daily	
			3 -	-	
Batch:		Started:	-	Stopped:	CONTIN
		Started:	Rea	Stopped:	CONTIN
MIANSERIN HYDROCHLOR	RIDE (Suspected)	Started:	-	Stopped: son: As necessary	
Batch: MIANSERIN HYDROCHLOR Batch: OLANZAPINE (Suspected)	RIDE (Suspected)	Started:	Rea	Stopped: son: As necessary Stopped:	CONTIN 05/07/2002
MIANSERIN HYDROCHLOI Batch:	RIDE (Suspected)	Started: 20.0 M Started:	Rea : Milligram	Stopped: son: As necessary Stopped:	
MIANSERIN HYDROCHLOI Batch:	RIDE (Suspected)	Started: 20.0 M Started:	Reas Milligram Reas	Stopped: son: As necessary Stopped: son: As necessary	
MIANSERIN HYDROCHLOR Batch: OLANZAPINE (Suspected) Batch:	RIDE (Suspected)	20.0 M Started:	Reas Milligram Reas	Stopped: son: As necessary Stopped: son: As necessary	05/07/2002
MIANSERIN HYDROCHLOR Batch: OLANZAPINE (Suspected)	RIDE (Suspected)	20.0 M Started:	Reas Milligram Reas Milligram	Stopped: son: As necessary Stopped: son: As necessary	05/07/2002

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number:	177334	Seq: 1				Gender:	F	
Reported:	22/07/2002					Weight:		
Hospitalisation:						Age:	75	
Onset Date:	08/07/2002					DOB:	13/10/1926	
Outcome:	Recovered				С	ausality:	Causality possible	
Reaction Detail						-		
Medicine Deta	ils:							
RANITIDINE (Suspe				Reason:				
		300.0	Milligram	Daily				
Batch:		Started:		·	Stopped:	15/07/2002	2	
MAGNESIUM PLUS	(Suspected)			Reason:				
		1.0	Dose Unspe	ecified Daily				
Batch:		Started:			Stopped:	11/07/2002	2	
Laboratory Inv	vestigations:							
Additional Info	ormation							
Additional init	ormation:							

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 177622
 Seq: 1
 Gender: F

 Reported:
 02/08/2002
 Weight:

Hospitalisation: Hospitalisation prolonged
Onset Date:

DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Muscle twitching.	
Asthenia			
Psychotic disorder			Admitted to hospital. patient is currently being titrated off olanzapine and commenced on quetiapine.
Suicide attempt			

Medicine Details:

ZYPREXA (Suspected)		Reason: Unspe	cified psychosis	
Tablet	25.0 Milligram	Daily	Oral	
Batch:	Started:	Sto	opped:	

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Prescribed overdose - apparent dose was at 20mg/daily. patient history - cerebral palsy with weakness in the left leg.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 177631
 Seq: 1
 Gender:
 F

 Reported:
 02/08/2002
 Weight:

Hospitalisation: Age: 17

Onset Date: 12/07/2002 **DOB**: 01/01/1985

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast enlargement			
Breast pain			

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other	er drug)	Reason: Depres	ssion	
Oral application	20.0 Milligram	Daily	Oral	
Batch:	Started:	Sto	opped:	
SOLIAN (Suspected)		Reason: Unspe	cified schizophrenia	
Tablet	100.0 Milligram	Daily	Oral	
Batch:	Started: 12/07/2002	Sto	opped:	7D
ZYPREXA (Suspected)		Reason: Unspe	cified schizophrenia	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 12/07/2002	Sto	opped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred within 24 hours of the first dose of amisulpride, worse in the first 2-3 days. solian was initiated at 100mg for 7 days and then increased to 200mg/day. zyprexa was reduced from 15mg to 12.5mg to 10mg/mane.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 177716 Seq: 1 Gender: M
Reported: 05/08/2002 Weight:
Hospitalisation: Age: 92

Onset Date: 20/07/2002 **DOB:** 23/02/1910

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia			
Blood creatine phosphokinase incr			
Hepatic function abnormal			Zyprexa ceased. patient died 24/7/02.
Hypercalcaemia			
Leukocytosis			
Lymphocytosis			
Prothrombin level increased			
Renal failure acute			
Troponin increased			

Medicine Details:

nealence Details.				
UREMIDE (Other drug)		Reason	: Polyuria	
	40.0	Milligram Da	ily	
Batch:	Started:	L TERM	Stopped:	24/07/2002
HYDOPA (Other drug)		Reason	: Essential beni	ign hypertension
	750.0	Milligram Da	ily	
Batch:	Started:	L TERM	Stopped:	24/07/2002
SITRIOL (Other drug)		Reason	:	
	500.0	Microgram Da	ily	
Batch:	Started:	L TERM	Stopped:	24/07/2002
COLOXYL WITH SENNA (Other drug)		Reason	: Constipation	
	4.0	Dose Unspecified Da	ily	
Batch:	Started:	L TERM	Stopped:	24/07/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	(<45)	20/07/2002	534	
	ALT = SGPT	(<45)	23/07/2002	1060	
	AST = SGOT	(<40)	20/07/2002	260	
	AST = SGOT	(<40)	23/07/2002	849	
	Calcium	(2.15-2.60)	20/07/2002	2.78	
	Creatine	(<200)	20/07/2002	627	
	GGT = SGGT =	(<50)	20/07/2002	147	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 177716
 Seq: 1
 Gender: M

 Reported:
 05/08/2002
 Weight:

Hospitalisation: Age: 92

Onset Date: 20/07/2002 **DOB**: 23/02/1910

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Medicine Details:

PANADEINE FORTE (Other drug) Reason: Pain

4.0 Dose Unspecified Daily

Batch: Started: L TERM Stopped: 24/07/2002

SOMAC (Other drug) Reason: Other diseases of esophagus

40.0 Milligram Daily

Batch: Started: 19/07/2002 **Stopped:** 24/07/2002

OROXINE (Other drug) Reason: Thyrotoxicosis w/o ment goiter

Tablet 100.0 Microgram Alternate days Oral

Batch: Started: L TERM Stopped: 24/07/2002

THYROXINE SODIUM (Other drug) Reason: Thyrotoxicosis w/o ment goiter

125.0 Microgram Alternate days

Batch: Started: L TERM Stopped: 24/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =	(<50)	23/07/2002	219	
	Haemoglobin	(120-180)	22/07/2002	92	
	Lymphocytes	(1.00-4.00)	22/07/2002	9.81	
	Neutrophils	(2.00-8.00)	22/07/2002	11.75	
	Prothrombin time	(8-14)	23/07/2002	21	
	SAP = ALP	(40-110)	20/07/2002	157	
	SAP = ALP	(40-110)	23/07/2002	319	

