

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 2476
 Seq: 1
 Gender:
 F

 Reported:
 05/09/1990
 Weight:

Hospitalisation: Age: 68

Onset Date: 09/07/1990 DOB: 01/02/1922

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Pruritus			Mianserin hcl ceased. peanut oil/aqueous cream
Rash			·

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected	d)	Reason: De	epression	
Oral application	50.0 Milligram	Daily		Oral
3atch:	Started: 05/05/1990		Stopped:	20/07/1990
ALLOPURINOL (Suspected)		Reason:		
Oral application	300.0 Milligram	Daily		Oral
3atch:	Started: 05/01/1990		Stopped:	19/07/1990
SUCRALFATE (Suspected)		Reason:		
SUCRALFATE (Suspected) Oral application	4.0 Gram	Reason: Daily		Oral
	4.0 Gram 3tarted: 30/06/1990		Stopped:	Oral 22/07/1990
Oral application			Stopped:	
Oral application 3atch:		Daily	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Case Sequenced to: 67571/3



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

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Case Number: 58996 Seq: 1 Gender: M

Reported: 22/02/1989 Weight:

Hospitalisation: Age: 62Y
Onset Date: 10/02/1989
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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	Preferred Term	Severity	Report Description	Treatment
	Agranulocytosis			

Medicine Details:

DIGOXIN (Other drug)			Reason:	Otr&nos disor	rd of heart rhythm
	250.0	Microgram	Daily		
Заtch:	Started:			Stopped:	
MODURETIC (Other drug)			Reason:	Congestive he	eart failure
Tablet	1.0	Dose Unspe	cified Daily		Oral
3atch:	Started:			Stopped:	
QUININE SULPHATE (Other drug)			Reason:	Pain in limb	
Tablet	300.0	Milligram	Daily		Oral
Зatch:	Started:			Stopped:	
CAPOTEN (Suspected)			Reason:	Congestive he	eart failure
Tablet	49.0	Milligram	Daily		Oral
Зatch:	Started: 24	12/1988		Stopped:	17/02/1989

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Case Number:	58996 Se	q: 1		Gender: M	
Reported:	22/02/1989			Weight:	
Hospitalisation:				Age: 62Y	
Onset Date:	10/02/1989			DOB:	
Outcome:	Recovered		(Causality: Caus	sality possible
Reaction Detai					
Medicine Deta					
MIANSERIN HYDR	OCHLORIDE (Suspected	i)	Reason: Depression		
Tablet		20.0 Milligram	Daily	Oral	
3atch:		3tarted: 24/12/1988	Stopped:	17/02/1989	
1 -1 1 1 -	() ()				
Laboratory In	vestigations:				
Additional Inf	ormation:				
Additional iiii	omation.				

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Case Number: 58999 Seq: 1 Gender: F

Reported: 24/02/1989 Weight:
Hospitalisation: Age: 71Y

Onset Date: 12/02/1989 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			Expectorant

Medicine Details:

TOLVON (Suspected)

Tablet

40.0 Milligram
Daily
Oral

3atch:
\$tarted:
\$topped: 12/02/1989

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Histology				Agranulocytosis (maturation arrest) diagnosed on bone marrow



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report D	Detai l
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Case Number: 59102 Seq: 1 Gender: F

Reported: 28/02/1989 Weight: 64.00 Hospitalisation: Age: 43Y

Onset Date: 01/02/1989 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

 Tablet
 60.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 17/01/1989
 3topped:
 13/02/1989

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Causality: Causality possible

Report Detail

 Case Number:
 59279
 Seq:
 1
 Gender:
 F

 Reported:
 17/03/1989
 Weight:
 51.00

 Hospitalisation:
 Age:
 68Y

Onset Date: DOB:

Outcome: Not yet recovered

Reaction Detai

Caci	ion Detai		_	
	Preferred Term	Severity	Report Description	Treatment
Hepat	tic function abnormal			

Medicine Details:

MIANSERIN HYDROCHLORI	DE (Suspected)	Reason:	Manic depressive psycho, depre	
	40.0 Milligram	Daily		
3atch:	Started: 07/03/1989		Stopped: 12/03/1989	
MIANSERIN HYDROCHLORI	DE (Suspected)	Reason:	Manic depressive psycho, depre	
	60.0 Milligram	Daily		
3atch:	Started: 08/03/1989		Stopped: 12/03/1989	
MIANSERIN HYDROCHLORI	DE (Suspected)	Reason:	Manic depressive psycho, depre	
	80.0 Milligram	Daily		
3atch:	Started: 08/03/1989		Stopped: 12/03/1989	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details	
	Biochemistry				On 40mg: on 80mg: two days after cessation: I Id 273 ld 253 ggt 20 ggt 114 ggt 90	ld 187 alt 25



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

ospitalisatio Onset Dat Outcom	ed: 16/03/19							
Onset Dat Outcom		89					Weight:	
Outcom							_	70Y
	te: 12/03/19	89					DOB:	
	ne: Recovere	ed					Causality:	Causality possible
action Det	tai							
Prefe	erred Term	Sev	erity/	F	Report D	escription		Treatment
lalaise							Obs	ervation
leutropenia								
yrexia								
Rash								
ledicine D								
FRUSEMIDE (O	Other drug)				Reason:		e heart failure	
				/lilligram	Da	aily		L TEDM
3atch:	/DDGGUU GDUD		arted:			Stoppe		L TERM
AMILORIDE HY	YDROCHLORID	E (Other drug)	50 N	Ailliaram	Reason:	_	e heart failure	
Zatahı		24		/lilligram	Di	aily	.d.	L TERM
3atch:	ODIUM (Other o		arted:		Reason:	Stoppe Myxedem		LIERIVI
INTROXINE SC	JUIUWI (Other t	irug)	100 0 N	/licrogram		aily	a	
3atch:		St	arted:	licrogram	D	^₃ iiy }toppe	ed:	L TERM
	DIUM (Other d				Reason:			
	, - 3 4 -	. ,	3.0 N	/lilligram		ternate days		
3atch:		3t	arted:	J		3toppe	ed:	L TERM
	Investiga		Deta Tool	<u> </u>	<u>I</u>		5 1	:15
Date	Туре	Range	Date Teste	d Res	suit		Deta	IIIS



Case Number: 59474

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: F

lospitalisation: Onset Date:						Weight: Age: DOB:	70Y	
Outcome:								
	Recovered					יסטע:		
eaction Deta		Causality:			Causality possible			
	i							
Medicine Det								
MIANSERIN HYDE	ROCHLORIDE (Suspecto			Reason:	Depression			
			0.0					
3atch:		Started:	01/03/1989		Stopped:	12/03/1989		
ALLOPURINOL (S	Suspected)			Reason:	Gout			
			0.0 Milligram	Daily				
3atch:		Started:	12/03/1989		Stopped:	12/03/1989		
a baratarı lı	waatigatiana							
_aboratory in	nvestigations:							
Additional In	formation:							
auditional in	iorination:							



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report De	etail						
	ber: 59570	Seq: 1				Gender:	
	ted: 04/04/198	39				Weight:	
Hospitalisat Onset D						Age: DOB:	30Y
	v ate: v me: Recovere	d					Causality probable
Reaction D		u				Causanty.	Causality probable
	eferred Term	Sever	ity	Repor	Description		Treatment
Oedema				·	•		
Medicine TOLVON (Su Tabl	ispected) et	Start	10.0 Milli ed: 21/03/1		on: Depression Daily Stopped:	Oral 25/03/1989	
Laborato	ry Investigat		Date Tested	Result		Detai	le.
Date	Туре	Range	Jale Tesleu	Result		Detai	15
Additiona	ıl Informatio	n:					



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: 59591 Reported: 31/03/1989 ospitalisation: Onset Date: Outcome: Recovered	Seq: 1		Gender: F Weight: 66.00 Age: 84Y DOB: Causality: Causality probable			
eaction Detai Preferred Term	Severity	Report Do	escription	Treatment		
Confusional state	- Coroni,					
Madiaina Dataila.						
Medicine Details: TOLVON (Suspected)		Reason:	Depression			
	20.0 Milli	gram Da				
3atch:	Started:		Stopped:			
.aboratory Investigatio						
Date Type	Range Date Tested	Result		Details		
Additional Information:						
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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Do	etail
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Case Number: 59788 Seq: 1 Gender: F

Reported: 11/04/1989 Weight: 84.00 Hospitalisation: Age: 49Y

Onset Date: 04/04/1989 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Confusional state			

Medicine Details:

TOLVON (Suspected)Reason:Specific disorders of sleepTablet10.0 MilligramDailyOral

 3atch:
 3tarted:
 03/04/1989
 3topped:
 06/04/1989

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 60670
 Seq:
 1
 Gender:
 M

 Reported:
 31/05/1989
 Weight:
 48.00

Hospitalisation: Age: 80

Onset Date: 26/05/1989 DOB: 02/05/1909
Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Cachon Detai			
Preferred Term	Severity	Report Description	Treatment
Hallucination			
Urinary retention			

Medicine Details:

PROTHIADEN (Other drug)

75.0 Milligram Daily

3atch: 3tarted: 05/05/1989 3topped: 09/05/1989

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

30.0 Milligram Daily

Reason:

Depression

3atch: 3tarted: 10/05/1989 **3topped:** 26/05/1989

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

10.0 Milligram Daily

3atch: **3tarted**: 26/05/1989 **3topped**: 29/05/1989

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 61004
 Seq:
 1
 Gender:
 M

 Reported:
 23/06/1989
 Weight:

Hospitalisation: Age: 73Y

Onset Date: 16/06/1989 **DOB**:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			Cease drugs, antibiotics,

Medicine Details:

MYLANTA (Suspected)		Reason:	
Oral application	10.0 Millilitre	As necessary	Oral
3atch:	Started:	Stopped:	
TOLVON (Suspected)		Reason: Depression	
Oral application	80.0 Milligram	Daily	Oral
3atch:	Started: 17/05/1989	Stopped:	16/06/1989
CAPOTEN (Suspected)		Reason: Chron isch hear	rt dis no hyper
	25.0 Milligram	Daily	
3atch:	Started: 01/05/1989	Stopped:	16/06/1989
RANITIDINE (Suspected)		Reason: Other diseases	of esophagus
	150.0 Milligram	Daily	
3atch:	3tarted: 01/05/1989	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 wcc 0.7 3% segmented neutrophils 73% lymphocyte 23% monocytes

Additional Information:

Digoxin 62.5rg the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 61004
 Seq:
 1
 Gender:
 M

 Reported:
 23/06/1989
 Weight:

Hospitalisation: Age: 73Y
Onset Date: 16/06/1989
DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Detai

Medicine Details:

DIGOXIN (Suspected)		Reason:	Chron isch heart dis no hyper	
Oral application	62.0 Microgram	Daily	Oral	
3atch:	Started:		Stopped:	
FRUSEMIDE (Suspected)		Reason:	Congestive heart failure	
Oral application	120.0 Milligram	Daily	Oral	
3atch:	Started:		Stopped:	
MIDAMOR (Suspected)		Reason:		
Oral application	5.0 Milligram	Daily	Oral	
3atch:	Started:		Stopped:	
THEO-DUR (Suspected)		Reason:	Otr respiratory systm diseases	
Oral application	500.0 Milligram	Daily	Oral	
3atch:	Started:		Stopped:	

Laboratory Investigations:

Additional Information:

Digoxin 62.5rg the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail					
Case Number: Reported: Hospitalisation:	61004 23/06/1989	Seq: 1		Gender: Weight: Age:	
Onset Date:	16/06/1989			DOB:	
	Death, maybe dr	ug		Causality:	Causality possible
Reaction Detai					
Medicine Deta	aile:				
GAVISCON (Suspe			Reason:		
Granules			4.0 Dose Unspecified Daily	Oral	
3atch:		Starte	ed: Sto	pped:	
Labouetowyla					
Laboratory In	vestigations:				
Additional Inf Digoxin 62.5rg the dosage start date i		s not nec ccurate bu	cessarily accurate but indicates that st ut indicates that start occurred someti	tart occurred some ime during the mor	etime during the month. the nth.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

eport Det	ail						
ase Numbe	er: 62016	Seq:	1			Gender:	F
Reporte	d: 18/08/198	9				Weight:	
spitalisatio	n:					Age:	55Y
Onset Dat	te: 05/08/198	9				DOB:	
Outcom	e: Recovere	d				Causality:	Causality probable
action De		<u> </u>				i i	
	rred Term	Seve	erity	Repor	t Description		Treatment
onvulsion							
izziness							
ncope							
edicine D	etails:						
OLVON (Susp				Reas	on: Depression		
Tablet			40.0 Milligram Daily Oral				
3atch:		3ta	Started : 03/08/1989 Stopped : 05/08/1989)
aboratorv	Investigat	ions:					
Date	Туре	Range	Date Tested	Result		Detai	ls
dditional	Informatio	n:					
ort Run 01/08	/200 02·06PN	Database: pu	sime	Δ	DRS004		Page 16 of 33



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 62653 Seq: 1 Gender: M
Reported: 25/09/1989 Weight:

 Hospitalisation:
 Age: 76

 Onset Date: 07/09/1989
 DOB: 18/01/1913

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			
Neutropenia			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspecte	d)	Reason:	Depression	
Tablet	60.0 Milligram	Weel	kly	Oral
3atch:	3tarted: 28/08/1989		Stopped:	06/09/1989
ALLOPURINOL (Suspected)		Reason:	Gout	
Oral application	100.0 Milligram	Daily		Oral
3atch:	3tarted: 05/07/1989		Stopped:	18/09/1989
CAPTOPRIL (Suspected)		Reason:	Essential ben	ign hypertension
Oral application	37.0 Milligram	Daily		Oral
3atch:	3tarted: 21/08/1989		Stopped:	
CARTORRII (Cuenceted)				
CAPTOPRIL (Suspected)		Reason:	Essential ben	ign hypertension
Oral application	75.0 Milligram	Reason: Daily		ign hypertension Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 2% of wbc count 2.6 x 10,000mu/l (7/9/89). wbc 2.9 neutrophil 0% (18/9/89). wbc rose to 3.8 (20/9/89) 4.6 (22/9/89).