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 177716
 Seq: 1
 Gender: M

 Reported:
 05/08/2002
 Weight:

Hospitalisation: Age: 92

Onset Date: 20/07/2002 **DOB**: 23/02/1910

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

2.5 Milligram Daily

Batch: Started: 18/04/2002 **Stopped:** 21/07/2002

ZOTON (Suspected) Reason: Other diseases of esophagus

30.0 Milligram Daily

Batch: Started: 01/03/2000 Stopped: 18/07/2002

Laboratory Investigations:

<u> </u>	i y miroodigadionoi								
Date	Туре	Range	Date Tested	Result	Details				
	Troponin	(<0.05)	20/07/2002	2.00					
	White blood cells	(3.5-11.0)	22/07/2002	22.3					

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 177743
 Seq: 1
 Gender: U

 Reported:
 01/08/2002
 Weight:

Hospitalisation: Age: 19

Onset Date: 03/05/2002 **DOB**: 02/10/1982

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Urticaria		,	Patient required a visit to doctor. patient was treated with phenergan and prednisolone. medication ceased.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

20.0 Milligram Daily

Batch: Started: S TERM Stopped: 03/05/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Dose had been increased from 10mg to 20mg four weeks earlier. no previous history of allergies, but gets very mild eczema in dry weather.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 177890
 Seq: 1
 Gender:
 F

 Reported:
 09/08/2002
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 18/07/2002
Age: 44Y
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			Patient was hospitalised. clonidine was ceased.

Medicine Details:

Medicine Details.				
LITHIUM CARBONATE (Other drug)		Reason:		
	0.0			
Batch:	Started:	Stop	ped:	
CLONIDINE HYDROCHLORIDE (Oth	ner drug)	Reason:		
	0.0			
Batch:	Started:	Stop	ped:	
ZYPREXA (Suspected)		Reason: Unspecif	personality disor	der
Tablet	30.0 Milligram	Daily	Oral	
Batch:	Started: 01/06/2002	Stop	ped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of diabetes and obesity.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 177891
 Seq: 1
 Gender: M

 Reported:
 09/08/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 20Y
Onset Date: 28/07/2002 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	todotion Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Drug ineffective			Patient was hospitalised.	ĺ
	Psychotic disorder				

Medicine Details:

ZYPREXA (Suspected) Reason: Othr&unspec metabolic diseases

 Tablet
 10.0 Milligram
 Daily
 Oral

 Batch:
 Started: 01/04/2002
 Stopped: 28/07/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date and stop dates are not necessarily accurate but indicates zyprexa was started and stopped sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 177892
 Seq: 1
 Gender: M

 Reported:
 09/08/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 20Y

Onset Date: 28/07/2002 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		4 days after treatment exp. seizure for 10 minutes	

Medicine Details:

ZYPREXA (Suspected) Reason: Othr&unspec metabolic diseases

 Tablet
 15.0 Milligram
 Daily
 Oral

 Batch:
 Started: 01/04/2002
 Stopped: 28/07/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The onset date is not necessarily accurate but indicates onset sometime in the month. the dose start and stop dates are not necessarily accurate but indicates zyprexa was started and stopped sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 178000
 Seq: 1
 Gender:
 F

 Reported:
 12/08/2002
 Weight:
 45.00

Hospitalisation: Admitted to hospital **Age**: 78

Onset Date: 04/08/2002 **DOB**: 03/08/1924

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Blood creatine phosphokinase incr			
Confusional state			Patient was hospitalised. ceased olanzapine temporarily. restarted 8/8/02.

Medicine Details:

AMILORIDE HYDROCHLORIDE (Other drug)			Reason:	Essential beniç	gn hypertension
Oral application	5.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
ASPIRIN (Other drug)			Reason:	Acute,ill-def ce	rebrovascular disease w/o hyperte
Oral application	150.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
DIGOXIN (Other drug)			Reason:	Otr&nos disord	of heart rhythm
Oral application	250.0	Microgram	Daily		Oral
Batch:	Started:			Stopped:	
OLANZAPINE (Suspected)			Reason:	Schizophrenia	
Tablet	5.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	04/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 178558 Seq: 1 Gender: M

Reported: 30/08/2002 Weight: 108.00 Hospitalisation: Age: 50Y

Onset Date: 13/08/2002 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Try ceasing first mirtazapine and then olanzopine.

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE	(Suspected)	Reason: Depression	
Tablet	50.0 Milligram	As necessary	Oral
Batch:	Started: 01/08/2002	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 01/04/2002	Stopped:	03/08/2002
MIRTAZAPINE (Suspected)		Reason: Depression	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 01/08/2002	Stopped:	
LORAZEPAM (Suspected)		Reason: Depression	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 01/08/2002	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils				Neutrophil count 1.46.

Additional Information:

The dose start dates are not necessarily accurate but indicates mirtazapine, lorazepam, chlorpramazine, olanzopine were started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:					
Case Number: 178564 Reported: 30/08/2002 Hospitalisation: Onset Date: Outcome: Recovered	Seq: 1		Gender: U Weight: Age: 38 DOB: 21/03/1964 Causality: Causality probable		
eaction Details: Preferred Term	Severity	Report Descri	otion Treatment		
Increased appetite Weight increased	20.0,		Patient recovered 23/8/02.		
Medicine Details: OLANZAPINE (Suspected)			pecified psychosis		
Tablet Batch:	15.0 Millių Started: 12/08/20		Oral Stopped: 27/08/2002		
Laboratory Investigation	ns:				
Laboratory Investigation Date Type	IS: Range Date Tested	Result	Details		

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 178592
 Seq: 1
 Gender: M

 Reported:
 04/09/2002
 Weight:

Hospitalisation: Admitted to hospital **Age**: 39

Onset Date: 12/08/2002 **DOB:** 30/08/1962

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest			
Cardiomyopathy			
Hypocalcaemia			
Hypokalaemia			
Hyponatraemia			
Neuroleptic malignant syndrome			Patient died: 16/8/02.
Pyrexia			
Shock			