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Hespitalisation: Age: 76 Onset Date: 07/09/1989 Outcome: Recovered Causality: Causality possible Reaction Detail Medicine Details: SEPTRIN FORTE (Suspected) Tablet 1.0 Dose Unspecified Daily Started: 11/08/1989 itopped: 05/09/1989 Laboratory Investigations: Additional Information:	Case Number:	62653	Seq: 1	Gender: M	
Onset Date: 07/09/1989 DOB: 18/01/1913 Causality: Causality possible Reaction Detail Medicine Details: SEPTRIN FORTE (Suspected) Tablet 1.0 Dose Unspecified Daily Oral 3atch: 3tarted: 11/08/1989 3topped: 05/09/1989 Laboratory Investigations:	Reported:	25/09/1989		Weight:	
Outcome: Recovered Reaction Detail Medicine Details: SEPTRIN FORTE (Suspected) Tablet 1.0 Dose Unspecified Daily Oral 3atch: Started: 11/08/1989 Stopped: 05/09/1989 Laboratory Investigations:	Hospitalisation:			Age : 76	
Medicine Details: SEPTRIN FORTE (Suspected) Tablet 1.0 Dose Unspecified Daily Tablet 3atch: Started: 11/08/1989 Stopped: 05/09/1989 Laboratory Investigations:	Onset Date:	07/09/1989		DOB : 18/01/1913	
Medicine Details: SEPTRIN FORTE (Suspected) Tablet 1.0 Dose Unspecified Daily Tablet 3atch: Started: 11/08/1989 Stopped: 05/09/1989 Laboratory Investigations:	Outcome:	Recovered		Causality: Causality possible	
Medicine Details: SEPTRIN FORTE (Suspected) Tablet 1.0 Dose Unspecified Daily Oral 3atch: 3tarted: 11/08/1989 Nopped: 05/08/1989 Laboratory Investigations:	Reaction Detai	İ			
SEPTRIN FORTE (Suspected) Tablet 1.0 Dose Unspecified Daily Oral 3atch: 3tarted: 11/08/1989 3topped: 05/09/1989 Laboratory Investigations:					
SEPTRIN FORTE (Suspected) Tablet 1.0 Dose Unspecified Daily Oral 3atch: 3tarted: 11/08/1989 3topped: 05/09/1989 Laboratory Investigations:					
SEPTRIN FORTE (Suspected) Tablet 1.0 Dose Unspecified Daily Oral 3atch: 3tarted: 11/08/1989 3topped: 05/09/1989 Laboratory Investigations:					
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SEPTRIN FORTE (Suspected) Tablet 1.0 Dose Unspecified Daily Oral 3atch: 3tarted: 11/08/1989 3topped: 05/09/1989 Laboratory Investigations:					
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SEPTRIN FORTE (Suspected) Tablet 1.0 Dose Unspecified Daily Oral 3atch: 3tarted: 11/08/1989 3topped: 05/09/1989 Laboratory Investigations:					
SEPTRIN FORTE (Suspected) Tablet 1.0 Dose Unspecified Daily Oral 3atch: 3tarted: 11/08/1989 3topped: 05/09/1989 Laboratory Investigations:	Madiaina Dat	oilo			
Tablet 1.0 Dose Unspecified Daily Oral 3atch: 3tarted: 11/08/1989 3topped: 05/09/1989 Laboratory Investigations:				Coason: Othr diseases of urinary tract	\neg
3atch: 3tarted: 11/08/1989 3topped: 05/09/1989 Laboratory Investigations:		(Suspected)		·	
Laboratory Investigations:			Startod		
	Satcii.		otarteu.	3. 11/06/1969 3topped. 03/09/1969	
	l abauatau lu				
Additional Information:	Laboratory in	ivestigations:			
Additional Information:					
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Additional information:	Additional Int	formation			
	Additional in	formation:			

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 62994 Seq: 1 Gender: F

Reported: 23/10/1989 Weight:
Hospitalisation: Age: 77Y

Onset Date: 28/09/1989 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

10404011 2044			=
Preferred Term	Severity	Report Description	Treatment
Visual disturbance			Tolvon withdrawn, quinine dose reduced to 300mg daily

Medicine Details:

TOLVON (Suspected) Reason: Depression

30.0 Milligram Daily

3atch: 3tarted: 22/09/1989 3topped: 28/09/1989

QUININE SULPHATE (Suspected) Reason:

600.0 Milligram Daily

3atch: 3tarted: 13/09/1989 **3topped:**

AMIODARONE HYDROCHLORIDE (Suspected) Reason: Otr&nos disord of heart rhythm

600.0 Milligram Daily

3atch: Started: Stopped:

AMIODARONE HYDROCHLORIDE (Suspected) Reason: Otr&nos disord of heart rhythm

200.0 Milligram Daily

3atch: 3tarted: 28/09/1989 3topped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Rei	port	: Det	tail
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 Case Number:
 63050
 Seq:
 1
 Gender:
 M

 Reported:
 11/10/1989
 Weight:

Hospitalisation: Age: 77Y

Onset Date: 02/10/1989 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Encephalopathy			

Medicine Details:

DIGOXIN (Other drug)		;	Reason:		
Oral application	250.0	Microgram	Daily	Oral	I
3atch:	Started:			Stopped:	
METOPROLOL TARTRATE (Other drug)		;	Reason:		
Oral application	200.0	Milligram	Daily	Oral	ı
3atch:	Started:			Stopped:	
STELAZINE (Other drug)		;	Reason:		
STELAZINE (Other drug) Oral application	4.0		Reason: Daily	Oral	I
, , ,	4.0 Started:			Oral	1
Oral application		Milligram			I
Oral application 3atch:		Milligram	Daily		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Case Number:	63050	Seq: 1			Gender:	M	
Reported:	11/10/1989				Weight:		
Hospitalisation:					Age:	77Y	
Onset Date:	02/10/1989				DOB:		
Outcome:	Recovered			C	Causality:	Causality certa	iin
Reaction Detai							
Medicine Deta							
TOLVON (Suspect			Reason:	Depression			
Oral applic	ation	30.0 Milligram	Daily		Oral		
3atch:		3tarted: 05/07/1989		Stopped:	02/10/1989		
Laboratory In	vestigations:						
Additional Inf	formation:						
Conort Pup 01/09/200	02:06DN Data	phaea: nucima	VDB600	04		Daga 01	of 220

Report Run 01/08/200 02:06PN Database: pusime ADRS004 Page 21 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 63241 Seq: 1 Gender: M

Reported: 08/11/1989 Weight: 80.00 Hospitalisation: Age: 60Y

Onset Date: 28/10/1989 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

todottott Botal			
Preferred Term	Severity	Report Description	Treatment
Neutropenia			Pt recovered well on antibiotics. wcc rose within 2 days of ceasing mianserin.
Sepsis			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

30.0 Milligram Daily

3atch: 3tarted: 01/08/1989 3topped: 28/10/1989

NORFLOXACIN (Suspected) Reason: Othr diseases of urinary tract

80.0 Milligram Daily

3atch: 3tarted: 02/10/1989 3topped: 28/10/1989

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 wcc 0.1x 10/9/I



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 63524
 Seq:
 1
 Gender:
 M

 Reported:
 30/11/1989
 Weight:
 76.00

 Hospitalisation:
 Age:
 56Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Back pain			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected)	Reason:	Depression
	30.0 Milligram	Daily	
Зatch:	Started: 01/01/1986		Stopped:
PANADEINE (Suspected)		Reason:	Pain in joint
Tablet	12.0 Dose Unspec	cified Daily	Oral
3atch:	Started: 01/01/1970		Stopped:
SOLPRIN (Suspected)		Reason:	Pain in joint
	1.2 Gram	Daily	
Зatch:	Started: 01/01/1986		Stopped:
BRUFEN (Suspected)		Reason:	Other diseases of joint
	1.2 Gram	Daily	
Зatch:	Started: 01/01/1986		Stopped: 31/01/1986

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run 01/08/200 02:06PN Database: pusime ADRS004 Page 23 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 63681 Seq: 1 Gender: F

Reported: 08/12/1989 Weight: 60.00 Hospitalisation: Age: 61

Onset Date: 07/12/1989 **DOB**: 25/07/1928

Outcome: Recovered Causality: Causality possible

Reaction Detai

154511511 25141			<u> </u>
Preferred Term	Severity	Report Description	Treatment
Neutropenia			1v antibiotics
Pharyngitis			
Pyrexia			
Sepsis			

Medicine Details:

TOLVON (Suspected)		Reason:	Depression	
	20.0 Milligram	Daily		
3atch:	Started: 27/10/1989		Stopped:	30/10/1989
TOLVON (Suspected)		Reason:	Depression	
	80.0 Milligram	Daily		
3atch:	Started: 30/10/1989		Stopped:	18/11/1989
TOLVON (Suspected)		Reason:	Depression	
	120.0 Milligram	Daily		
3atch:	Started: 18/11/1989		Stopped:	08/12/1989

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 17/10/89 7/12 9/12 11/12 12/12 13/12 15/12 20/12 wbc 10.30 0.80 1.70 4.34 3.56 4.20 6.00 5.24



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Case Number: 63857 Seq: 1 Gender: F

Reported: 20/12/1989 Weight: 77.00 Hospitalisation: Age: 64Y

Onset Date: 20/12/1989 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Confusional state			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

Oral application 30.0 Milligram Daily Oral

3atch: **3tarted**: 06/12/1989 **3topped**: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 64280 Seq: 1 Gender: F

Reported: 07/02/1990 Weight: 70.00
Hospitalisation: Age: 76Y

Onset Date: 06/02/1990 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agitation			
Tremor			

Medicine Details:

TOLVON (Suspected)		Reason:	Depression	
Tablet	10.0 Milligram	Daily	Oral	
3atch:	Started: 06/02/1990		Stopped: 06/02/1990	
SEREPAX (Suspected)		Reason:		
	30.0 Milligram	Daily		
3atch:	Started: 01/01/1980		Stopped:	
		3	Connected begins by markensing	
MINIPRESS (Suspected)		Reason:	Essential benign hypertension	
MINIPRESS (Suspected) Tablet	5.0 Milligram	Reason: Daily	Oral	
` ' '	5.0 Milligram 3tarted: 01/09/1989		3 ,.	
Tablet	· ·		Oral	
Tablet 3atch:	· ·	Daily Reason:	Oral Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 64289 Seq: 1 Gender: F

Reported: 06/02/1990 Weight: 75.00 Hospitalisation: Age: 77Y

Onset Date: 03/12/1989 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

1040404			-
Preferred Term	Severity	Report Description	Treatment
Arthritis			Cessation of tolvon.
Red blood cell sedimentation rate			

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	Depression
Tablet	500.0 Milligram	Daily	, Oral
3atch:	Started: 17/11/1989		Stopped: 21/11/1989
TEMAZEPAM (Other drug)		Reason:	Specific disorders of sleep
Capsule	20.0 Milligram	Daily	oral Oral
3atch:	Started: 17/11/1989		Stopped:
COLOXYL WITH SENNA (Other drug)		Reason:	Constipation
Tablet	2.0 Dose Unspe	cified Daily	, Oral
3atch:	Started: 23/11/1989		Stopped:
TOLVON (Suspected)		Reason:	Depression
Tablet	50.0 Milligram	Daily	oral Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: 642	89 Seq: 1	Gender:	F
Reported: 06/0	2/1990	Weight:	75.00
Hospitalisation:		Age:	
Onset Date: 03/1	2/1989	DOB:	
Outcome: Rec	overed	Causality:	Causality probable
Reaction Detai			
Medicine Details:			
TOLVON (Suspected)		Reason: Depression	
Tablet	80.0 Milligram	Daily Oral	
3atch:	Started: 28/11/1989	\$topped: 15/12/1989)
Laboratory Invoc	tigations:		
Laboratory Inves	ugations.		
Additional Inform	ation:		

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 64320
 Seq:
 1
 Gender:
 F

 Reported:
 23/01/1990
 Weight:

Hospitalisation:
Onset Date:
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Anaemia			
Thrombocytopenia			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

20.0 Milligram Daily

3atch: Started: 01/01/1987 **Stopped:** 18/01/1990

SULFASALAZINE (Suspected) Reason: Diverticula of colon

1.5 Gram Daily

3atch: 3tarted: 01/01/1987 3topped: 18/01/1990

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details		
	Haematology				1 30/1/90 hb:	9.1 (11.5-16.5) platelets:	98 (150-450)

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report l	Detail
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 Case Number:
 64415
 Seq:
 1
 Gender:
 F

 Reported:
 31/10/1989
 Weight:
 76.00

 Hospitalisation:
 Age:
 75Y

Onset Date: 31/10/1989 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Pruritus			Prednisolone 5mg tabs qid. dr gave injection of depo-medrol
Rash			10ma

Medicine Details:

KEFLEX (Suspected)		Reason: Other prophylactic procedures
	500.0 Milligram	1 time
3atch:	Started: 31/10/1989	Stopped:
TOLVON (Suspected)		Reason:
	40.0 Milligram	Daily
3atch:	Started:	Stopped:
VALIUM (Suspected)		Reason:
	1.0 Dose Unspe	pecified Daily
3atch:	Started:	Stopped:
VOLTAREN (Suspected)		Reason:
	3.0 Dose Unspe	pecified Daily
3atch:	Started:	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number:	64415	Seq:	1		Ger	nder:	F	
Reported:	31/10/1989	_			We	ight:	76.00	
lospitalisation:						_	75Y	
Onset Date:	31/10/1989					OB:		
Outcome:	Not yet recovered	b			Causa	ality:	Causality possib	ole
eaction Detai								
Medicine Det								
MODURETIC (Sus	pected)			Reason:				
			1.0 Dose Unspe	cified Daily				
3atch:		3ta	rted:		Stopped:			
CLINORIL (Suspe	cted)			Reason:				
			400.0 Milligram	Daily				
3atch:		3ta	rted: 24/10/1989		Stopped:			
Laboratory In	vestigations:							
	J							
Additional Inf	formation:							
eport Run 01/08/200	0 02:06PN Datab	oase: pu	sime	ADRS004			Page 31	of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail		
Case Number: 64610	Seq: 1	Gender: F
Reported: 02/03/1990		Weight: 44.00

Hospitalisation: Age: 58Y
Onset Date: 20/12/1989
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

todotion Dotai			
Preferred Term	Severity	Report Description	Treatment
Choreoathetosis			Tolvon ceased, small dose
Hyperkinesia			.P
Tardive dyskinesia			

Medicine Details:

 TOLVON (Suspected)
 Reason:
 Depression

 Tablet
 60.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 20/12/1989
 3topped: 13/02/1990

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 64628 Seq: 1 Gender: F

 Reported:
 07/03/1990
 Weight:
 57.00

 Hospitalisation:
 Age:
 83Y

Onset Date: 07/01/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Jaundice			

Medicine Details:

PANADEINE (Suspected)	Reason:				
	1.0 Dose Unspecified As necessary				
3atch:	Started:	Stopped:			
TOLVON (Suspected)		Reason: Depression			
Tablet	30.0 Milligram	Daily Oral			
3atch:	3tarted: 15/10/1988	Stopped: 10/01/1990			
FLUCLOXACILLIN SODIUM (Suspected)		Reason: Otr cellulitis&abscess of leg			
Capsule	1.0 Gram	Daily Oral			
3atch:	3tarted: 27/11/1989	Stopped: 24/12/1989			
CEPHALEXIN (Suspected)		Reason: Otr cellulitis&abscess of leg			
Capsule	1.0 Gram	Daily Oral			
3atch:	3tarted: 30/11/1989	Stopped: 24/12/1989			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result		Details	
	Biochemistry				7/1/90 5/4/90 range bili: 281 58 (0-42 u/l) alp:	66 8 (0-20 umol/l) ast: 611 82 (<130 u/l) ggt:	376



Case Number: 64628

Reported: 07/03/1990

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: F

laanitaliaatian.	07/03/1990					Weight:	57.00	
ospitalisation:						Age:	83Y	
Onset Date:	07/01/1990					DOB:		
Outcome:	Recovered				С	ausality:	Causality poss	ible
action Detai								
ledicine Deta								1
LANOXIN PG (Susp	pected)			Reason:	Congestive he			
Tablet			0 Microgram	Daily		Oral		
3atch:		Started:			Stopped:			
PERIACTIN (Suspe	cted)			Reason:	Rash			
Tablet			0 Milligram	Daily		Oral		
3atch:		Started: 2	2/09/1989		Stopped:	14/11/1989		
GENTAMICIN SULF	PHATE (Suspected)			Reason:				
			0 Milligram	Daily				
3atch:		Started:			Stopped:			
Jaton.								
					•			
	vestigations:							
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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

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Case Number: 64955 Seq: 1 Gender: F

Reported: 29/03/1990 Weight: 81.00 Hospitalisation: Age: 49Y

Onset Date: 23/02/1990 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Stomatitis			

Medicine Details:

TOLVON (Suspected) Reason: Depression

 Tablet
 20.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 23/02/1990
 3topped:
 28/02/1990

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

	Re	port	Detail
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 Case Number:
 65024
 Seq:
 1
 Gender:
 F

 Reported:
 05/04/1990
 Weight:
 56.00

Hospitalisation:
Onset Date:
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

30.0 Milligram Daily

3atch: Started: 21/03/1990 Stopped: 04/04/1990

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: 66211	•				
Reported: 28/06/1990			V	Veight:	
spitalisation:				Age: 40Y	
Onset Date: 27/05/1990				DOB:	
Outcome: Recovered			Cau	usality: Causality probable	
ction Detai	1 2 1				
Preferred Term	Severity	Repo	ort Description	Treatment	
adycardia					
potension ncope					
edicine Details:	isnected)	}ea	son:		
Oral application		/lilligram)ral	
3atch:	Started: 27/0		-	7/05/1990	
ahoratory Invostigation	ne:				
hboratory Investigation		ed Result		Details	
.,,,,,	- tango Date Foots			2 ottaile	
Date Type	Range Date Teste	d Result		Details	
Additional Information:					
ort Run 01/08/200 02:06PN I	Database: pusime		ADRS004	Page 37 of 33	