Medicine Details:

OLANZAPINE (Suspected)		Reason:
Tablet	0.0	Oral
Batch: Started:		Stopped:
EPILIM (Suspected)		Reason:
Tablet	0.0	Oral
Batch:	Started:	Stopped:
EFEXOR (Suspected)		Reason:
Oral application	0.0	Oral
Batch:	Started:	Stopped:
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 16/07/2002	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Calcium	1.12 - 1.30	15/08/2002	0.9	
	Creatine	30 - 200 IÚ/L	15/08/2002	1360	
	Potassium	3.5 - 5.5	15/08/2002	2.9	
	Sodium	135 - 145	15/08/2002	129	

Additional Information:

Risk factors were: obesity, known aortic valve stenosis. the patient presented to the emergency department, collapsed and could not be resuscitated. the patient died on 16/08/02.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 178787
 Seq: 1
 Gender:
 F

 Reported:
 06/09/2002
 Weight:
 46.00

 Hospitalisation:
 Age:
 87Y

Onset Date: 15/07/2002 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Decreased phenytoin dose. recommend increasing epilim if further fits.

Medicine Details:

FOSINOPRIL (Other drug)	Re	eason:	
Tablet	0.0		Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Other drug)	Re	eason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 12/07/2002	Stopped:	15/07/2002
COLOVVI WITH SENNA (Other drug)	D	eason:	
COLOXYL WITH SENNA (Other drug)	N	eason:	
Tablet	4.0 Dose Unspecifie		Oral
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \			Oral
Tablet	4.0 Dose Unspecifie Started: 13/07/2002	d Daily	Oral
Tablet Batch:	4.0 Dose Unspecifie Started: 13/07/2002	d Daily Stopped:	Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		12/07/2002	70	O/a alt 59
	ALT = SGPT		16/07/2002	114	O/a alt 59
	AST = SGOT		16/07/2002	48	
	GGT = SGGT =		12/07/2002	308	O/a ggt 256
	GGT = SGGT =		16/07/2002	397	O/a ggt 256
	Pharmacokinetics	PHENYTOIN	12/07/2002	49	
	Pharmacokinetics	PHENYTOIN	16/07/2002	10	

Additional Information:

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Gender: F

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:		
Case Number: 178787	Seq: 1	

Reported: 06/09/2002 Weight: 46.00 Hospitalisation: Age: 87Y

Onset Date: 15/07/2002 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ATENOLOL (Other drug)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stoppe	d: CONTIN
METFORMIN HYDROCHLORIDE (Other d	rug)	Reason: Diabetes m	ellitus
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started:	Stoppe	d:
GLICLAZIDE (Other drug)		Reason: Diabetes m	ellitus
Tablet	80.0 Milligram	Daily	Oral
Batch:	Started:	Stoppe	d:
METRONIDAZOLE (Suspected)		Reason:	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 10/07/2002	Stoppe	d : 16/07/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP		12/07/2002	137	_o/a alp 174.
	SAP = ALP		16/07/2002	146	_o/a alp 174.

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

 Case Number:
 178787
 Seq: 1
 Gender:
 F

 Reported:
 06/09/2002
 Weight:
 46.00

 Hospitalisation:
 Age:
 87Y

Onset Date: 15/07/2002 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

EPILIM (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 13/07/2002	Stopped:	
PHENYTOIN SODIUM (Suspected)		Reason: Convulsions	
Capsule	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CEPHALEXIN (Suspected)		Reason: Othr diseases	of urinary tract
Capsule	1.5 Gram	Daily	Oral
Batch:	Started: 10/07/2002	Stopped:	16/07/2002
OLANZAPINE (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2002	Stopped:	16/07/2002

Laboratory Investigations:

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

lospitalisatio Onset Da	er: 178791 ed: 06/09/2002 on: ate: 15/07/2002 ne: Unknown	Seq:	1			С	DO	t: e: 77Y
eaction De		1 0-		D				Taradasasad
Prei Orthostatic hy	ferred Term ypotension	Se	everity	Керо	ort De	scription	Ę	Treatment Dianzapine dose decreased to find by with view to further decrease to 2.5mg mane and fing nocte.
Medicine E OLANZAPINE Tablet Batch ERGOCALCIF Capsu	(Other drug) : EROL (Other drug)		tarted:	Rea Milligram Rea Thousand Internal	Daily	Schizophrenia Stopped:	Oral	CONTIN
Batch		St	tarted:	mousand internal	Daily	Stopped:	Olai	CONTIN
CALCIUM CAF	RBONATE (Other d	rug)		Rea	son:			
			600.0	Milligram	Daily		Oral	
Tablet								0.01.1711.1
Tablet Batch		St	tarted:			Stopped:		CONTIN
Batch		St	tarted:	Rea	son:	Stopped: Pain		CONTIN
Batch	: OL (Other drug)	St		Rea Gram	son: Daily		Oral	CONTIN
Batch PARACETAMO	o: OL (Other drug)						Oral	CONTIN
Batch PARACETAMO Tablet Batch	o: OL (Other drug)	Si	4.0			Pain	Oral	
Batch PARACETAMO Tablet Batch	o: OL (Other drug)	Si	4.0	Gram		Pain		
Batch PARACETAMO Tablet Batch	:: OL (Other drug) :: / Investigatio	sı ons:	4.0	Gram		Pain		CONTIN

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Report Details:

Case Number: 178791

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

t:
e: 77Y
В:
y: Causality possible
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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1 Severity K+	Report Description level up to 6	Gender: F Weight: Age: 56 DOB: 03/04/1946 Causality: Causality probable Treatment Olanzapine ceased.	
Severity		Weight: Age: 56 DOB: 03/04/1946 Causality: Causality probable Treatment	
		Age: 56 DOB: 03/04/1946 Causality: Causality probable Treatment	
		DOB: 03/04/1946 Causality: Causality probable Treatment	
		Causality: Causality probable Treatment	
		Treatment	
K+	level up to 6	Olanzapine ceased.	
0.0	Reason:		
	Result	Details	
07/06/2002			
	0.0 Started: ge Date Tested 07/06/2002	Started: Stopp	

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 178822 Seq: 1 Gender: F

Reported: 09/09/2002 Weight: 71.00
Hospitalisation: Admitted to hospital Age: 76

Onset Date: 23/08/2002 DOB: 14/03/1926

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Patient was hospitalised. date of recovery 30.8.02.

Medicine Details:

ASPIRIN (Other drug)	Reason:	Prophylaxis

100.0 Milligram Daily

Batch: Started: 25/07/2002 Stopped:

ATORVASTATIN (Other drug) Reason:

40.0 Milligram Daily

Batch: Started: Stopped:

METOPROLOL TARTRATE (Other drug) Reason:

200.0 Milligram Daily

Batch: Started: Stopped:

OLANZAPINE (Suspected) Reason: Otr spec symp psychopathol nec

Tablet 2.5 Milligram As necessary Oral

Batch: Started: 18/07/2002 **Stopped:** 23/08/2002

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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 178822	Seq: 1		Gender: F	=	
Reported: 09/09/2002		,	Weight: 7	71.00	
Hospitalisation: Admitted to hosp	oital		Age: 7		
Onset Date: 23/08/2002			DOB: 1	14/03/1926	
Outcome: Recovered		Ca	ausality: (Causality possible	
Reaction Details:					
Medicine Details:					
CLOPIDOGREL (Suspected)		Reason: Prophylaxis			
Tablet	75.0 Milligram		Oral		
Batch:	Started: 25/07/2002	Stopped:	23/08/2002		
Laboratory Investigations:					
Additional Information:					

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 178829
 Seq: 1
 Gender: M

 Reported:
 10/09/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 84Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Prostatic disorder		Prostatomegaly	
Pancytopenia			
Renal failure acute			
Urinary retention			Patient was hospitalised.

Medicine Details:

wedicine Details:					
LITHIUM CARBONATE (Other drug)			Reason:		
	750.0	Milligram	Daily		
Batch:	Started:			Stopped:	
OLANZAPINE (Suspected)			Reason:		
Tablet	5.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	08/08/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

178829 is a seq of 178830

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 178830 Seq: 1 Gender: M

Reported: 10/09/2002 Weight:
Hospitalisation: Age: 84Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Lithium toxicity	Ceased olanzapine.

Medicine Details:

Miculcine Details.					
LITHIUM CARBONATE (Interaction)			Reason:		
Oral application	750.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
OLANZAPINE (Interaction)			Reason:		
Tablet	5.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	08/08/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

178830 is a seq of 178829.

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Date Range: 1 Jan 2000 To 31 Dec 2002 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: 178835 Seq: 1 Gender: F

Reported: 09/09/2002 Weight:
Hospitalisation: Age: 26

Onset Date: 02/08/2002 **DOB**: 31/12/1975

Outcome: Unknown Causality: Causality possible

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Weight increased			Deceased olanzapine to 5mg daily from 10mg on 21/8/02.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

Tablet 10.0 Milligram Daily Oral

Batch: Started: 02/08/2002 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 178848 Seq: 1 Gender: F

Reported: 11/09/2002 Weight: 95.00 Hospitalisation: Age: 26

Onset Date: **DOB**: 04/09/1976

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Weight increased		Went from 73kg to 95kg. nov 01 to sep 02.	Diet, exercise, change antipsychotic.

Medicine Details:

neulcine Delans.				
PAROXETINE HYDROCHLORIDE (Othe	Reason: Depress	ion		
	60.0 Milligram	Daily		
Batch:	Started:	Stopped:		CONTIN
SODIUM VALPROATE (Suspected)		Reason:		
Tablet	1.0 Gram	Daily	Oral	
Batch:	Started: 31/10/2001	Stopped:		CONTIN
OLANZAPINE (Suspected)		Reason:		
Oral application	5.0 Milligram	Daily	Oral	
Batch:	Started: 21/11/2001	Stop	ped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number:178931Seq: 1Gender:FReported:11/09/2002Weight:0.00Hospitalisation:Admitted to hospitalAge: 99U

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

toaction Botano.			
Preferred Term	Severity	Report Description	Treatment
Neonatal disorder		Congenital aqueduct stenosis leading to hydrocephalus	Baby may need shunt
Congenital brain damage Congenital hydrocephalus			

Medicine Details:

ZYPREXA (Suspected)Reason:Unspecified psychosis10.0MilligramDailyOral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Male baby date of birth 25/8/02, born to mother who was taking olanzapine 10mg daily through pregnancy. Diagnosided antenally by uss congenites aqueduct stenosis -> hydrocephalus.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 179053 Seq: 1 Gender: M

Reported: 16/09/2002 Weight: 70.00 Hospitalisation: Age: 40

Onset Date: 05/06/2002 **DOB**: 30/01/1962

Outcome: Recovered Causality: Causality possible

Reaction Details:

- :									
	Preferred Term	Severity	Report Description	Treatment					
	Hyperglycaemia			Patient required a visit to doctor. date of recovery: 30/7/02.					

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 20.0 Milligram Daily Oral

Batch: Started: 08/01/2002 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Sugar levels were performed prior to olanzapine and were normal sugar on 5/6/02 9.1.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 179107
 Seq: 1
 Gender:
 F

 Reported:
 18/09/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 50Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

leaction Details.							
Preferred Term	Severity	Report Description	Treatment				
Neuroleptic malignant syndrome							
Neurosis			All medications withdrawn. patient hospitalised.				

Medicine Details:

Medicine Details.				
NEULACTIL (Suspected)		Reason:		
	0.0			
Batch:	Started:		Stopped:	
ZOLOFT (Suspected)		Reason:	Depression	
Tablet	50.0 Millig	ram Daily		Oral
Batch:	Started: 23/03/20	02	Stopped:	04/04/2002
ZYPREXA (Suspected)		Reason:		
Tablet	10.0 Millig	ram Daily		Oral
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Relevant history - mental retardation.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 179124
 Seq: 1
 Gender:
 F

 Reported:
 19/09/2002
 Weight:

Hospitalisation: Admitted to hospital **Age**: 37

Onset Date: 26/08/2002 DOB: 16/10/1964

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•					
	Preferred Term	Severity	Report Description	Treatment	ĺ
	Hepatocellular damage	Life threatening		Ceased zyprexa and largactil. patient was hospitalised.	1

Medicine Details:

Medicine Details.			
LARGACTIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	100.0 Milligram	1 time Oral	
Batch:	Started: 23/08/2002	Stopped: 23/08/2002	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started: 25/08/2002	Stopped: 27/08/2002	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		25/08/2002	48	
	ALT = SGPT		26/08/2002	490	
	ALT = SGPT		01/09/2002	496	
	ALT = SGPT		28/08/2002	704	
	AST = SGOT		25/08/2002	45	
	AST = SGOT		26/08/2002	289	
	AST = SGOT		28/08/2002	143	