Case Number: 66212

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: M

anitaliantias:	90	Weight: 77.00						
spitalisation: Onset Date: 11/06/199)O	Age: 23Y DOB:						
Outcome: Recovere			Causality: Causality probabl				abla	
action Detai	u				Causa	iity. Cai	usanty probe	abie
Preferred Term	Seve	rity	Repor	t Descript	ion		Treatment	
radycardia								
ypotension								
yncope								
ledicine Details:	E (Suspected)		Reas	on:				
Oral application	- (40.0 Millig		1 time	Oral			
3atch:	Star	ted: 11/06/19			topped:			
aboratory Investigat Date Type	Range	Date Tested	Result			Details		
dditional Informatio	n .	l						
dditional Informatio	n:							



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Reported: 28/06/1990						
	Seq: 1		Gender: M			
		Weight: 82.00				
ospitalisation:			Age : 24Y			
Onset Date: 27/05/1990			DOB:			
Outcome: Recovered			Causality: Causality certain			
action Detai			<u>,</u>			
Preferred Term	Severity	Report Descr	ription Treatment			
radycardia						
ypotension						
yncope			Lay flat			
yncope						
ledicine Details:						
MIANSERIN HYDROCHLORIDE (Suspected)	Reason:				
Oral application	40.0 Mi	lligram 1 time	Oral			
3atch:	3tarted: 27/05/	1990	Stopped:			
		T				
_aboratory Investigatio		T 5 " I				
_aboratory Investigatio	Pange Date Tested	Result	Details			
	Range Date Tested	Result	Details			



Case Number: 66214

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: F

lospitalisatio Onset Dat Outcom	te: 03/06/1990 te: Recovered		Weight: 55.00 Age: 26Y DOB: Causality: Causality probable					
eaction De Prefe	tai erred Term	Sev	erity	Repor	t Descri	otion	Treatment	
Bradycardia Hypotension Malaise Syncope				1.2	,			
Medicine D	etails:	(Suspected)		Reas	on:			
	plication	(,	40.0 Milli		1 time	Oral		
3atch:		3ta	rted: 03/06/1	990		Stopped:		
I aboratory	Investigatio	ons:						
Date	Туре	Range	Date Tested	Result			Details	
Additional	Information	:			L			
eport Run 01/08	/200 02:06PN	Database: pu	sime	P	DRS004		Page 40 of 3	336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 66868 Seq: 1 Gender: F

Reported: 03/08/1990 Weight: 50.00 Hospitalisation: Age: 87Y

Onset Date: 30/07/1990 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

	1	i	1
Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			Prophylactic antibiotics.
Malaise			
Pyrexia			

Medicine Details:

TOLVON (Suspected)

Tablet

30.0 Milligram

Daily

Oral

3atch: 3tarted: 01/06/1990 3topped: 23/07/1990

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.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 67150 Seq: 1 Gender: F

Reported: 22/08/1990 Weight:
Hospitalisation: Age: 72Y

Onset Date: 21/08/1990 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Convulsion			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspecte	ed)	Reason:	Depression	
Tablet	240.0 Milligram	Daily		Oral
3atch:	Started: 14/08/1990		Stopped:	21/08/1990
LARGACTIL (Suspected)		Reason:	Depression	
Tablet	25.0 Milligram	Daily		Oral
3atch:	Started: 01/01/1983		Stopped:	21/08/1990
BROMAZEPAM (Suspected)		₹eason:	Anxiety neuro	esis
BROMAZEPAM (Suspected) Tablet	3.0 Milligram	Reason: Daily	Anxiety neuro	sis Oral
` ' '	3.0 Milligram Started: 01/01/1983		Anxiety neuro	
Tablet	ğ		Stopped:	Oral
Tablet 3atch:	ğ	Daily	Stopped:	Oral 20/08/1990

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

 Case Number:
 67150
 Seq:
 1
 Gender:
 F

 Reported:
 22/08/1990
 Weight:

Hospitalisation: Age: 72Y
Onset Date: 21/08/1990 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

M		ine	 u	

VOLTAREN (Suspected) Reason: Unspecified arthritis

100.0 Milligram Daily

3atch: 3tarted: 01/01/1989 3topped: 22/08/1990

Laboratory Investigations:

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 67218 Seq: 1 Gender: F

Reported: 03/09/1990 Weight: 75.00 Hospitalisation: Age: 77

Onset Date: 04/07/1990 **DOB**: 12/04/1913

Outcome: Death, maybe drug Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage			

Medicine Details:

PANADOL (Suspected)		Reason: Pain	
Oral application	500.0 Milligram	As necessary	Oral
3atch:	Started:	Stopped:	07/08/1990
VALIUM (Suspected)		Reason:	
Oral application	5.0 Milligram	As necessary	Oral
3atch:	Started:	Stopped:	07/08/1990
DYAZIDE (Suspected)		Reason: Edema and di	ropsy
Oral application	1.0 Dose Unspec	ified Daily	Oral
3atch:	Started:	Stopped:	07/08/1990
ZANTAC (Suspected)		Reason: Peptic ulcer n	os w/o ment perf
Oral application	300.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	07/08/1990

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Case Number: 67218

Reported: 03/09/1990

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: F

Weight: 75.00

ospitalisation:					Age: 77	•	
Onset Date: 04/07/1990					DOB : 12	2/04/1913	
Outcome: Death, maybe drug				C	Causality: Ca	ausality possi	ible
action Detai							
dicine Details:							
APTOPRIL (Suspected)			Reason:	Essential ben	ign hypertension	1	
Oral application		Milligram	Daily		Oral		
3atch:	Started:			Stopped:	07/08/1990		
DLVON (Suspected)			Reason:	Depression			
Oral application		Milligram	Daily		Oral		
3atch:	Started:			Stopped:	07/08/1990		
boratory Investigations:							
, , , , , , , , , , , , , , , , , , , ,							
lditional Information:							
t Run 01/08/200 02:06PN Database	e: pusime		ADRS00)4		Page 45	of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 67552
 Seq:
 1
 Gender:
 F

 Reported:
 26/09/1990
 Weight:
 50.00

 Hospitalisation:
 Age:
 76Y

Onset Date: 10/09/1990 DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agitation	-		
Confusional state			
Pancytopenia			
Purpura			

Medicine Details:

TOLVON (Suspected)			Reason:	Depression	
Oral application	40.0	Milligram	Daily		Oral
Зatch:	Started:			Stopped:	
GLIBENCLAMIDE (Suspected)			Reason:	Depression	
GLIBENCLAMIDE (Suspected) Tablet	10.0	Milligram	Reason: Daily	•	Oral

Laboratory Investigations:

	<i>y</i> ga.				
Date	Туре	Range	Date Tested	Result	Details
	Haematology Misclassified at				1 9/9 10/9 hb: 115-165 58 78 wbc:4.0-11.0 1.4 2.1 plt:150-400 2 7 10/9 11/9 12/9 13/9 14/9 15/9 16/9 17/0 18/0 27/0 1/10 1/10 1/10 1/10 1/10 1/10 1/10 1

Additional Information:

Patient died of a cerebral haemorrhage.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 67565 Seq: 1 Gender: F

 Reported:
 27/09/1990
 Weight:
 50.00

 Hospitalisation:
 Age:
 73Y

Onset Date: 10/09/1990 DOB:
Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Pancytopenia			Transfusion platelet & rbc's

Medicine Details:

MIANSERIN HYDROCHLORIDE (S	suspected)	Reason:	Depression	
	50.0 Milligram	Daily		
3atch:	Started:		Stopped: 10/09/1990	
DAONIL (Suspected)		Reason:	Diabetes mellitus	
DAONIL (Suspected) Oral application	10.0 Milligram	Reason: Daily		

Laboratory Investigations:

	,				
Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 platelet= 4000 hb= 5.8gm/dl (12-14) wcc=1,400

Additional Information:



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 68249
 Seq:
 1
 Gender:
 M

 Reported:
 13/11/1990
 Weight:
 75.00

 Hospitalisation:
 Age:
 66Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Diplopia			
Visual disturbance			

Medicine Details:

NICOTINIC ACID (Suspected)		Reason:	Othr&unspec metabolic diseases
	500.0 Milligram	Daily	
Зatch:	3tarted: 01/01/1983		Stopped: 13/11/1990
INDOCID (Suspected)		Reason:	Gout
	500.0 Milligram	Daily	
Batch:	3tarted: 01/01/1984		Stopped: 31/01/1985
INDERAL (Suspected)		Reason:	Essential benign hypertension
	80.0 Milligram	Daily	
3atch:	3tarted: 01/01/1982		Stopped: 31/01/1984
CLONAZEPAM (Suspected)		Reason:	Convulsions
	1.0 Milligram	Daily	
	1.0 Milligram	Daily	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Gender: M

Report Detail

Case Number: 68249 Seq: 1

Reported: 13/11/1990 Weight: 75.00
Hospitalisation: Age: 66Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

TOLVON (Suspected)		Reason:	
	10.0 Milligram	Daily	
3atch:	3tarted: 01/01/1986	Stopped:	
WARFARIN SODIUM (Suspected)		Reason:	
	4.0 Milligram	Daily	
3atch:	3tarted: 01/01/1988	Stopped:	
CAPTOPRIL (Suspected)		Reason: Essential benign hypertension	
	37.0 Milligram	Daily	
3atch:	Started: 01/05/1990	Stopped:	

Laboratory Investigations:

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 68570 Seq: 1 Gender: F

Reported: 21/08/1990 Weight: 48.00 Hospitalisation: Age: 75Y

Onset Date: 28/11/1989 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Lymphopenia			

Medicine Details:

FLUNITRAZEPAM (Other drug)		Reason:	Specific disor	ders of sleep
Tablet	1.0 Milligram	Daily		Oral
Batch:	Started: 01/11/1989		Stopped:	
MULTI-B FORTE (Other drug)		Reason:		
	1.0 Dose Unspec	ified Daily		
Batch:	Started: 01/11/1989		Stopped:	
TOLVON (Suspected)		Reason:	Depression	
Tablet	100.0 Milligram	Daily		Oral
3atch:	Started: 01/11/1989		Stopped:	30/07/1990

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 28/11/89 30/7/90 range wcc 4.4 4.6 lymphocytes 0.8 1.3 (1.5-4.0)

Additional Information:

(baekau) dr s freiberg, st george hosp, kogarah, nsw pat.vc the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 68646
 Seq: 1
 Gender: F

 Reported:
 14/11/1990
 Weight:

Hospitalisation: Age: 74Y

Onset Date: 13/08/1990 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Orthostatic hypotension			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Sus	pected)	Reason:
	30.0 Milligram	1 time
3atch:	Started: 03/07/1990	Stopped:
HALOPERIDOL (Suspected)		Reason: Manic depressive psycho, depre
	1.5 Milligram	Daily
3atch:	Started: 23/07/1990	Stopped: 30/08/1990
MIANSERIN HYDROCHLORIDE (Sus	pected)	Reason:
MIANSERIN HYDROCHLORIDE (Susp	pected) 60.0 Milligram	Reason: Daily
MIANSERIN HYDROCHLORIDE (Susp	•	
	60.0 Milligram 3tarted: 04/07/1990	Daily
3atch:	60.0 Milligram 3tarted: 04/07/1990	Daily 3topped: 09/07/1990

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Reported: 14/11/1990 Weight: Hospitalisation: Age: 74Y Onset Date: 13/08/1990 DOB: Outcome: Recovered Causality: Causality possible Reaction Detail Medicine Details: MIANSERIN HYDROCHLORIDE (Suspected) Reason: 60.0 Milligram Daily 3atch: 3tarted: 26/07/1990 3topped: 13/08/1990
Onset Date: 13/08/1990 DOB: Outcome: Recovered Causality: Causality possible Reaction Detai Medicine Details: MIANSERIN HYDROCHLORIDE (Suspected) Reason: 60.0 Milligram Daily
Outcome: Recovered Reaction Detail Medicine Details: MIANSERIN HYDROCHLORIDE (Suspected) 60.0 Milligram Daily Causality: Causality possible Reason:
Medicine Details: Mianserin hydrochloride (Suspected) 60.0 Milligram Daily
Medicine Details: MIANSERIN HYDROCHLORIDE (Suspected) 60.0 Milligram Daily
MIANSERIN HYDROCHLORIDE (Suspected) Reason: 60.0 Milligram Daily
MIANSERIN HYDROCHLORIDE (Suspected) Reason: 60.0 Milligram Daily
MIANSERIN HYDROCHLORIDE (Suspected) Reason: 60.0 Milligram Daily
MIANSERIN HYDROCHLORIDE (Suspected) Reason: 60.0 Milligram Daily
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MIANSERIN HYDROCHLORIDE (Suspected) Reason: 60.0 Milligram Daily
MIANSERIN HYDROCHLORIDE (Suspected) Reason: 60.0 Milligram Daily
MIANSERIN HYDROCHLORIDE (Suspected) Reason: 60.0 Milligram Daily
3atch: 3tarted: 26/07/1990 3topped: 13/08/1990
Laboratory Investigations:
Additional Information:



Additional Information:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: 68807 Reported: 14/12/1990 Hospitalisation: Onset Date: 08/08/1990 Outcome: Not yet rec	1		Wei A D	der: F ght: Age: 49Y OB: Ility: Causality possible
Reaction Detai Preferred Term	Severity	Report Des	scription	Treatment
Anorexia	Coverity	report Dec	onpaon	rreatment
Insomnia				
Weight decreased				
Medicine Details: TOLVON (Suspected)		Reason:	Depression	
102VON (Guspecteu)	20 1	Dose Unspecified Daily		
Batch:	Started: 24/0			3/1990
PROZAC (Suspected)		Reason:	Depression	
	1.0	Dose Unspecified Daily	,	
3atch:	3tarted: 08/0	8/1990	3topped: 26/10	0/1990
Laboratory Investigation	ons:			
Date Type	Range Date Teste	ed Result		Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Rep	00	rt	D	eta	il
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Case Number: 68862 Seq: 1 Gender: F

Reported: 18/12/1990 Weight: 53.00 Hospitalisation: Age: 78Y

Onset Date: 12/12/1990 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

80.0 Milligram Daily

3atch: **3tarted**: 11/12/1990 **3topped**: 12/12/1990

Laboratory Investigations:

					
Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 12/12/90 r.r. platelets 85 (150-400)

Additional Information:



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 68917
 Seq:
 1
 Gender:
 M

 Reported:
 20/12/1990
 Weight:
 80.00

 Hospitalisation:
 Age:
 49Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			Celestone-m cream

Medicine Details:

Medicine Details.						
TRANXENE (Other drug)		Reason:				
	0.0					
3atch:	Started:	Stopped:				
TOLVON (Suspected)		Reason: Depression				
	140.0 Milligram	Daily				
3atch:	3tarted: 01/01/1988	Stopped:	CONTIN			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report	Detail
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Case Number:69555Seq:1Gender:MReported:15/02/1991Weight:Hospitalisation:Admitted to hospitalAge:61Y

Onset Date: 20/12/1990 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

- Courtier Dotai	<u> </u>		
Preferred Term	Severity	Report Description	Treatment
Bradycardia			Admission to cardiology unit, telemetry monitoring, cease mianserin, review psychiatric medication. commenced on alprazolam.
Bradycardia			
Hypotension			
Nausea			
Syncope			

Medicine Details:

DISPRIN (Other drug)			Reason:	Acute myocar	d infarc,no hypert	
Tablet	150.	0 Milligram	Daily		Oral	
Зatch:	Started: 1	0/08/1990		Stopped:		CONTIN
TEMAZEPAM (Other drug)			Reason:	Disturbance o	of sleep	
Capsule	10.	0 Milligram	Daily		Oral	
3atch:	Started:			Stopped:		
LITHIUM CARBONATE (Other drug)			Reason:			
Tablet	750.	0 Milligram	Daily		Oral	
3atch:	Started:			Stopped:		CONTIN
MIANSERIN HYDROCHLORIDE (Suspecte	ed)		Reason:			
	30.	0 Milligram	Daily			
3atch:	Started: 1	2/12/1990		Stopped:	13/12/1990	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Reported: 15/02/1991 Hospitalisation: Admitted to hospi Onset Date: 20/12/1990 Outcome: Recovered Reaction Detai	ital		Weight: Age: DOB: Causality:	
Medicine Details: MIANSERIN HYDROCHLORIDE (Suspection) 3atch:	cted) 60.0 Milligram Started: 16/12/1990	Reason: Daily	3topped: 20/12/1990	
Laboratory Investigations:				
Additional Information:				

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 70068 Seq: 1 Gender: M
Reported: 20/03/1991 Weight:

Hospitalisation: Age: 82Y
Onset Date: 06/03/1991
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Arthralgia			

Medicine Details:

SOTALOL HYDROCHLORIDE (Other drug)

80.0 Milligram
Daily

3atch: Started: 01/10/1990
Stopped:

TOLVON (Suspected)

Reason: Depression

20.0 Milligram Daily

3atch: 3tarted: 05/03/1991 3topped:

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.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 70128 Seq: 1 Gender: F

Reported: 27/03/1991 Weight: 54.00 Hospitalisation: Age: 78Y

Onset Date: 12/12/1990 **DOB:**

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			

Medicine Details:

VALIUM (Other drug) Reason: Anxiety neurosis

4.0 Milligram Daily

3atch: 3tarted: 01/01/1989 3topped:

METHYLCELLULOSE (Other drug) Reason: Constipation

2.0 Dose Unspecified Daily

3atch: 3tarted: 01/01/1989 3topped:

LACTULOSE (Other drug) Reason: Constipation

20.0 Millilitre Daily

3atch: 3tarted: 01/01/1989 3topped:

NIFEDIPINE (Other drug) Reason: Essential benign hypertension

80.0 Milligram Daily

3atch: 3tarted: 01/01/1989 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 23/10/90 22/11 12/12 13/12 15/12 17/12 19/12 21/12 27/12 28/12 plt 391 241 85 -83 -94 -102 -103 -102 -120 -91 31/12 3/1/91 30/1 4/2 11/2 18/2 20/2 25/2 27/2 ref range plt -126 155 -124 -119 -123 -120 -144 -104 -120 (120-400)

Additional Information:

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

Report Run 01/08/200 02:06PN Database: pusime ADRS004 Page 59 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 70128 Seq: 1 Gender: F

Weight: 54.00

Reported: 27/03/1991 **Hospitalisation:**

Age: 78Y

Onset Date: 12/12/1990

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detai

				tai	

TOLVON (Suspected) Reason: Depression

80.0 Milligram Daily

3atch: 3tarted: 08/11/1990 3topped: 12/12/1990

Laboratory Investigations:

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 70489
 Seq:
 1
 Gender:
 F

 Reported:
 24/12/1990
 Weight:
 77.00

 Hospitalisation:
 Age:
 73Y

Onset Date: 21/12/1990 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Neaction Detai	-		
Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			
Pneumonia			Isolation.iv gentamicin/ticarcillin sodium

Medicine Details:

COLOXYL (Other drug)		Reason:	
	0.0		
3atch:	Started:	Stopped:	
PINDOLOL (Other drug)		Reason:	
	10.0 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN
TOLVON (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
3atch:	3tarted: 14/11/1990	Stopped:	21/12/1990
ZYLOPRIM (Suspected)		Reason: Gout	
Tablet	150.0 Milligram	Daily	Oral
3atch:	Started: 01/07/1990	Stopped:	21/12/1990

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result		Details				
	Haematology				1	21/12/90	27/12/90	wcc	1.8 nil neut	2.7

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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 70771
 Seq:
 1
 Gender:
 M

 Reported:
 19/04/1991
 Weight:
 59.00

 Hospitalisation:
 Age:
 62Y

Onset Date: 31/12/1990 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Botai			
Preferred Term	Severity	Report Description	Treatment
Rash vesicular			Cease penicillamine, diprosone cream

Medicine Details:

PENICILLAMINE (Suspected)		Reason:	Progressive syster	nic sclerosis
	750.0 Milligram	Daily		
3atch:	Started: 01/11/1989		Stopped: 10/	01/1991
RANITIDINE (Suspected)		Reason:		
	300.0 Milligram	Daily		
3atch:	Started: 01/07/1990		Stopped:	CONTIN
PREDNISOLONE (Suspected)		Reason:		
	10.0 Milligram	Daily		
3atch:	3tarted: 01/11/1990		Stopped:	CONTIN
MIANSERIN HYDROCHLORIDE (Suspecte	d)	Reason:		
	20.0 Milligram	Daily		
3atch:	3tarted: 01/07/1990		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail			
Case Number: 7077	1 Seq: 1	Gender:	M
Reported: 19/04	•	Weight:	
Hospitalisation:	, 166 1	Age:	
Onset Date: 31/12	2/1990	DOB:	021
Outcome: Not ye			Causality possible
Reaction Detai	01.00070.00	- Cuacumy.	caddanty possible
reaction Detail			
Medicine Details:			
FELODIPINE (Suspected)		Reason:	
	5.0 Milligram	Daily	
3atch:	Started: 18/10/1990	Stopped:	CONTIN
			_
l alaamatama luusaati			
Laboratory Investi	igations:		

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 71157 Seq: 1 Gender: F
Reported: 03/06/1991 Weight:
Hospitalisation: Age: 75Y

Onset Date: 29/11/1990 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

reduction Botal			
Preferred Term	Severity	Report Description	Treatment
Deafness			
Tinnitus			

Medicine Details:

AMINOGLUTETHIMIDE (Suspected)		Reason:	Malignant neo	plasm of breast	
Tablet	500.0 Milligram	Daily		Oral	
3atch:	Started: 19/09/1990		Stopped:	28/03/1991	
MORPHINE MIXTURE, GOVERNMENT STORES (Suspected)			Pain		
Tablet	60.0 Millilitre	Daily		Oral	
Batch:	31/08/1990		Stopped:		CONTIN
HYDROCORTISONE ACETATE (Suspecte	d)	Reason:	Malignant nec	plasm of breast	
HYDROCORTISONE ACETATE (Suspecter Oral application	d) 50.0 Milligram	Reason: Daily	Malignant neo	oplasm of breast Oral	
` '	•		Malignant ned	•	
Oral application	50.0 Milligram		J	Oral	
Oral application 3atch:	50.0 Milligram	Daily	Stopped:	Oral	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Hospitalisation: Onset Date: Outcome: Reaction Detai	03/06/1991 29/11/1990 Not yet recovered	Seq: 1		C	Gender: Weight: Age: DOB: ausality:		
Medicine Det							_
VALIUM (Suspecte	ed)	4-0	Reason:				
Tablet		15.0 Milligram	Daily		Oral		
3atch:		31/08/1990		Stopped:		CONTIN	
TOLVON (Suspect	ted)		Reason:				
Tablet		60.0 Milligram	Daily		Oral		
3atch:		31/08/1990		Stopped:	14/05/1991		
MEGOSTAT (Susp	ected)		Reason:				
Tablet		40.0 Milligram	Daily		Oral		
3atch:		Started: 31/08/1990		Stopped:		CONTIN	
Laboratory In	vestigations:						
Additional Inf	formation:						



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 71296
 Seq:
 1
 Gender:
 M

 Reported:
 11/06/1991
 Weight:
 74.00

 Hospitalisation:
 Age:
 80Y

Onset Date: 24/05/1991 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

104011011 20141					
Preferred Term	Preferred Term Severity Report Description		Treatment		
Confusional state			Mianserin ceased. patient had? viral infection which may have contributed to increased		
Hepatic function abnormal					

Medicine Details:

TOLVON (Suspected)		Reason: Depression
	60.0 Milligram	Daily
Зatch:	3tarted: 01/02/1991	Stopped: 28/05/1991
DIAMICRON (Suspected)		Reason: Diabetes mellitus
	320.0 Milligram	Daily
3atch:	Started:	Stopped:
GLUCOPHAGE (Suspected)		Reason: Diabetes mellitus
	2.0 Gram	Daily
3atch:	Started:	Stopped:
MOGADON (Suspected)		Reason: Specific disorders of sleep
	5.0 Milligram	Daily
3atch:	Started:	Stopped:

Laboratory Investigations:

	<u> </u>				
Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				09/07/90 24/05/91 27/05 30/05 3/06 7/06 alk phos 91 u/l 230 405 394 266 207 ast 12 u/l 122 78 35 15 10 alt 8 u/l 117 141 90 43 22 ggt 11

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Repor	t Detail
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 Case Number:
 71296
 Seq:
 1
 Gender:
 M

 Reported:
 11/06/1991
 Weight:
 74.00

 Hospitalisation:
 Age:
 80Y

Onset Date: 24/05/1991 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

ZANTAC (Suspected)

Reason: Ulcer of stomach w/o ment perf

300.0 Milligram Daily

3atch: Started: 01/02/1991 Stopped:

LIQUIFILM TEARS (Suspected)

6.0 Dose Unspecified Daily

3atch: Started: Stopped:

Laboratory Investigations:

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 71558
 Seq:
 1
 Gender:
 F

 Reported:
 26/06/1991
 Weight:

Hospitalisation: Age: 78Y

Onset Date: 11/04/1991 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Malaise		Unwell	
Hepatic function abnormal			
Red blood cell sedimentation rate			

Medicine Details:

TOLVON (Suspected)			Reason:	Depression	
Tablet	20.0	Milligram	Daily		Oral
3atch:	Started: 01/	03/1991		Stopped:	15/04/1991
INDERAL (Suspected)			Reason:	Palpitation	
Tablet	60.0	Milligram	Daily		Oral
Batch:	Started:	L	TERM	Stopped:	15/04/1991
MURELAX (Suspected)			Reason:	Specific disor	ders of sleep
Tablet	30.0	Milligram	Daily		Oral
3atch:	Started:	L	TERM	Stopped:	15/04/1991

Laboratory Investigations:

	,				
Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Very high ast, alp, ggt, low protein and albumin.

Additional Information:

All medications ceased and patient recommenced on amitriptyline two days later with no adverse effect and biliruim level remained normal. previous similar reaction to chlorpromazine 30 yrs ago with abnormal lft's. 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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number:72050Seq:1Gender:FReported:01/08/1991Weight:Hospitalisation:Age:

Onset Date: 14/07/1991 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hepatocellular damage	Liver damage		

Medicine Details:

VALIUM (Suspected)		Reason:	
	2.5 Milligram	1 time	
3atch:	3tarted: 04/07/1991	Stopped:	
TOLVON (Suspected)		Reason: Depression	
	80.0 Milligram	Daily	
3atch:	Started: 08/07/1991	Stopped:	09/07/1991
TOLVON (Suspected)		Reason: Depression	
	100.0 Milligram	Daily	
3atch:	Started: 09/07/1991	Stopped:	16/07/1991

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT		16/07/1991	139	
	AST = SGOT		24/07/1991	267	
	Bilirubin		16/07/1991	50	
	Bilirubin		24/07/1991	34	
	GGT = SGGT =		16/07/1991	377	
	GGT = SGGT =		24/07/1991	142	
	SAP = ALP		16/07/1991	265	

Additional Information:



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report D	etai								
Case Num	nber:	72050	Seq:	: 1				Gender:	F
_		01/08/199	91			Weight:			
ospitalisa						Age:			
		14/07/199						DOB:	
		Not yet re	ecovered				C	Causality:	Causality possible
action E	Detai								
ledicine	Deta	ails:							
VALIUM (Su					Reas	on:			
				2.5 Mill	igram	1 time			
3atc			31	tarted: 04/07/1	991		Stopped:		
TOLVON (S	uspect	ed)			Reas		Depression		
				80.0 Mill		Daily			
3atc			31	tarted: 08/07/1			Stopped:	09/07/1991	
TOLVON (St	uspect	ed)			Reas		Depression		
2-4-	L .			100.0 Mill		Daily	\	40/07/4004	
3atc	:n:		51	tarted: 09/07/1	991		Stopped:	16/07/1991	
aborato	ry In	vestigat	ions:						
Date		Туре	Range	Date Tested	Result			Deta	ils
	SAP =	: ALP		24/07/1991	194				
Additiona	al Inf	ormatio	n:						



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 72115
 Seq:
 1
 Gender:
 F

 Reported:
 16/07/1991
 Weight:

Hospitalisation:
Onset Date: 16/06/1991
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detail

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
Neutropenia	Required Visit to Doctor		

Medicine Details:

LASIX (Other drug)	Reason:			
	40.0 Milligram	Daily		
3atch:	Started:	Stopped	d:	
ALLOPURINOL (Other drug)	Reason:			
	300.0 Milligram	Daily		
3atch:	Started:	Stopped	d:	
LANOXIN (Other drug)		Reason:		
	250.0 Microgram	Daily		
3atch:	Started:	Stopped	d:	
SLOW-K (Other drug)		Reason:		
Tablet	1.2 Gram	Daily	Oral	
3atch:	Started:	Stopped	d: CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets	150-450 X 10/9	05/04/1991	518	
	Platelets	150-450 X 10/9	18/04/1991	279	
	Platelets	150-450 X 10/9	17/06/1991	477	
	Platelets	150-450 X 10/9	12/06/1991	-	
	Platelets	150-450 X 10/9	04/07/1991	461	
	Platelets	150-450 X 10/9	15/07/1991	438	
	Platelets	150-450 X 10/9	08/07/1991	491	

Additional Information:

Patient had severe vascular disease of her (r) lower limb - finally had a below knee amputation . subsequently depressed - placed on tolvon after psychiatric consultation. recovered fully after ceasing tolvon. tovlon was given 20 mg at night on 15/05/91, increased to 30 mg at night on 17/05/91 and subsequently increased to 40 mg at night on 30/05/91

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 72115 Seq: 1 Gender: F

Reported: 16/07/1991 Weight:
Hospitalisation: Age: 76Y

Onset Date: 16/06/1991 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Medicine Details:

Modionio Botano.				
TOLVON (Suspected)		Reason:	Depression	
Tablet	40.0 Milligram	Daily		Oral
Зatch:	Started: 15/05/1991		Stopped:	02/07/1991

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets	150-450 X 10/9	02/07/1991	516	
	Platelets	150-450 X 10/9	01/07/1991	505	
	White blood cells	7.5-3.5 X 10/9	05/04/1991	11.0	
	White blood cells	7.5-3.5 X 10/9	18/04/1991	13.1	
	White blood cells	7.5-3.5 X 10/9	12/06/1991	12.5	
	White blood cells	7.5-3.5 X 10/9	17/06/1991	10.9	
	White blood cells	7.5-3.5 X 10/9	01/07/1991	2.6	

Additional Information:

Patient had severe vascular disease of her (r) lower limb - finally had a below knee amputation . subsequently depressed - placed on tolvon after psychiatric consultation. recovered fully after ceasing tolvon. tovlon was given 20 mg at night on 15/05/91, increased to 30 mg at night on 17/05/91 and subsequently increased to 40 mg at night on 30/05/91

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 72115
 Seq:
 1
 Gender:
 F

 Reported:
 16/07/1991
 Weight:

Hospitalisation:
Onset Date: 16/06/1991
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Medicine Details:

LASIX (Other drug)		Reason:	
	40.0 Milligram	Daily	
3atch:	Started:	Stopped:	:
ALLOPURINOL (Other drug)		Reason:	
	300.0 Milligram	Daily	
3atch:	Started:	Stopped:	:
LANOXIN (Other drug)		Reason:	
	250.0 Microgram	Daily	
3atch:	Started:	Stopped:	:
SLOW-K (Other drug)		Reason:	
Tablet	1.2 Gram	Daily	Oral
3atch:	Started:	Stopped:	: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells	7.5-3.5 X 10/9	02/07/1991	2.9	
	White blood cells	7.5-3.5 X 10/9	04/07/1991	3.3	
	White blood cells	7.5-3.5 X 10/9	08/07/1991	7.6	
	White blood cells	7.5-3.5 X 10/9	15/07/1991	10.0	