Additional Information:

Previous hepatotoxicity with chlorpromazine.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 179124
 Seq: 1
 Gender:
 F

 Reported:
 19/09/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 37

Onset Date: 26/08/2002 DOB: 16/10/1964

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.			
LARGACTIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	100.0 Milligram	1 time Oral	
Batch:	Started: 23/08/2002	Stopped: 23/08/2002	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started: 25/08/2002	Stopped: 27/08/2002	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT		01/09/2002	67	
	GGT = SGGT =		25/08/2002	38	
	GGT = SGGT =		26/08/2002	154	
	GGT = SGGT =		28/08/2002	264	
	GGT = SGGT =		01/09/2002	226	

Additional Information:

Previous hepatotoxicity with chlorpromazine.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 179256 Seq: 1 Gender: M
Reported: 08/10/2002 Weight:
Hospitalisation: Age: 89Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Hypertonia			
Salivary hypersecretion			Olanzapine ceased.
Tremor			

Medicine Details:

vieuicine Delans.				
DIGOXIN (Other drug)		Reason:		
Tablet	125.0 Mi	crogram Daily		Oral
Batch:	Started:		Stopped:	
WARFARIN SODIUM (Other drug)		Reason:	Otr&nos disord	of heart rhythm
Tablet	5.0 Mi	lligram Daily		Oral
Batch:	Started:		Stopped:	
OLANZAPINE (Suspected)		Reason:		
Tablet	2.5 Mi	lligram Daily		Oral
Batch:	Started: 28/08/2	2002	Stopped:	05/09/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Date of onset of reaction unknown. diagnosis of lewy body dementia. very sensitive to eps effects of antipsych- otics. this report is a seq of 179257.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 179287 Seq: 1 Gender: F
Reported: 20/09/2002 Weight:

Hospitalisation: Admitted to hospital Age: AE
Onset Date: 28/07/2002
DOB:

Uniset Date: 20/07/2002

Outcome: Unknown Causality: Causality possible

Reaction Details:

deaction Details.							
Preferred Term	Severity	Report Description	Treatment				
Confusional state							
Myalgia							
Neuroleptic malignant syndrome			Patient was hospitalised. zyprexa ceased.				
Pyrexia							

Medicine Details:

Medicine Details.						
MICARDIS (Other drug)			Reason:			
Oral application	40.0	Milligram	Daily		Oral	
Batch:	Started:	L	TERM	Stopped:		CONTIN
ZYPREXA (Suspected)			Reason:	Unspecified ps	sychosis	
Tablet	2.5	Milligram	Daily		Oral	
Batch:	Started: 01/	04/2001		Stopped:	28/08/2002	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start and stop dates are not necessarily accurate but indicates the drug was started and stopped sometime in the month. medical history included: hypertension. patient is 103 years old.

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DOB: 28/06/1974

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE, ZYPREXA, Zyprexa IM, Zyprexa Zydis

Report Details:

Gender: M Case Number: 179288 Seq: 1 Reported: 20/09/2002 Weight:

Hospitalisation: Admitted to hospital Age: 27

Onset Date: 11/05/2002 Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

ouotion botano.							
Preferred Term	Severity	Report Description	Treatment				
Convulsion			Patient was admitted to hospital. olanzapine treatment was discontinued on 20/6/02, venlafaxine hcl continues.				
Hypertonia Syncope							

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)		Reason: Unspecified so	chizophrenia
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 02/05/2002	Stopped:	20/06/2002
EFEXOR (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 02/05/2002	Stopped:	CONTIN

Laboratory Investigations:

	and the angular tree.				
Date	Туре	Range	Date Tested	Result	Details
	Electroencephalog				On 22/6/02 an electroencephalogram performed was abnormal the record contained epiletiform activity seen on one occasion during the resting record. there were no focal features. a computerised tomography scan performed on 12/5/02 was normal. electroencephalaography/abnormal/22/6/02, computerised axial tomography/cat/ normal 12/5/02.

Additional Information:

Medical history included: schizophrenia, no history of seizures. nocturnal bed wetting since age 6 years old. the patient also had no history of electrolyte imbalance, eclampsia, liver failure, renal failure, hypertensive encephalopathy, meningitis, encephalitis/abscess, head trauma, stroke and no history of any anticonvulsant medications. on the 12/6/02 the dose of olanzapine was increased to 30mg/daily.the patients venlafaxine dose had also been increased to 300mg/daily.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Detai	ls:

 Case Number:
 179412
 Seq: 1
 Gender:
 F

 Reported:
 26/09/2002
 Weight:

Hospitalisation: Admitted to hospital **Age**: 49

Onset Date: 06/08/2002 **DOB**: 08/11/1952

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Non-accidental overdose.	
Coma			Patient was admitted to hospital and admitted to icu, treated with iv fluids, was ventilated and given other medicines in icu.
Delirium			
Hallucination			

Medicine Details:

TRIFEME 28 (Other drug)		Reason: Contraception	
Oral application	0.0	Oral	
Batch:	Started: 01/06/2002	Stopped:	
BEKUNIS-TABLET (Other drug)		Reason: Constipation	
Tablet	0.0	Oral	
Batch:	Started: 01/06/2002	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.5 Gram	Total Oral	
Batch:	Started:	Stopped:	
EPILIM (Suspected)		Reason:	
Tablet	10.0 Gram	Total Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

<u> </u>	y mirodugudono.						
Date	Туре	Range	Date Tested	Result	Details		

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:				
Case Number: 179412 Reported: 26/09/2002 Hospitalisation: Admitted to the Onset Date: 06/08/2002 Outcome: Recovered Reaction Details:	Seq: 1		Gender: F Weight: Age: 49 DOB: 08/11/1952 Causality: Causality possible	
Medicine Details:				_
SERENACE (Suspected)		Reason:		
Tablet Batch:	100.0 Gram Started:	Total Stopped:	Oral	
Laboratory Investigation	าร:			
Additional Information:				

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 179421
 Seq: 1
 Gender: M

 Reported:
 26/09/2002
 Weight:

Hospitalisation: Age: 41Y

Onset Date: 19/09/2002 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touction bottom			
Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus			Olanzapine ceased.
Polydipsia			
Polyuria			
Visual disturbance			

Medicine Details:

 OLANZAPINE (Suspected)
 Reason:
 Unspecified psychosis

 Oral application
 300.0
 Milligram
 Daily
 Oral

Batch: Started: 01/01/2000 **Stopped:** 19/09/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No family history for diabetes, no risk factors.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 179509 Seq: 1 Gender: M
Reported: 01/10/2002 Weight:
Hospitalisation: Age: 71

Onset Date: 07/08/2002 DOB: 25/06/1931

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Cachon Details.			
Preferred Term	Severity	Report Description	Treatment
Neutropenia	Life threatening	Life threatening.	Cessation of both olanzapine and mirtazapine. treated with amoxycillin and metronidazole. patient deceased on 09/08/02.
Pneumonia			

Medicine Details:

AMOXYCILLIN SODIUM (Other drug)			Reason:		
Oral application	2.0	Gram	Daily	Oral	
Batch:	Started:			Stopped:	
METRONIDAZOLE (Other drug)			Reason:		
Oral application	1.0	Gram	Daily	Oral	
Batch:	Started:			Stopped:	
PRAZOSIN HYDROCHLORIDE (Other drug)			Reason:		
Oral application	4.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
OXAZEPAM (Other drug)			Reason:		
Oral application	130.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				Neutrophils 0.58, lylmphocytes 0.32, monocytes 0.11, eosinophils 0.03. wcc 1.6, rcc 3.99, hct 0.39. moderate neutropenia, with a left shift.
	Radiololgy				Chest x-ray shows right sided patchy opacity.

Additional Information:

Prior history of aspiration pneumonia.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report	Details:
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Case Number: 179509 Seq: 1 Gender: M
Reported: 01/10/2002 Weight:

Hospitalisation: Age: 71

Onset Date: 07/08/2002 DOB: 25/06/1931
Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Ν	1	е	d	Ī	Ci	n	е	D	е	ta	il	S	
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SENOKOT (Other drug)		Rea	ason:	
Tablet	2.0	Dose Unspecified	Daily	Oral
Batch:	Started:			Stopped:
TEMAZEPAM (Other drug)		Rea	ason:	
Oral application	10.0	Milligram	Daily	Oral
Batch:	Started:			Stopped:
PARACETAMOL (Other drug)		Rea	ason:	
Oral application	4.0	Gram	Daily	Oral
Batch:	Started:			Stopped:
MIRTAZAPINE (Suspected)		Rea	ason:	
Tablet	0.0			Oral
Batch:	Started:			Stopped:

Laboratory Investigations:

Additional Information:

Prior history of aspiration pneumonia.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Case Number: 179 Reported: 01/7 Hospitalisation: Onset Date: 07/0 Outcome: Dea	08/2002 ath, maybe drug	: 1				
Medicine Details				D		
OLANZAPINE (Suspector Tablet	ea)	10.0	Milligram	Reason: Daily	Oral	
Batch:	9	tarted:	wiiiigram	Dally	Stopped:	
Laboratory Inves	stigations:					
Additional Inform Prior history of aspiration						

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Caca Nun	nber: 179589	Sog. 1			Gender: F	
	orted: 04/10/2002	Seq: 1			sender: r Veight:	
ospitalisa				•	Age: 33Y	
Ospitalisa Onset I					DOB:	
	ome: Not yet recov	arad		Ca	u sality : Causa	lity nossible
eaction [=	cieu		Oa.	usanty. Causa	iity possible
	referred Term	Severity	Report Do	escription	Т	reatment
Conjunctivit		1111		P		
Eye pain						
Headache						
Photophobi	ia					
Pruritus	-					
Madiaina	Details:					
ZYPREXA (\$			Reason:			
	ouspecteu,	0.0	reason.			
Bat	tch:	Started:		Stopped:		
ZOLOFT (Su	uspected)		Reason:	Depression		
Tab	olet	25.0 N	Ailligram Daily	•	Oral	
Tub						
	tch:	Started: 04/09	9/2002	Stopped:		
Bat	ory Investigation		9/2002	Stopped:		
Bat	ory Investigation			Stopped:	Details	

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 179757
 Seq: 1
 Gender: M

 Reported:
 08/10/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 68Y
Onset Date: 28/09/2002 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touction Details.			
Preferred Term	Severity	Report Description	Treatment
Coma			
Delirium			Pateint was hospitalised. zyprexa ceased. treated with 2.5mg haloperidol deconoate.
Hallucination			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 01/08/2002 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for zyprexa is not necessarily accurate but indicates the drug was started sometime in the month. within 24 hours of starting att his increased dose the patient experienced delirium.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 179758 Gender: M Seq: 1 Weight: Reported: 08/10/2002

Hospitalisation: Admitted to hospital Age: 55Y Onset Date: 04/09/2002 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Pateint was hospitalised. zyprexa ceased and whitched to serequel.

Medicine Details:						
DIAZEPAM (Other drug)		Reason:				
	0.0					
Batch:	Started:	Stopped:				
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia				
Tablet	20.0 Milligram	Daily Oral				
Batch:	Started: 01/01/1998	Stopped: 01/01/2002				

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start and stop dates for zyprexa are not accurate but indicates it was started and stopped sometime in the year. patient history: long history of schizophrenia.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 180257 Seq: 1 Gender: U

Reported: 31/10/2002 **Weight:** 60.00

Hospitalisation: Admitted to hospital Age:
Onset Date: 11/10/2002 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

٠,	todotion botanoi			
	Preferred Term	Severity	Report Description	Treatment
	Diabetes mellitus			Patient was hospitalised. ceased olanzapine. started insulin.

Medicine Details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

 Tablet
 20.0 Milligram
 Daily
 Oral

 Batch:
 Started: 01/01/1999
 Stopped: 15/10/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not accurate but indicates the drug was started sometime in the year. sequelae: diabetes life long.