Additional Information:

Patient had severe vascular disease of her (r) lower limb - finally had a below knee amputation . subsequently depressed - placed on tolvon after psychiatric consultation. recovered fully after ceasing tolvon. tovlon was given 20 mg at night on 15/05/91, increased to 30 mg at night on 17/05/91 and subsequently increased to 40 mg at night on 30/05/91

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail								
Case Number: 721	115 Se	q : 1				Gender:	F	
Reported: 16/	07/1991					Weight:		
Hospitalisation:						Age:	76Y	
Onset Date: 16/						DOB:		
Outcome: Re	covered				C	Causality:	Causality probable	
Reaction Detai								
Medicine Details TOLVON (Suspected)) -			Reason:	Depression			
Tablet		40	0.0 Milligram	Daily	Depression	Oral		
3atch:			15/05/1991	Daily	Stopped:	02/07/1991		
- Julioni			10/00/1001		жорроц.	02/07/1001		
Laboratory Inves	stigations:							
•	-							

Additional Information:

Patient had severe vascular disease of her (r) lower limb - finally had a below knee amputation . subsequently depressed - placed on tolvon after psychiatric consultation. recovered fully after ceasing tolvon. tovlon was given 20 mg at night on 15/05/91, increased to 30 mg at night on 17/05/91 and subsequently increased to 40 mg at night on 30/05/91

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 72245 Seq: 1 Gender: M

Reported: 13/08/1991 Weight: 78.00 Hospitalisation: Age: 71Y

Onset Date: 28/06/1991 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

10404011 20441			
Preferred Term	Severity	Report Description	Treatment
Chest pain			

Medicine Details:

RENITEC (Other drug)		Reason:	Essential ben	ign hypertension
Tablet	5.0 Milligram	Daily		Oral
Зatch:	3tarted: 01/05/1990		Stopped:	
TOL VON (Supported)		Reason:	Depression	
TOLVON (Suspected)		veason.	Depression	
Tablet	30.0 Milligram	Daily	•	Oral

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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 72352
 Seq:
 1
 Gender:
 F

 Reported:
 25/07/1991
 Weight:

Hospitalisation: Age: 40Y

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

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

60.0 Milligram Daily

3atch: **3tarted**: 01/02/1991 **3topped**:

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.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 72354
 Seq: 1
 Gender:
 F

 Reported:
 25/07/1991
 Weight:

Hospitalisation:
Onset Date: 21/04/1991
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

•	Caction Botal			
	Preferred Term	Severity	Report Description	Treatment
	Leukopenia			
	Thrombocytopenia			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

80.0 Milligram Daily

3atch: 3tarted: 17/04/1991 3topped: 21/04/1991

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets	150-400	19/04/1991	175	
	Platelets	150-400	22/04/1991	138	
	Platelets	150-400	23/04/1991	133	
	White blood cells	4-11	19/04/1991	3.8	
	White blood cells	4-11	22/04/1991	3.3	
	White blood cells	4-11	23/04/1991	4.1	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 72392 Seq: 1 Gender: F

Reported: 03/08/1991 Weight:
Hospitalisation: Age: 66Y

Onset Date: 01/07/1991 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

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Preferred Term	Severity	Report Description	Treatment
Arthritis		Painful & stiff knees, fingers, wrists	
Rash		Pinpoint rash on both lower legs	
Pharyngitis			

Medicine Details:

MIDAMOR (Other drug)	Reason:	
Tablet	2.0 Dose Unspecified Weel	kly Oral
3atch:	Started: L TERM	Stopped:
CHLOTRIDE (Other drug)	Reason:	
Tablet	2.0 Dose Unspecified Weel	kly Oral
3atch:	Started: L TERM	Stopped:
INDERAL (Other drug)	Reason:	Palpitation
Tablet	40.0 Milligram Daily	Oral
Заtch:	Started: 19/10/1984	Stopped:
FELDENE (Other drug)	Reason:	Unspecified arthritis
Capsule	20.0 Milligram Daily	Oral
3atch:	Started: 15/10/1990	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.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

-	\sim	 	eta	

 Case Number:
 72392
 Seq:
 1
 Gender:
 F

 Reported:
 03/08/1991
 Weight:
 Weight:

Hospitalisation:
Onset Date: 01/07/1991
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Medicine Details:

PREMARIN (Other drug) Reason: Essential benign hypertension 625.0 Microgram Daily 3tarted: 01/01/1989 3atch: Stopped: **MIANSERIN HYDROCHLORIDE (Suspected)** Reason: Unspecified arthritis Tablet 60.0 Milligram Daily Oral 3atch: 3tarted: 07/06/1991 Stopped: 05/07/1991

Laboratory Investigations:

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report	: Detail
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Case Number: 72464 Seq: 1 Gender: F

Reported: 09/08/1991 Weight:
Hospitalisation: Age: 61Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Nightmare			Tolvon changed to fluoxetine.

Medicine Details:

TOLVON (Suspected)	3			
	30.0 Milligram	Daily		
3atch:	Started: 08/01/1991		Stopped:	
TOLVON (Suspected)	5	eason:		
	50.0 Milligram	Daily		
3atch:	Started : 09/01/1991		Stopped:	
TOLVON (Suspected)	२	eason:		
	60.0 Milligram	Daily		
3atch:	Started : 10/01/1991		Stopped:	11/01/1991

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Rep	00	rt	D	eta	il
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 Case Number:
 72982
 Seq:
 1
 Gender:
 M

 Reported:
 12/09/1991
 Weight:
 73.00

 Hospitalisation:
 Age:
 70Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

todotion Botal		E	
Preferred Term	Severity	Report Description	Treatment
Mouth ulceration		Ulcerated mouth lesions	
Agranulocytosis			

Medicine Details:

OXAZEPAM (Other drug)		Reason:	
	15.0 Milligram	Daily	
3atch:	Started:	Stopped:	27/08/1991
TEMAZEPAM (Other drug)		Reason:	
	20.0 Milligram	Daily	
3atch:	Started:	Stopped:	27/08/1991
TOLVON (Suspected)		Reason: Depression	
	100.0 Milligram	Daily	
3atch:	Started: 20/07/1991	Stopped:	27/08/1991

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 73241 Seq: 1 Gender: M

Reported: 10/10/1991 Weight:
Hospitalisation: Age: 75Y

Onset Date: 25/09/1991 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Confusional state Severe		Acute brain syndrome	

Medicine Details:

CISAPRIDE (Other drug)			Reason:	Peptic ulcer nos w/o ment perf
	15.0	Milligram	Daily	
3atch:	Started:			Stopped:
RANITIDINE (Other drug)			Reason:	Peptic ulcer nos w/o ment perf
	150.0	Milligram	Daily	
Заtch:	Started:			Stopped:
CAPTOPRIL (Other drug)			Reason:	Congestive heart failure
	50.0	Milligram	Daily	
3atch:	Started:			Stopped:
MULTIVITE (Other drug)			Reason:	
	1.0	Dose Unspe	cified Daily	
3atch:	Started:			Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: 73241	Seq: 1	Gender: M
Reported: 10/10/1991		Weight:
Hospitalisation:		Age : 75Y
Onset Date: 25/09/1991		DOB:
Outcome: Recovered		Causality: Causality possible
Reaction Detai		
Acaetton Betai		
Medicine Details:		
FOLIC ACID (Other drug)		Reason:
	5.0 Milligram	Daily
3atch:	Started:	Stopped:
		Reason:
MIANSERIN HYDROCHLORIDE (Suspe	ected)	
MIANSERIN HYDROCHLORIDE (Suspe	ected) 0.0	Reason:
	ected)	
MIANSERIN HYDROCHLORIDE (Suspe	ected) 0.0	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	ected) 0.0	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	ected) 0.0	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	ected) 0.0	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	ected) 0.0	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	ected) 0.0	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	0.0 Started:	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	0.0 Started:	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	0.0 Started:	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	0.0 Started:	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	0.0 Started:	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	0.0 Started:	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	0.0 Started:	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	0.0 Started:	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	0.0 Started:	Reason:
MIANSERIN HYDROCHLORIDE (Suspension): Laboratory Investigations:	0.0 Started:	Reason:
MIANSERIN HYDROCHLORIDE (Suspe	0.0 Started:	Reason:
MIANSERIN HYDROCHLORIDE (Suspension): Laboratory Investigations:	0.0 Started:	Reason:
MIANSERIN HYDROCHLORIDE (Suspension): Laboratory Investigations:	0.0 Started:	Reason:
MIANSERIN HYDROCHLORIDE (Suspension): Laboratory Investigations:	0.0 Started:	Reason:



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 73807 Seq: 1 Gender: F
Reported: 30/10/1991 Weight: 52.00

 Hospitalisation:
 Age: 75

 Onset Date: 21/10/1991
 DOB: 26/03/1916

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Lft's increased.	
Confusional state			
Coordination abnormal			
Nystagmus			
Somnolence			

Medicine Details:

TEGRETOL (Suspected)		Reason:	Convulsions	
	200.0 Milligram	Daily		
3atch:	Started: 09/10/1991		Stopped:	14/10/1991
TEGRETOL (Suspected)		Reason:	Convulsions	
	400.0 Milligram	Daily		
3atch:	3tarted: 14/10/1991		Stopped:	23/10/1991
MIANSERIN HYDROCHLORIDE (Su	spected)	Reason:		
	20.0 Milligram	Daily		
3atch:	Started:		Stopped:	

Laboratory Investigations:

Laborato	ory investigations.								
Date	Туре	Range	Date Tested	Result	Details				
	AST = SGOT	< 40 U/L	02/10/1991	20					
	AST = SGOT	< 40 U/L	16/10/1991	25					
	AST = SGOT	< 40 U/L	21/10/1991	63					
	AST = SGOT	< 40 U/L	23/10/1991	74					
	AST = SGOT	< 40 U/L	04/11/1991	92					
	AST = SGOT	< 40 U/L	06/11/1991	80					
	AST = SGOT	< 40 U/L	31/10/1991	80					

Additional Information:

Patient has had no known previous allergies. mianserin dose was increasing from 20 mg to 70 mg nocte within 4 weeks.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 73807 Seq: 1 Gender: F

Reported: 30/10/1991 Weight: 52.00 Hospitalisation: Age: 75

Onset Date: 21/10/1991 **DOB:** 26/03/1916

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

TEGRETOL (Suspected) Reason: Convulsions

200.0 Milligram Daily

3atch: 3tarted: 09/10/1991 3topped: 14/10/1991

TEGRETOL (Suspected) Reason: Convulsions

400.0 Milligram Daily

3atch: **3tarted**: 14/10/1991 **3topped**: 23/10/1991

MIANSERIN HYDROCHLORIDE (Suspected) Reason:

20.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT	< 40 U/L	30/10/1991	80	
	AST = SGOT	< 40 U/L	28/10/1991	67	
	Bilirubin	< 20 UMOL/L	02/10/1991	7	
	Bilirubin	< 20 UMOL/L	16/10/1991	7	
	Bilirubin	< 20 UMOL/L	21/10/1991	9	
	Bilirubin	< 20 UMOL/L	23/10/1991	11	
	Bilirubin	< 20 UMOL/L	28/10/1991	24	

Additional Information:

Patient has had no known previous allergies. mianserin dose was increasing from 20 mg to 70 mg nocte within 4 weeks.

Report Run 01/08/200 02:07PN Database: pusime ADRS004 Page 85 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 73807 Seq: 1 Gender: F

Reported: 30/10/1991 Weight: 52.00 Hospitalisation: Age: 75

Onset Date: 21/10/1991 **DOB**: 26/03/1916

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

TEGRETOL (Suspected)		Reason:	Convulsions	
	200.0 Milligram	Daily		
Зatch:	Started: 09/10/1991		Stopped:	14/10/1991
TEGRETOL (Suspected)		Reason:	Convulsions	
	400.0 Milligram	Daily		
Зatch:	3tarted: 14/10/1991		Stopped:	23/10/1991
MIANSERIN HYDROCHLORIDE (Su	spected)	Reason:		
	20.0 Milligram	Daily		
3atch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	< 20 UMOL/L	30/10/1991	18	
	Bilirubin	< 20 UMOL/L	31/10/1991	26	
	Bilirubin	< 20 UMOL/L	04/11/1991	15	
	Bilirubin	< 20 UMOL/L	06/11/1991	16	
	GGT = SGGT =	< 30 U/L	02/10/1991	,0	
	GGT = SGGT =	< 30 U/L	16/10/1991	115	
	GGT = SGGT =	< 30 U/L	23/10/1991	290	

Additional Information:

Patient has had no known previous allergies. mianserin dose was increasing from 20 mg to 70 mg nocte within 4 weeks.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 73807 Seq: 1 Gender: F

Reported: 30/10/1991 Weight: 52.00 Hospitalisation: Age: 75

Onset Date: 21/10/1991 **DOB:** 26/03/1916

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

TEGRETOL (Suspected) Reason: Convulsions

200.0 Milligram Daily

3atch: 3tarted: 09/10/1991 3topped: 14/10/1991

TEGRETOL (Suspected) Reason: Convulsions

400.0 Milligram Daily

3atch: **3tarted**: 14/10/1991 **3topped**: 23/10/1991

MIANSERIN HYDROCHLORIDE (Suspected) Reason:

20.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =	< 30 U/L	31/10/1991	505	
	GGT = SGGT =	< 30 U/L	30/10/1991	510	
	GGT = SGGT =	< 30 U/L	28/10/1991	428	
	GGT = SGGT =	< 30 U/L	21/10/1991	213	
	ĜĜT = SGGT =	< 30 U/L	04/11/1991	510	
	ĜĜT = SGGT =	< 30 U/L	06/11/1991	610	
	SAP = ALP	30-115 U/L	02/10/1991	95	

Additional Information:

Patient has had no known previous allergies. mianserin dose was increasing from 20 mg to 70 mg nocte within 4 weeks.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 73807 Seq: 1 Gender: F

Reported: 30/10/1991 Weight: 52.00 Hospitalisation: Age: 75

Onset Date: 21/10/1991 **DOB:** 26/03/1916

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

TEGRETOL (Suspected) Reason: Convulsions

200.0 Milligram Daily

3atch: 3tarted: 09/10/1991 **3topped:** 14/10/1991

TEGRETOL (Suspected) Reason: Convulsions

400.0 Milligram Daily

3atch: **3tarted**: 14/10/1991 **3topped**: 23/10/1991

MIANSERIN HYDROCHLORIDE (Suspected) Reason:

20.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	30-115 U/L	16/10/1991	131	
	SAP = ALP	30-115 U/L	21/10/1991	191	
	SAP = ALP	30-115 U/L	23/10/1991	235	
	SAP = ALP	30-115 U/L	28/10/1991	339	
	SAP = ALP	30-115 U/L	30/10/1991	386	
	SAP = ALP	30-115 U/L	31/10/1991	423	
	SAP = ALP	30-115 U/L	04/11/1991	500	

Additional Information:

Patient has had no known previous allergies. mianserin dose was increasing from 20 mg to 70 mg nocte within 4 weeks.

Report Run 01/08/200 02:07PN Database: pusime ADRS004 Page 88 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 73807 Seq: 1 Gender: F

Reported: 30/10/1991 Weight: 52.00 Hospitalisation: Age: 75

Onset Date: 21/10/1991 **DOB**: 26/03/1916

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

TEGRETOL (Suspected) Reason: Convulsions

200.0 Milligram Daily

3atch: Started: 09/10/1991 Stopped: 14/10/1991

TEGRETOL (Suspected) Reason: Convulsions

400.0 Milligram Daily

3atch: **3tarted**: 14/10/1991 **3topped**: 23/10/1991

MIANSERIN HYDROCHLORIDE (Suspected) Reason:

20.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

_	· _	_			
Date	Type	Range	Date Tested	Result	Details
	71	ŭ			
	SAP = ALP	30-115 U/I	06/11/1991	525	
	SAP = ALP	30-115 U/L	06/11/1991	525	

Additional Information:

Patient has had no known previous allergies. mianserin dose was increasing from 20 mg to 70 mg nocte within 4 weeks.

Report Run 01/08/200 02:07PN Database: pusime ADRS004 Page 89 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 73971
 Seq:
 1
 Gender:
 M

 Reported:
 07/11/1991
 Weight:
 83.00

 Hospitalisation:
 Age:
 76Y

Onset Date: 01/11/1991 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

INDERAL (Other drug)		Reas	on.			
MDEITAL (Other drug)	30.0	Milligram	Daily			
3atch:	Started:			Stopped:		CONTIN
ROHYPNOL (Other drug)		Reas	on:			
Tablet	0.5	Dose Unspecified	Daily		Oral	
3atch:	Started:			Stopped:		CONTIN
TOLVON (Suspected)		Reas	on:	Depression		
Tablet	2.0	Dose Unspecified	Daily		Oral	
3atch:	Started:	L TERM		Stopped:	07/11/1991	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		05/11/1991	11	
	Neutrophils		13/11/1991	72	
	White blood cells	3.5-11.5	05/11/1991	2.3	
	White blood cells	3.5-11.5	13/11/1991	7.5	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report De	tail						
Case Numl Report Hospitalisati Onset D	ber: 74777 ted: 13/12/199 ion: ate: 12/08/199 me: Recovere	01	1		C	Gender: Weight: Age: DOB:	60.00 74Y
	ferred Term	Seve	erity	Report	Description		Treatment
Atrial fibrillat	ion						
Medicine MIANSERIN I Table 3atch	HYDROCHLORIDE et		160.0 Milli rted: 11/08/19		Depression Daily Stopped:	Oral 14/08/199	1
Laborator	y Investigat	ions:					
Date	Туре	Range	Date Tested	Result		Deta	ils
Additiona	l Informatio	n:					



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 75153 Gender: F Seq: 1 Reported: 16/01/1992 Weight:

Hospitalisation: Admitted to hospital Age: 71Y

Onset Date: 10/01/1992 DOB: Causality: Causality probable

Outcome: Recovered with sequelae

Reaction Detail

Veaction Detai			
Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			
Neutropenia			Admitted for investigation and antibiotics.

Medicine Details:

ANGININE (Other drug)		Reason:	Angina pector	is w/o hyperten	
Tablet	1.0 Dose Unspe	ecified Daily		Sublingual	
3atch:	Started: 01/01/1985		Stopped:		CONTIN
LASIX (Other drug)		Reason:	Edema and di	ropsy	
Oral application	40.0 Milligram	Daily		Oral	
3atch:	3tarted: 01/01/1985		Stopped:		CONTIN
TOLVON (Suspected)		Reason:	Depression		
Tablet	80.0 Milligram	Daily		Oral	
3atch:	Started: 01/11/1991		Stopped:	10/01/1992	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells				09/01/92 wcc 2.7

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail					
Case Number: 75289 Reported: 29/01/1992 Iospitalisation:	Seq: 1			Gender: Weight: Age:	
Onset Date:				DOB:	
Outcome: Recovered			C	ausality:	Causality possible
eaction Detai Preferred Term	Severity	Report Des	crintion	1	Treatment
Hallucination	Seventy	Пероп Без	СПРШОП	-	rreatment
Medicine Details: FRUSEMIDE (Other drug)	40.0 Mill	Reason: igram Daily			
3atch:	Started:	,	Stopped:		CONTIN
POTASSIUM NOS (Other drug)		Reason:			
	1.2 Gra	am Daily			
3atch: MIANSERIN HYDROCHLORIDE (Su	Started:	200000	Stopped:		CONTIN
MIANSERIN HTDROCHLORIDE (Su	20.0 Mill	Reason: igram Daily	Depression		
3atch:	Started:		Stopped:	24/01/1992	
THIORIDAZINE HYDROCHLORIDE	(Suspected)	Reason:	Depression		
	20.0 Mill	igram Daily			
	Started:		Stopped:	24/01/1992	
3atch:	Juitou.				
Laboratory Investigation		Result		Detail	s



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Re	po	rt	D	et	ta	i
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 Case Number:
 76380
 Seq:
 1
 Gender:
 F

 Reported:
 03/04/1992
 Weight:

Hospitalisation: Age: 78Y

Onset Date: 19/03/1992 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

 Tablet
 40.0 Milligram
 Daily
 Oral

 3atch:
 Started:
 13/01/1992
 Stopped:
 19/03/1992

Laboratory Investigations:

<u> Lubolutoi</u>	y mivoongat				
Date	Туре	Range	Date Tested	Result	Details
	White blood cells				When first started, dose was 200mg nocte. wcc= 6.1, in march wcc = 3.9. after stopping mianserin for 1 week wcc = 4.9.



Report Detail

Case Number: 76421

Reported: 07/04/1992

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: F

spitalisation Onset Date						Weight: 65.0	0	
Onset Date	n:					-		
	e:		Severe Severe Severe Severe Reason: 0.0 Reason: 6.0 Milligram Daily Reason: 250.0 Microgram Daily Reason: 250.0 Microgram Daily Reason: 160.0 Milligram Daily Reason:					
Outcome	e: Recovered		Age: 74Y DOB: Causality: Causali Severity Report Description Tre ere ere ere ere ere ere 1.00 Started: Stopped: Reason: 6.0 Milligram Daily Started: Stopped: Reason: 250.0 Microgram Daily Started: Stopped: Reason: 250.0 Microgram Daily Started: Stopped: Reason: 250.0 Microgram Daily Started: Stopped: Reason: 160.0 Milligram Daily Started: Stopped:	sality probable				
action Det		Severe Severe Severe 0.0 Started: 6.0 Started: 250.0 Started: 0ther drug) 160.0 Started:						
Prefer	red Term	Sev	rerity	Repor	t Description		Treatment	
nxiety								
yperhidrosis								
ghtmare		Severe	;					
edicine D	etails:							
				Reas	on:			
·	-		0.0					
3atch:		Sta	arted:		Stopped:			
VARFARIN SOI	DIUM (Other drug)			₹eas				
			6.0 Millig	ıram	Daily			
3atch:		Sta			-			
OIGOXIN (Other	r drug)			₹eas				
			250.0 Micro	ogram	Daily			
3atch:		Sta	arted:		Stopped:			
/ERAPAMIL HY	DROCHLORIDE (Other drug)		Reas	on:			
			160.0 Millig	ıram	Daily			
3atch:	e Details: AM (Other drug) ch: Other drug) ch: IL HYDROCHLORIDE (Other drug) ch: C	Sta	arted:		Stopped:			
Julioni								
	1							
aboratory			Date Tested	Result	Ι	Details		
			Date Tested	Result		Details		



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

	76421	Seq: 1		Gender:		
Reported:	07/04/1992			Weight:	65.00	
ospitalisation:				Age:	74Y	
Onset Date:				DOB:		
Outcome:	Recovered		(Causality:	Causality probabl	е
action Detai						
ledicine Deta	ils:					
TOLVON (Suspecte			Reason: Depression			
		20.0 Milligram	Daily			
3atch:		3tarted: 02/01/1992	Stopped:	28/03/1992		
			, toppou.	20,00,1002		
			лоррош	20,00,1002		
			жоррош	20/00/1002		
			Хоррош	20,00,1002		
			лоррош	20/00/1002		
			Хоррош	20/00/1002		
			Хоррош	20/00/1002		
			Хоррош	20/00/1002		
			Хоррош	20/00/1002		
			Хоррош	20/00/1002		
aboratory Inv	vestigations:		Хоррош	20/00/1002		
aboratory Inv	vestigations:		Хоррош	20/00/1002		
aboratory Inv	vestigations:		Хоррош	20/00/1002		
aboratory Inv	vestigations:		Хоррош	20/00/1002		
aboratory Inv	vestigations:		Хоррош	20/00/1002		
aboratory Inv	vestigations:		Хоррош	20/00/1002		
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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report De	etail				
Case Num	ber: 76787	Seq: 1		Gei	nder: M
Repor	ted: 10/04/1992	2		We	ight:
Hospitalisat	ion:				Age : 68Y
Onset D	ate: 24/09/199	1			OOB:
Outco	me: Recovered	İ		Caus	ality: Causality probable
Reaction D		 			
Pre	ferred Term	Severity	Report	Description	Treatment
Eczema					
Pruritus					
Medicine					
MIANSERIN	HYDROCHLORIDE		Reaso		
3atch		60.0 Started: 20		Daily Stopped: 23/1	0/1991
	·-	744.404. 20		уюрров:	
<u>Laborato</u>	ry Investigati	ons:			
Date	Туре	Range Date Tes	sted Result		Details
A .l. d!&:	ıl Informatior				



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

ase Number: 76		Seq:	1				Gender		
Reported: 28	/04/1992						_	: 75.00	
ospitalisation: Onset Date: 11	/02/1002						Age DOB	: 70Y	
		rod				,			ity possible
Outcome: No eaction Detai	ot yet recove	reu				•	Jausanty	. Causai	ity possible
Preferred T	erm	Sev	/erity	Report	Desc	ription		Tre	atment
)ysphagia				•		•			
Pharyngitis									
Skin exfoliation									
MEDAMOR (Other drug				Reas					
MIDAMOR (Other drug	3)		2.5 Mill		on: Daily				
3atch:		34.	arted:	iigraiii	Dally	Mannadi			
Julion.		วเล	arteu.			stoppea:			
DINDEVAN (Other dru	g)) L	arteu.	Reaso	on:	Stopped:			
	g)	51	25.0 Mill		on: Daily	морреа:			
	g)					Stopped:			
DINDEVAN (Other dru	g)		25.0 Mill arted:	ligram Reaso	Daily on:				
DINDEVAN (Other dru 3atch: LASIX (Other drug)	g)	Sta	25.0 Mill arted: 20.0 Mill	ligram Reaso	Daily	Stopped:			
DINDEVAN (Other dru 3atch: LASIX (Other drug) 3atch:		Sta	25.0 Mill arted:	ligram Reaso ligram	Daily on: Daily	Stopped:	incoulation.		tion
DINDEVAN (Other drug) 3atch: LASIX (Other drug) 3atch: INFLUENZA VACCINE		Sta	25.0 Mill arted: 20.0 Mill arted:	ligram Reaso ligram	Daily Daily Daily Dn:	Stopped:			tion
3atch: LASIX (Other drug) 3atch: INFLUENZA VACCINE		St.	25.0 Mill arted: 20.0 Mill arted: 1.0 Mill	ligram Reaso ligram Reaso lilitre	Daily on: Daily	Stopped: Stopped: Prophylactic	inoculation		tion
3atch: LASIX (Other drug) 3atch: INFLUENZA VACCINE Injection 3atch:	: (Suspected)	St:	25.0 Mill arted: 20.0 Mill arted:	ligram Reaso ligram Reaso lilitre	Daily Daily Daily Dn:	Stopped:			tion
3atch: LASIX (Other drug) 3atch: INFLUENZA VACCINE Injection 3atch: aboratory Inve	(Suspected)	St:	25.0 Mill arted: 20.0 Mill arted: 1.0 Mill	ligram Reaso ligram Reaso lilitre	Daily Daily Daily Dn:	Stopped: Stopped: Prophylactic		us	tion
Batch: LASIX (Other drug) 3atch: INFLUENZA VACCINE Injection 3atch: aboratory Inve	(Suspected)	\$t: \$t: \$t:	25.0 Mill arted: 20.0 Mill arted: 1.0 Mill arted: 10/03/1	ligram Reaso ligram Reaso lilitre 1992	Daily Daily Daily Dn:	Stopped: Stopped: Prophylactic	Intraveno	us	tion



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Case Number:	76789	Seq: 1				Gender:	M	
	28/04/1992	•				Weight:		
Hospitalisation:						Age:		
Onset Date:	11/03/1992					DOB:		
Outcome:	Not yet recovered	t				Causality:	Causality possi	ble
Reaction Detai								
Medicine Deta	ails:							
TOLVON (Suspecte	ed)			Reason:	Depression			
Tablet			40.0 Milligram	Daily		Oral		
3atch:		Started:	10/03/1992		Stopped	13/03/1992	2	
Laboratory In	vestigations:							
_	•							
Additional laf								
Additional Inf	ormation:							
) 02:07PN Datah			ADRS00			Page 00	

Report Run 01/08/200 02:07PN Database: pusime ADRS004 Page 99 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 77006
 Seq:
 1
 Gender:
 F

 Reported:
 28/04/1992
 Weight:

Hospitalisation: Admitted to hospital Age: 91Y

Onset Date: 16/04/1992 DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			
Neutropenia			
Sepsis			

Medicine Details:

3atch:

TOLVON (Suspected) Reason: Depression
Tablet 3.0 Dose Unspecified Daily Oral

16/04/1992

Stopped:

Started: 01/03/1992

Laboratory Investigations:

Laborator	y ilivootigat				
Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin				96
	Neutrophils				1%
	Platelets				240
	White blood cells				1.1

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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 77152
 Seq:
 1
 Gender:
 F

 Reported:
 20/05/1992
 Weight:

Hospitalisation: Age: 56

Onset Date: 01/01/1992 **DOB:** 11/05/1935

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Arthralgia			
Malaise			
Pain			
Rash			

Medicine Details:

WARFARIN SODIUM (Other drug)		Reason: Pulmonary embolism&infarction	
Tablet	0.0	Daily Oral	
3atch:	Started: 01/01/1984	Stopped:	
ALDACTONE (Other drug)		Reason: Essential benign hypertension	
Tablet	50.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1984	Stopped:	
LASIX (Other drug)		Reason: Essential benign hypertension	
Oral application	40.0 Milligram	Daily Oral	
3atch:	Started: 01/01/1984	Stopped:	
TEMAZEPAM (Other drug)		Reason: Essential benign hypertension	
Capsule	10.0 Milligram	Daily Oral	
3atch:	Started: 01/01/1984	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Stopped tolvon, symptoms settled over two weeks. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 77152 Seq: 1 Gender: F

Reported: 20/05/1992 Weight:
Hospitalisation: Age: 56

Onset Date: 01/01/1992 **DOB:** 11/05/1935

Outcome: Recovered Causality: Causality probable

Reaction Detai

Medicine Details:

Medicine Details.				
QUININE (Other drug)		Reason:	Pain in limb	
Oral application	300.0 Milligram	Daily		Oral
3atch:	Started: 01/01/1984		Stopped:	
TOLVON (Suspected)		Reason:	Depression	
Tablet	20.0 Milligram	Daily		Oral
3atch:	Started: 04/12/1991		Stopped:	08/05/1992

Laboratory Investigations:

Additional Information:

Stopped tolvon, symptoms settled over two weeks. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Case Number: 77171 Seq: 1 Gender: F

Reported: 19/05/1992 Weight: 65.00 Hospitalisation: Age: 63Y

Onset Date: 04/05/1992 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

104041011 20441		-	
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

TOLVON (Suspected) Reason: Depression

 Tablet
 60.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/05/1992
 3topped:
 09/05/1992

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 77559
 Seq:
 1
 Gender:
 F

 Reported:
 10/06/1992
 Weight:
 80.00

Hospitalisation: Age: 69Y

Onset Date: 21/04/1992 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Arthralgia			
Hepatitis			
Myalgia			
Pyrexia			

Medicine Details:

SLOW-K (Other drug)		Reason:	Congestive hea	rt failure	
Tablet	4.0 Dose Unsp	ecified Daily		Oral	
3atch:	Started:		Stopped:		CONTIN
ISORDIL (Other drug)		Reason:	Congestive hea	rt failure	
Tablet	20.0 Milligram	Daily		Oral	
3atch:	Started:		Stopped:		CONTIN
EDECRIL (Other drug)		Reason:	Congestive hea	rt failure	
Tablet	100.0 Milligram	Daily		Oral	
Зatch:	Started:		Stopped:		CONTIN
TOLVON (Suspected)		Reason:	Pain in joint		
Tablet	30.0 Milligram	Daily		Oral	
3atch:	Started: 01/02/1992		Stopped:	29/04/1992	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		28/04/1992	411	
	AST = SGOT		28/04/1992	241	
	Bilirubin		28/04/1992	22	
	GGT = SGGT =		28/04/1992	479	
	SAP = ALP		28/04/1992	152	