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Report Details:

Case Number: 180261

Reported: 31/10/2002

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Seq: 1

Oneot Date		hospital	Age : 52Y				
Oliset Date	e : 23/09/2002				DC	DB:	
Outcome	e: Recovered					Causali	ty: Causality possible
action Det	ails:						
Prefe	rred Term	Sev	erity	Repo	rt Description	on	Treatment
ardiomyopath	ny						
ardiomyopath	ıy						
onfusional sta	ate						
onsciousness	s fluctuating						
elirium							
lectrocardiogr	ram abnormal						
lyocardial infa	arction						
sychotic disor	rder	Severe	•				Haloperidol. Patient admitted to hospital. Started on digoxin metoprolol, ramipril
roponin increa	ased						
ledicine De	etails:						
HALOPERIDOL				Reas	on: Psycho	osis asso w otr p	phys cond
Batch:		Sta	rted:		Sto	pped:	
TEMAZEPAM (O	Other drug)			Reas	on:		
Batch:		Sta	rted:		Sto	pped:	
CIPRAMIL (Other	er drug)			Reas	on:		
Oral app	olication		40.0 Milli	Milligram Daily Oral			
Batch:		Sta	rted:		Sto	pped:	
OLANZAPINE (S	Suspected)			Reas	on:		
			0.0				
Batch:		Sta	rted:	Stopped : 28/09/2001			
aboratory	Investigatio	ne:					
Date	Type		Date Tested	Result		D	etails
17/12/2002 Oth		- I I I I I I I I I I I I I I I I I I I					- 1
17/12/2002 Ott	ici uala						



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

180261	Seq: 1			Gender:	1
31/10/2002				Weight:	0.00
	tal				
			Ca		Causality possible
				•	, , , , , , , , , , , , , , , , , , ,
ils:					
ected)		Reason:	Unspecified ps	ychosis	
	600.0 Milligram	Daily		Oral	
	Started: 28/09/2001		Stopped:	22/09/2002	
vestigations:					
vestigations: ormation:					
		Admitted to hospital 23/09/2002 Recovered Is: ails: ected) 600.0 Milligram	Admitted to hospital 23/09/2002 Recovered s:	Admitted to hospital 23/09/2002 Recovered Ca S: **Ils:** **Reason: Unspecified ps: 600.0 Milligram Daily	Admitted to hospital 23/09/2002 DOB: Recovered Causality: S:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 180282 Seq: 1 Gender: F

Reported: 01/11/2002 Weight: 95.00 Hospitalisation: Age: 46

Onset Date: 10/07/2002 **DOB**: 25/07/1955

Outcome: Recovered Causality: Causality probable

Reaction Details:

caction betains.			
Preferred Term	Severity	Report Description	Treatment
Periorbital oedema			Rsistant to duretic. ceased olanzepine. required a visit to doctor.

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other	drug)	Reason:	Depression	
	20.0 Milligram	Daily		
Batch:	Started: 01/01/2000		Stopped:	CONTIN
IRBESARTAN (Other drug)		Reason:	Essential benign hyperte	ension
	300.0 Milligram	Daily		
Batch:	Started: 01/01/2001		Stopped:	CONTIN
LITHICARB (Other drug)		Reason:		
	1.2 Gram	Daily		
Batch:	Started: 01/01/1990		Stopped:	CONTIN
SODIUM VALPROATE (Other drug)		Reason:		
	600.0 Milligram	Daily		
Batch:	Started: 01/01/1990		Stopped:	

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 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	180282	Seq: 1		Gender:	
Reported:	01/11/2002			Weight:	95.00
ospitalisation:				Age:	
Onset Date:					25/07/1955
	Recovered			Causality:	Causality probable
action Detai	ls:				
Andinina Dati	-il-:				
Medicine Deta PREMARIN (Other			Reason:	Menopausal symptoms	
. ALMARIN (Onle)	u. ug,	300.0 Microgram	Daily	menopaada dyniptonia	
Batch:		Started: 01/01/2000	Daily	Stopped:	
		-12.10a. 5 1/5 1/2000			
OLANZAPINE (Sus	spected)		Reason:		
OLANZAPINE (Sus	spected)	5.0 Milligram	Reason:		
	spected)	5.0 Milligram Started:	Reason: Daily	Stopped:	
OLANZAPINE (Sus	spected)	5.0 Milligram Started:		Stopped:	
	spected)			Stopped:	
	spected)			Stopped:	
	spected)			Stopped:	
	spected)			Stopped:	
	spected)			Stopped:	
Batch:		Started:		Stopped:	
Batch:		Started:		Stopped:	
		Started:		Stopped:	
Batch:		Started:		Stopped:	
Batch:		Started:		Stopped:	
Batch:		Started:		Stopped:	
Batch:		Started:		Stopped:	
Batch:		Started:		Stopped:	
Batch:		Started:		Stopped:	
Batch:	vestigations	Started:		Stopped:	
Batch:	vestigations	Started:		Stopped:	
Batch:	vestigations	Started:		Stopped:	
Batch:	vestigations	Started:		Stopped:	
Batch:	vestigations	Started:		Stopped:	



Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

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

Case Number: 180470 Seq: 1 Gender: M
Reported: 11/11/2002 Weight:

Hospitalisation: Admitted to hospital Age: 19
Onset Date: DOB: 23/08/1983

Outcome: Recovered Causality: Causality possible

Reaction Details:

touotion Dotumor			
Preferred Term	Severity	Report Description	Treatment
Pyrexia		Auroneunic instability.	
Blood creatine phosphokinase incr			
Blood pressure fluctuation			
Leukocytosis			
Neuroleptic malignant syndrome			Ceased neuroleptics. patient hospitalised.

Medicine Details:

Medicine Details.			
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	30.0 Milligram	Daily Oral	
Batch:	Started: 30/09/2002	Stopped: 17/10/2002	
HALOPERIDOL (Suspected)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 30/09/2002	Stopped : 17/10/2002	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 180527 Seq: 1 Gender: M

Reported: 11/11/2002 Weight:
Hospitalisation: Age: 67Y

Onset Date: 28/03/2002 DOB:

Outcome: Not yet recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified psychosis

Tablet 2.5 Milligram Daily Oral

Batch: Started: 01/03/2002 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for the drug zyprexa is not necessarily accurate but indicates the drug was started sometime in the month.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 180696 Seq: 1 Gender: M
Reported: 18/11/2002 Weight: 88.00

 Hospitalisation:
 Age: 44

 Onset Date: 21/08/2002
 DOB: 13/09/1957

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anorexia			
Anxiety			
Asthenia			
Chills			
Dizziness			
Hyperhidrosis			
Malaise			
Myalgia			
Nausea			
Polyuria			Recovered 6/0/02.
Pruritus			

Medicine Details:

MIXTARD 30/70 (Other drug)		Reason:	
	0.0		
Batch:	Started: 01/06/2002	Stopped:	
ZOLOFT (Other drug)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started: 01/01/1997	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	3D

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also suffering from insomnia.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 180696 Seq: 1 Gender: M

Reported: 18/11/2002 Weight: 88.00 Hospitalisation: Age: 44

Onset Date: 21/08/2002 **DOB**: 13/09/1957

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting			

Medicine Details:

MIXTARD 30/70 (Other drug)		Reason:	
	0.0		
Batch:	Started: 01/06/2002	Stopped:	
ZOLOFT (Other drug)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started: 01/01/1997	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	3D

Laboratory Investigations:

Additional Information:

Patient was also suffering from insomnia.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 180765
 Seq: 1
 Gender: M

 Reported:
 18/12/2002
 Weight:
 0.00

Hospitalisation: Age: 84

Onset Date: DOB: 15/02/1918

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Somnolence	Life threatening	Very drowsy, extreme hypertonicity.	Oral Roxithromycin, Salbutamol Nebuliser and Ipratropium Bromide.
Hypertonia	Life threatening		
Serotonin syndrome	Life threatening		

Medicine Details:

AVANZA (Interaction)		Reason:	Unspecified ps	sychosis
Tablet	30.0 Milligram			Oral
Batch:	Started: 29/04/2002		Stopped:	18/09/2002
REMINYL (Interaction)		Reason:		
Tablet	8.0 Milligram	Daily		Oral
Batch:	Started: 26/08/2002		Stopped:	18/09/2002
ZYPREXA (Interaction)		Reason:	Unspecified ps	sychosis
Tablet	5.0 Milligram	Daily		Oral
Batch:	Started: 18/09/2002		Stopped:	
DIGOXIN (Other drug)		Reason:		
	62.5 Microgram			

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
18/12/2002	Other data				

Additional Information:

Patient was also taking Zyprexa 5mg, Warfarin 5mg and Lasix 40mg.

Patient history: Anaemia of chronic disease/mild renal impairment prior to starting galatamine and with mild mixed dementing illness - diagnosed July 02 as probable athrosclerotic disease and extensive small vessel cerebrovascular disease and a long history of major depression query psychotic element. He also had a history of atrial fibrillation and congestive cardiac failure. Clin Microbiol Infect 2003; 9: 1215-1218.

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DOB: 02/02/1929

Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

 Case Number:
 180798
 Seq: 1
 Gender:
 F

 Reported:
 18/12/2002
 Weight:
 85.00

Hospitalisation: Hospitalisation prolonged **Age**: 73

Outcome: Unknown Causality: Causality possible

Reaction Details:

Onset Date: 16/10/2002

Preferred Term	Severity	Report Description	Treatment
Tremor	Severe	Severe tremor, stiffness, shuffling gait, some drooilg, sedation and confusion, akathisia	Admitted to hospital.
Akathisia	Severe		
Confusional state	Severe		
Extrapyramidal disorder	Severe		
Gait disturbance	Severe		
Musculoskeletal stiffness	Severe		
Salivary hypersecretion	Severe		
Sedation	Severe		

Medicine Details:

Medicine Details.			
ZYPREXA (Suspected)		Reason: Unspecified page	sychosis
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 13/06/2002	Stopped:	09/10/2002
EPILIM (Suspected)	ı	Reason:	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 13/06/2002	Stopped:	09/10/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

	ils:				
Case Number	: 180800	Seq: 1		Gend	er: F
Reported	: 18/12/2002			Weig	nt : 0.00
lospitalisation	:			Α <u>ς</u>	je: 16
Onset Date):			DC	DB : 10/05/1986
Outcome	: Not yet recov	rered		Causali	ty: Causality possible
eaction Deta	ails:				
Prefer	red Term	Severity	Report	Description	Treatment
Weight increase	ed		Weight gain		Patient weaned off Risperidone ad weaned onto Quetiapine Fumarate.
Medicine De	tails:				
OLANZAPINE (S	uspected)		Reaso	n:	
Tablet				Oral	
Batch:		Started:		Stopped:	
ahoratory l	nvostigation	ne:			
Laboratory I			ed Result	D	etails
Laboratory I	nvestigation		ed Result	D	etails

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 180855 Seq: 1 Gender: M

Reported: 19/12/2002 Weight: 0.00
Hospitalisation: Age: 99U
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced a seizure.	

Medicine Details:

EFEXOR (Other drug)			Reason:		
Capsule	150.0	Milligram	Daily	Oral	
Batch:	Started:		S	Stopped:	
HALOPERIDOL (Other drug)			Reason:		
	10.0	Milligram	Daily	Oral	
Batch:	Started:		S	stopped:	
SODIUM VALPROATE (Other drug)			Reason:		
Tablet	1.0	Gram	Daily	Oral	
Batch:	Started:		S	stopped:	
ZYPREXA (Suspected)			Reason:		
Tablet	10.0	Milligram	Daily	Oral	
Batch:	Started:		9	stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Folate Sodium. Zyprexa was continued and increased from 20mg to 25mg.

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 180871 Seq: 1 Gender: F

Reported: 19/12/2002 Weight: 40.00 Hospitalisation: Admitted to hospital Age: 56

Onset Date: 09/11/2002 **DOB**: 20/10/1946

Outcome: Recovered 19/11/2002 Causality: Causality possible

Reaction Details:

Reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Pancytopenia		Pancytopenia, fever, mildly raised LFTs	Patient was hospitalised
Hepatic function abnormal			
Pyrexia			

Medicine Details:

Medicine Betails.			
DIAZEPAM (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	25.0 Milligram	Daily Oral	
Batch:	Started: 18/10/2002	Stopped : 10/11/2002	
SODIUM VALPROATE (Suspected)		Reason: Unspecified schizophrenia	
	2.0 Gram	Daily	
Batch:	Started: 29/10/2002	Stopped: 10/11/2002	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

patient was also taking Seretide

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Date Range: 1 Jan 2000 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 180955 Seq: 1 Gender: M

Reported: 21/12/2002 Weight: 0.00 Hospitalisation: Age: 50

Onset Date: 29/10/2002 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Generalised oedema		Water retention and gross swelling of total body area.	Diuretic

Medicine Details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 21/10/2002 **Stopped:** 30/10/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No allergy history

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