Additional Information:

Previous reaction to frusemide - rash the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Reported: 17/06 Reported: 17/06 Dispitalisation: Onset Date: 13/05 Outcome: Unknown	6/1992 5/1992	1			D	
Preferred Terr	m Sev	verity	Repoi	t Desc	cription	Treatment
Orthostatic hypotensio Syncope			·			
Medicine Details:						
Medicine Details: ADALAT (Other drug)			Reas	on:		
		20.0	Reas Milligram	on: Daily	Oral	
ADALAT (Other drug)	St	20.0 arted:			Oral Stopped:	CONTIN
ADALAT (Other drug) Tablet 3atch: LANOXIN PG (Other drug)		arted:	Milligram	Daily on:	Stopped:	CONTIN
ADALAT (Other drug) Tablet 3atch:		arted:	Milligram	Daily on:	Stopped:	
ADALAT (Other drug) Tablet 3atch: LANOXIN PG (Other drug) Tablet 3atch:	1)	arted:	Milligram	Daily on:	Stopped: Oral Stopped:	CONTIN
ADALAT (Other drug) Tablet 3atch: LANOXIN PG (Other drug) Tablet 3atch: ISORDIL (Other drug)	1)	2.0	Milligram Reas Dose Unspecified Reas	Daily on: Daily	Stopped:	CONTIN
ADALAT (Other drug) Tablet 3atch: LANOXIN PG (Other drug) Tablet 3atch: ISORDIL (Other drug) Tablet	1) St	2.0 sarted: 20.0	Milligram Reas Dose Unspecified	Daily on: Daily	Oral Stopped: Chron isch heart dis r Oral	CONTIN no hyper
ADALAT (Other drug) Tablet 3atch: LANOXIN PG (Other drug) Tablet 3atch: ISORDIL (Other drug) Tablet 3atch:	1) St	2.0	Reas Dose Unspecified Reas Milligram	Daily on: Daily on: Daily	Oral Stopped: Chron isch heart dis r Oral Stopped:	CONTIN no hyper CONTIN
ADALAT (Other drug) Tablet 3atch: LANOXIN PG (Other drug) Tablet 3atch: ISORDIL (Other drug) Tablet 3atch: BETALOC (Other drug)	1) St	2.0 sarted: 20.0 sarted:	Reas Dose Unspecified Reas Milligram	Daily on: Daily on: Daily on:	Oral Stopped: Chron isch heart dis r Oral Stopped: Chron isch heart dis r	CONTIN no hyper CONTIN
ADALAT (Other drug) Tablet 3atch: LANOXIN PG (Other drug) Tablet 3atch: ISORDIL (Other drug) Tablet 3atch: BETALOC (Other drug) Tablet) St	2.0 carted: 20.0 carted: 25.0	Reas Dose Unspecified Reas Milligram	Daily on: Daily on: Daily	Oral Stopped: Chron isch heart dis r Oral Stopped: Chron isch heart dis r Oral Oral	CONTIN no hyper CONTIN no hyper
Tablet 3atch: LANOXIN PG (Other drug) Tablet 3atch: ISORDIL (Other drug) Tablet 3atch: BETALOC (Other drug)) St	2.0 sarted: 20.0 sarted:	Reas Dose Unspecified Reas Milligram	Daily on: Daily on: Daily on:	Oral Stopped: Chron isch heart dis r Oral Stopped: Chron isch heart dis r	CONTIN no hyper CONTIN
ADALAT (Other drug) Tablet 3atch: LANOXIN PG (Other drug) Tablet 3atch: ISORDIL (Other drug) Tablet 3atch: BETALOC (Other drug) Tablet) St St	2.0 carted: 20.0 carted: 25.0	Reas Dose Unspecified Reas Milligram Reas	Daily on: Daily on: Daily on:	Oral Stopped: Chron isch heart dis r Oral Stopped: Chron isch heart dis r Oral Stopped:	CONTIN no hyper CONTIN no hyper



Report Detail

Case Number: 77663

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Gender: U

Conset Date: 13/05/1992	Reported: 17/06/1992				Weight:	
Causality: Causality possible Reaction Details: ZANTAC (Other drug) 3atch: 3tarted: 20.0 Milligram 3atch: 3tarted: 3t	ospitalisation:				Age:	
Company Comp	Onset Date: 13/05/1992				DOB:	
Company Comp	Outcome: Unknown			C	ausality:	Causality possible
	action Detai					
Reason:						
150.0 Milligram Daily Stopped: Sto						
Tablet Started:						
150.0 Milligram Daily Stopped: Sto						
Season:						
Season:						
Season:						
Season:						
150.0 Milligram Daily Stopped: Sto	ledicine Details:					
Started: Started: Stopped: ZOCOR (Other drug) Reason: 20.0 Milligram Daily 3atch: Started: Stopped: MOCLOBEMIDE (Suspected) Oral application Oral application Started: 16/04/1992 MIANSERIN HYDROCHLORIDE (Suspected) Tablet 20.0 Milligram Daily Oral Stopped: 14/05/1992 MIANSERIN HYDROCHLORIDE (Suspected) Tablet 20.0 Milligram Daily Oral Stopped: Oral Stopped: Stopped: Oral Stopped: Stopped: Oral	ZANTAC (Other drug)		Reason:			
Reason: 20.0 Milligram Daily 3atch: Started: Stopped: MOCLOBEMIDE (Suspected) Oral application 150.0 Milligram Daily Oral 3atch: Started: 16/04/1992 Oral MIANSERIN HYDROCHLORIDE (Suspected) Tablet 20.0 Milligram Daily Oral 3topped: 14/05/1992 Oral 3topped: 14/05/1992 Oral 3topped: Oral 3topped: Oral 3topped: Oral		150.0 Milligram	Daily			
3atch: Started: Stopped: MOCLOBEMIDE (Suspected) Oral application Started: 150.0 Milligram Daily Oral Atch: Started: 16/04/1992 Stopped: 14/05/1992 MIANSERIN HYDROCHLORIDE (Suspected) Tablet 20.0 Milligram Daily Oral Stopped: 14/05/1992 Oral Started: Started: Stopped: Stopped: Oral	3atch:	Started:		Stopped:		
Started: Stopped:	ZOCOR (Other drug)		Reason:			
MOCLOBEMIDE (Suspected) Reason: Depression Oral application 150.0 Milligram Daily Oral 3atch: 3tarted: 16/04/1992 3topped: 14/05/1992 MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression Tablet 20.0 Milligram Daily Oral 3atch: 3tarted: 3topped:		20.0 Milligram	Daily			
Oral application 150.0 Milligram Daily Oral 3atch: 3tarted: 16/04/1992 3topped: 14/05/1992 MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression Tablet 20.0 Milligram Daily Oral 3atch: 3tarted: 3topped: 3topped:	3atch:	Started:		Stopped:		
3atch: 3tarted: 16/04/1992 3topped: 14/05/1992 MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression Tablet 20.0 Milligram Daily Oral 3atch: 3tarted: 3topped:	MOCLOBEMIDE (Suspected)		Reason:	Depression		
MIANSERIN HYDROCHLORIDE (Suspected) Tablet 20.0 Milligram Daily Oral 3atch: 3tarted: 3topped:	Oral application	150.0 Milligram	Daily		Oral	
Tablet 20.0 Milligram Daily Oral 3atch: Started: Stopped:	3atch:	Started: 16/04/1992		Stopped:	14/05/1992	
3atch: Started: Stopped:		Suspected)	Reason:	Depression		
	MIANSERIN HYDROCHLORIDE (Daily		Oral	
		20.0 Milligram	Dany			
aboratory Investigations:	Tablet		Dany	Stopped:		
	Tablet 3atch:	Started:		Stopped:		
	Tablet 3atch:	Started:		3topped:		
	Tablet 3atch:	Started:		Stopped:		
	Tablet 3atch:	Started:		Stopped:		
	Tablet 3atch:	Started:		3topped:		
	Tablet 3atch:	Started:		Stopped:		
	Tablet 3atch:	Started:		Stopped:		
	Tablet 3atch:	Started:	July	Stopped:		
	Tablet 3atch:	Started:	July	3topped:		
dditional Information:	Tablet 3atch: aboratory Investigation	Started:	July	3topped:		
Additional Information:	Tablet 3atch: aboratory Investigation	Started:	July	Stopped:		
Additional Information:	Tablet 3atch: aboratory Investigation	Started:	July	Stopped:		
Additional Information:	Tablet 3atch: aboratory Investigation	Started:	July	3topped:		
Additional Information:	Tablet 3atch: aboratory Investigation	Started:	July	3topped:		
Additional Information:	Tablet 3atch: aboratory Investigation	Started:	July	Stopped:		
dditional Information:	Tablet 3atch: aboratory Investigation	Started:	July	Stopped:		



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 80648
 Seq:
 1
 Gender:
 F

 Reported:
 21/10/1992
 Weight:
 48.00

 Hospitalisation:
 Age:
 41Y

Onset Date: DOB:
Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

teaction Detai			
Preferred Term	Severity	Report Description	Treatment
Neutropenia			Gcsf 300 mcg daily
Thrombocytopenia			

Medicine Details:

AZATHIOPRINE (Suspected) Reason:

0.0

3atch: Started: 30/08/1992 Stopped:

CYCLOSPORIN-A (Suspected) Reason:

0.0

3atch: 310/08/1992 3topped:

METHYLPREDNISOLONE (Suspected) Reason:

0.0

3atch: 31/08/1992 3topped:

GANCICLOVIR (Suspected) Reason:

2.0 Dose Unspecified Daily

3atch: 3tarted: 04/10/1992 3topped: 18/10/1992

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets		17/10/1992	48	
	Platelets		18/10/1992	49	
	Platelets		20/10/1992	57	
	Platelets		19/10/1992	67	
	White blood cells		17/10/1992	1.80	
	White blood cells		18/10/1992	0.74	
	White blood cells		19/10/1992	0.40	



Report Detail

Hospitalisation:

Case Number: 80648

Reported: 21/10/1992

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Gender: F

Weight: 48.00

Age: 41Y

action Detai					
dicine Details: ANSERIN HYDROCHLORIDE (Suspected)		Reason:			
ANGERIN HTDROCHLORIDE (Guspecteu)	10.0 Milligram	Daily			
3atch: Sta	rted: 01/10/1992	Dany	Stopped:	18/10/1992	
MPHOTERICIN (Suspected)		Reason:			
Injection	25.0 Milligram	Daily		Intravenous	
3atch: Sta	rted: 26/09/1992		Stopped:		
MENTIN (Suspected)		Reason:			
	12.0 Gram	Daily			
3atch: Sta	rted: 09/10/1992				



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: 81062	Seq: 1		Gen	der: ⊦
Reported: 23/11/199	2		Wei	ght: 80.00
ospitalisation:				Age: 65Y
Onset Date:			D	OB:
Outcome: Unknown			Causa	lity: Causality possible
action Detai				
Preferred Term	Severity	Report De	escription	Treatment
ukopenia				
акороніа	<u> </u>			
edicine Details:				
OLVON (Suspected)		Reason:		
	0.0			
3atch:	Started:		Stopped:	
Juton.	Juitou.		Moppeu.	
boratory Investigati	one:			
	Range Date Teste	d Result		Details
Date Type	Natige Date Teste	u Result		Details
dditional Information	1:			
t Run 01/08/200 02:07PN	Database: pusime	ADRS	3004	Page 109 of 336
01/00/200 02.0/FN	Database. pusitife	ADIN		raye 109 01 330



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 81528
 Seq:
 1
 Gender:
 F

 Reported:
 10/12/1992
 Weight:
 58.00

 Hospitalisation:
 Age:
 80Y

Onset Date: 01/12/1992 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

I todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			
Pharyngitis			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

100.0 Milligram

3atch: 3tarted: 22/09/1992 **3topped:** 03/12/1992

PENICILLIN NOS (Suspected) Reason: Othr diseases of urinary tract

2.0 Gram Daily

3atch: 3tarted: 16/11/1992 **3topped:** 27/11/1992

CARDIZEM (Suspected) Reason: Chron ischem heart dis w hyper

Tablet 360.0 Milligram Daily Oral

3atch: Started: Stopped: CONTIN

ZANTAC (Suspected) Reason: Ulcer of duodenum w/o ment perf

Tablet 300.0 Milligram Daily Oral

3atch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report D)etail
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 Case Number:
 81528
 Seq:
 1
 Gender:
 F

 Reported:
 10/12/1992
 Weight:
 58.00

 Hospitalisation:
 Age:
 80Y

Onset Date: 01/12/1992 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

CARTIA (Suspected)			Reason:			
Tablet	100.0	Milligram	Daily		Oral	
3atch:	Started:			Stopped:		CONTIN
LASIX (Suspected)			Reason:	Chron isch he	eart dis no hyper	
	200.0	Milligram	Daily			
3atch:	Started:			Stopped:		CONTIN
CHLOROMYCETIN (Suspected)			Reason:	Conjunctivitis	and ophthalmia	
Eye Drops	8.0	Dose Unspe	cified Daily		Ophthalmic	
3atch:	Started: 18	/11/1992		Stopped:	27/11/1992	
TRANSIDERM-NITRO (Suspected)			Reason:	Chron isch he	eart dis no hyper	
	50.0	Milligram	Daily			

Laboratory Investigations:



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number:	81528	Seq: 1			Gender:	F
-	10/12/1992				Weight:	
lospitalisation:					Age:	
Onset Date:					DOB:	
Outcome: eaction Detai	Not yet recovere	d			Causality:	Causality possible
Medicine Det						
SLOW-K (Suspect	ed) dified release	6.0		ason:	Oral	
3atch:	umeu reiease	Started:	Dose Unspecifie	u Dally	Stopped:	CONTIN
VALIUM (Suspecte	ed)	marteu.	₹6	ason:	Anxiety neurosis	CONTIN
(2 sopoon	•	2.0	Milligram	Daily	,	
3atch:		Started:	-	,	Stopped:	CONTIN
MAXOLON (Suspe	ected)		₹€	ason:		
Tablet		30.0	Milligram	Daily	Oral	
3atch:		Started:			Stopped:	CONTIN
_aboratory In	vestigations:					
Additional Inf	formation:					



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 81708 Seq: 1 Gender: F

Reported: 15/12/1992 Weight: 72.00 Hospitalisation: Age: 44Y

Onset Date: 31/12/1991 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

todotion Botai			<u> - </u>
Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			Mianserin dose reduced to 20gm/day then stopped.

Medicine Details:

ALPRAZOLAM (Other drug)

Reason: Anxiety neurosis

0.0

3atch: Started: L TERM Stopped: CONTIN

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Anxiety neurosis

65.0 Milligram Daily

3atch: Started: L TERM Stopped:

Laboratory Investigations:

-		<u> </u>				
I	Date	Туре	Range	Date Tested	Result	Details
		Biochemistry				Av. mianserin dose/day (mg) with mean & standard deviation (sd) blood glucose dose fasting readings glucose (mmol/l) pm readings glucose (mmol/l) 65mg 8 9.8 sd 0.5 11 6.3 sd 1.2 40mg 10 8.4 sd 1.5 7 6.3 sd 0.9 20mg 11 7.0 sd 0.9 10 6.1 sd 0.7

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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail						
Case Number: 82695	Seq: 1				Gender:	
Reported: 18/02/1993					Weight:	
ospitalisation:					Age:	42Y
Onset Date: 30/01/1993					DOB:	
Outcome: Recovered				С	ausality:	Causality probable
eaction Detai	-					
Preferred Term	Severity		Report De	escription		Treatment
Agitation						
Dizziness						
Headache						
Nightmare						
Medicine Details: VALIUM (Other drug)			Reason:	Otr spec symp	psychopath	nol nec
		5.0 Milligra	am Da	ily		
3atch:	Started:	10/01/1993	3	Stopped:		CONTIN
TOLVON (Suspected)			Reason:	Depression		
	4	10.0 Milligra	am Da	ily		
3atch:	Started:	29/01/1993	3	Stopped:	02/02/1993	3
Laboratory Investigatio	ns:					
Date Type	Range Date	e Tested	Result		Detai	ils
	·					
Additional Information:						



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 82965 Seq: 1 Gender: M

Reported: 05/03/1993 Weight: 68.00 Hospitalisation: Age: 71Y

Onset Date: 03/03/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

racaction Betai			
Preferred Term	Severity	Report Description	Treatment
Bradycardia			Atropine, haemaccel.
Cardiac arrest			

Medicine Details:

CARDIPRIN 100 (Other drug)			₹eason:		
Tablet	100.0	Milligram	Daily	Oral	
3atch:	Started: 01	/03/1993		Stopped:	CONTIN
PERINDOPRIL (Other drug)			Reason:		
Tablet	2.0	Milligram	Daily	Oral	
3atch:	Started:			Stopped:	CONTIN
DILTIAZEM HYDROCHLORIDE (Other drug	1)		Reason:		
DILTIAZEM HYDROCHLORIDE (Other drug Tablet	90.0	Milligram	Reason: Daily	Oral	
` `	•	Milligram		Oral Stopped:	CONTIN
Tablet	90.0	Milligram			CONTIN
Tablet 3atch:	90.0		Daily		CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: M

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R L		 .,	-14	
110	\sim	 $\boldsymbol{-}$	eta	

Case Number: 82965 Seq: 1

Reported: 05/03/1993 Weight: 68.00 Hospitalisation: Age: 71Y

Onset Date: 03/03/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

		ine		

SEREPAX (Other drug)	Reason:					
	15.0	Milligram	Daily			
3atch:	Started:			Stopped:	01/03/1993	
IMDUR (Other drug)		5	eason:			
	30.0	Milligram	Daily			
3atch:	Started:			Stopped:		CONTIN
HEPARIN SODIUM (Other drug)		5	eason:			
	25.0	Thousand Inter	nat Daily			
3atch:	Started:			Stopped:		CONTIN
TOLVON (Suspected)		5	eason:	Depression		
Tablet	10.0	Milligram	Daily		Oral	
3atch:	Started: 03	/03/1993		Stopped:	03/03/1993	

Laboratory Investigations:



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 83090 Seq: 1 Gender: F

Reported: 11/03/1993 Weight: 47.00 Hospitalisation: Age: 79Y

Onset Date: 01/03/1993 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

DAONIL (Other drug)		Reason:	Diabetes mellitus	
	5.0 Milligram	n Daily	,	
Batch:	Started:		Stopped:	CONTIN
ANCOLAN (Other drug)		Reason:	Chronic sinusitis	
	25.0 Milligram	n Daily	1	
Зatch:	Started:		Stopped:	CONTIN
TILCOTIL (Other drug)		Reason:	Osteoarthritis	
	10.0 Milligram	n Daily	1	
Зatch:	Started:		Stopped:	
STEMETIL (Other drug)		Reason:		
	15.0 Milligram	n Daily	,	

Laboratory Investigations:

	<i>j</i> ga.					
Date	Туре	Range	Date Tested	Result	Details	
	Neutrophils		22/02/1993	2.64		
	Neutrophils		01/03/1993	0.05		
	White blood cells		22/02/1993	4.2		
	White blood cells		01/03/1993	1.7		



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Re	por	t D	etail
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Case Number: 83090 Seq: 1 Gender: F

Reported: 11/03/1993 Weight: 47.00 Hospitalisation: Age: 79Y

Onset Date: 01/03/1993 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Medicine Details:

ZANTAC (Other drug)		Reason:	Ulcer of stoma	nch w/o ment perf
	150.0 Milligram	Daily		
Зatch:	Started:		Stopped:	
ROCALTROL (Other drug)		Reason:	Osteoporosis	
	0.5 Microgram	Daily		
Batch:	Started:		Stopped:	CONTIN
PANADOL (Other drug)		Reason:	Pain	
	4.0 Gram	Daily		
3atch:	Started:		Stopped:	CONTIN
TOLVON (Suspected)		Reason:	Depression	
Tablet	70.0 Milligram	Daily		Oral
Заtch:	Started: 18/01/1993		Stopped:	02/03/1993

Laboratory Investigations:



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail				
Case Number: 83330	Seq: 1		G	Sender: F
Reported: 17/03/1993	·		V	Veight:
ospitalisation:				Age:
Onset Date: 05/03/1993				DOB:
Outcome: Recovered			Ca	usality: Causality probable
action Detai				<u> </u>
Preferred Term	Severity	Report Desc	ription	Treatment
izziness				Ceased tolvon
Gravitational oedema				
1alaise				
Veight increased				
ledicine Details: SURMONTIL (Other drug)		Reason:	Donroggion	
Tablet	150.0 Milli		Depression	Oral
Batch:	Started:	L TERM	Stopped:	on di
TOLVON (Suspected)	Juitou.	Reason:	Depression	
Tablet	40.0 Milli			Oral
3atch:	Started: 02/03/19		Stopped: 0	9/03/1993
ahoratory Investigatio	ne:			
		Result		Details
_aboratory Investigatio Date Type		Result		Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 83691
 Seq:
 1
 Gender:
 F

 Reported:
 31/03/1993
 Weight:
 73.00

 Hospitalisation:
 Age:
 72Y

 Onset Date:
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Dizziness			
Palpitations			
Pruritus			
Rash maculo-papular			Dilosyn , bethamethasone, sorbolene cream.

Medicine Details:

ZOCOR (Suspected)		Reason:	Othr&unspec n	netabolic diseases
Tablet	1.0 Dose Unspe	cified Daily		Oral
Зatch:	Started: 16/02/1993		Stopped:	16/02/1993
CAPOTEN (Suspected)		Reason:	Essential benig	gn hypertension
Oral application	100.0 Milligram	Daily		Oral
3atch:	Started: 01/01/1990		Stopped:	CONTIN
LASIX (Suspected)		Reason:	Congestive hea	art failure
Tablet	80.0 Milligram	Daily		Oral
3atch:	Started: 01/01/1983		Stopped:	CONTIN
VOLTAREN (Suspected)		Reason:	Osteoarthritis	
Tablet	200.0 Milligram	Daily		Oral
3atch:	Started: 01/01/1983		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

DOB:

Report Detail

 Case Number:
 83691
 Seq:
 1
 Gender:
 F

 Reported:
 31/03/1993
 Weight:
 73.00

 Hospitalisation:
 Age:
 72Y

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Onset Date:

Medicine Details:

OROXINE (Suspected)		Reason:	Myxedema	
Tablet	100.0 Microgram	Daily	Oral	
3atch:	Started: 01/01/1984		Stopped:	CONTIN
TOLVON (Suspected)		Reason:	Specific disorders of sleep	
Tablet	10.0 Milligram	Daily	Oral	
3atch:	Started: 01/01/1991		Stopped:	CONTIN

Laboratory Investigations:

Additional Information:

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

Report Run 01/08/200 02:07PN Database: pusime ADRS004 Page 121 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 83765 Seq: 1 Gender: F

Reported: 06/04/1993 Weight: 65.00 Hospitalisation: Age: 69Y

Onset Date: 01/08/1992 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

100000000000000000000000000000000000000		-	
Preferred Term	Severity	Report Description	Treatment
Arthralgia	Arthralgia in forearms.		
Myalgia			

Medicine Details:

LANOXIN (Other drug)			Reason:	Otr&nos disor	rd of heart rhythm
	250.0	Microgram	Daily		
Заtch:	Started:			Stopped:	CONTIN
SOLPRIN (Other drug)			Reason:	Acute,ill-def c	erebrovascular disease w/o hyperte
	150.0	Milligram	Daily		
Зatch:	Started:			Stopped:	CONTIN
QUININE BISULPHATE (Other drug)			Reason:	Pain in limb	
	1.0	Dose Unspe	cified Daily		
Зatch:	Started:			Stopped:	CONTIN
TOLVON (Suspected)			Reason:	Depression	
	60.0	Milligram	Daily		
3atch:	Started: 12	/07/1992		Stopped:	20/08/1992

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Hospitalisation: Onset Date: Outcome: Reaction Detai	06/04/1993 01/08/1992 Recovered	Seq: 1		Gender: Weight: Age: DOB: Causality:	65.00
Medicine Deta					
K. H. 3 (Suspected	1)		Reas		
			1.0 Dose Unspecified		
3atch:		Started	d:	Stopped:	CONTIN
Laboratory In	vestigations:				
Additional Inf	ormation:				



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report D	etail
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Case Number: 84625 Seq: 1 Gender: F
Reported: 19/05/1993 Weight:
Hospitalisation: Age: A6
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Pruritus			
Rash			Phenergan 25 mg

Medicine Details:

MOGADON (Suspected)	Reason:				
	5.0 Milligram	As ne	ecessary		
3atch:	Started:		Stopped:		
PROCTOSEDYL (Suspected)		Reason:	Hemorrhoids		
Suppository	2.0 Dose Uns	specified Daily		Rectal	
3atch:	3tarted: 11/05/1993		3topped:	16/05/1993	
ZANTAC (Suspected)		Reason:			
ZANTAC (Suspected)	300.0 Milligram				
ZANTAC (Suspected) 3atch:	300.0 Milligram		}topped:		
	· ·				
3atch:	· ·	Daily	Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail					
Case Number: 84625 Reported: 19/05/1993 ospitalisation: Onset Date:	Seq: 1			Gender: Weight: Age: DOB:	A6
Outcome: Not yet recovere eaction Detai	ed			Causality:	Causality possible
eaction Detai					
Medicine Details: STEMETIL (Suspected)			Reason:		
OTEMETIC (Ouspected)	15.0	Milligram	Daily		
Batch:	Started:			Stopped:	
TOLVON (Suspected)	00.0	N 42112	Reason:		
3atch:	3tarted:	Milligram	Daily	Stopped:	
Laboratory Investigations:					
Additional Information:					



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report l	Detail
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Case Number: 84660 Seq: 1 Gender: M

Reported: 21/05/1993 Weight: 97.00 Hospitalisation: Age: 30Y

Onset Date: 30/04/1993 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Neurosis		Agoraphobia	

Medicine Details:

TOLVON (Suspected) Reason: Depression

 Tablet
 60.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 28/04/1993
 3topped: 05/05/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Case Number: 84768 Seq: 1 Gender: F

Reported: 31/05/1993 Weight: 59.00 Hospitalisation: Age: 70Y

Onset Date: 12/05/1993 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Nightmare			
Sleep disorder			

Medicine Details:

TOLVON (Suspected) Reason: Depression

 Tablet
 20.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 12/05/1993
 3topped: 14/05/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 85144 Seq: 1 Gender: F

 Reported:
 08/06/1993
 Weight:

 Hospitalisation:
 Age: 64Y

 Onset Date:
 05/04/1993
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

104041011 20441		-	
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

PREDNISOLONE (Other drug)		Reason:	Other rheumatoid arthritis
	4.0	Milligram Daily	
Batch:	Started:	L TERM	Stopped:
FELDENE (Other drug)		Reason:	Other rheumatoid arthritis
	20.0	Milligram Daily	
3atch:	Started:	L TERM	Stopped:
CALTRATE (Other drug)		Reason:	Osteoporosis
	2.0	Dose Unspecified Daily	
3atch:	Started:	L TERM	Stopped:
3atch: AT-10 (Other drug)	Started:	L TERM	Stopped: Osteoporosis
	3tarted: 2.0		Osteoporosis

Laboratory Investigations:

	,				
Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		05/04/1993	73	
	AST = SGOT		05/04/1993	82	
	GGT = SGGT =		05/04/1993	561	
	LDH .		05/04/1993	212	
	SAP = ALP		05/04/1993	230	



Report Detail

Case Number: 85144

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: F

Onset Date: 05/04/1993 Outcome: Recovered			A C 4\/	
			Age: 64Y	
Outcome: Recovered			DOB:	
		(Causality: Causality possible	
action Detai				
ledicine Details:				
DOXYCYCLINE HYDROCHLORIDE (Sus			¶sit diseases	
	100.0 Milligram	Daily		
3atch:	Started: 24/03/1993	Stopped:	05/04/1993	
FOLVON (Suspected)			ns neuralg&neurit	
	10.0 Milligram	Daily		
3atch:	Started: 11/03/1993	Stopped:	05/04/1993	
ahayatamı layaatiyatiana				
aboratory Investigations:				
aboratory Investigations:				



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 85154 Seq: 1 Gender: M

Reported: 08/06/1993 Weight: 66.00 Hospitalisation: Age: 68Y

Onset Date: 22/03/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Muscle contractions involuntary			

Medicine Details:

LANOXIN (Other drug)		Reason:	Otr&nos disord of heart rhythm
	375.0 Microgram	Daily	
Зatch:	3tarted: 01/01/1985		Stopped:
BETALOC (Other drug)		Reason:	Otr&nos disord of heart rhythm
	50.0 Microgram	Daily	
Зatch:	3tarted: 01/01/1985		Stopped:
XANAX (Other drug)		Reason:	
XANAX (Other drug)	250.0 Microgram	Reason: Daily	
XANAX (Other drug) 3atch:	250.0 Microgram Started: 01/01/1986		Stopped:
, ,	•		
3atch:	•	Daily	Stopped: Depression

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: M

Re			

Case Number: 85154 Seq: 1

Reported: 08/06/1993 Weight: 66.00 Hospitalisation: Age: 68Y

Onset Date: 22/03/1993 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

M		ine	 u	

TOLVON (Suspected) Reason: Depression

30.0 Milligram Daily

3atch: 3tarted: 21/03/1993 **3topped:** 23/03/1993

Laboratory Investigations:

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Re	po	rt	D	et	ai∣
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Case Number: 86259 Seq: 1 Gender: F
Reported: 23/07/1993 Weight:
Hospitalisation: Age: 61Y

Onset Date: 31/12/1993 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Burning senation chest, neck, arms, legs	

Medicine Details:

DUCENE (Suspected)				
	0.0			
3atch:	Started:	Stopped:		
TOLVON (Suspected)		Reason:	Reason:	
	0.0			
3atch:	Started:	Stopped:		
PROZAC (Suspected)		Reason:		
	0.0			
3atch:	Started:	Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Allergies- tetracyclines photosensitivity (rash). - the date of onset is not accurate but indicates that onset occurred sometime during the year.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 86972
 Seq: 1
 Gender:
 F

 Reported:
 20/08/1993
 Weight:
 80.00

 Hospitalisation:
 Age: 53Y

 Onset Date:
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Botal		_	
Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Buzzing sensation in the perineal area.	
Tremor			

Medicine Details:

THIAMINE (Suspected)		Reason:		
	100.0 Milligram			
3atch:	Started:		Stopped:	CONTIN
SIMVASTATIN (Suspected)		Reason:	Othr&unspec	metabolic diseases
Tablet	20.0 Milligram	Daily		Oral
3atch:	Started: 01/08/1992		Stopped:	28/04/1993
MIANSERIN HYDROCHLORIDE (Suspecte	ed)	Reason:		
MIANSERIN HYDROCHLORIDE (Suspecte	e d) 50.0 Milligram	Reason: Daily		
MIANSERIN HYDROCHLORIDE (Suspected States) 3atch:	,		}topped:	CONTIN
	50.0 Milligram			CONTIN
Satch:	50.0 Milligram	Daily	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Reported: 20 ospitalisation: Onset Date: Outcome: N		Seq: 1				
Outcome: N					Gender: Weight: Age: DOB:	80.00 53Y
ction Detai	ot yet recovered				Causality:	Causality possible
edicine Detail		250.	0 Microgram	Reason:		
3atch:		Started:			Stopped:	CONTIN
YRIDOXINE HYDRO	CHLORIDE (Suspe		O M:II:	Reason:		
3atch:		Started:	0 Milligram	Daily	Stopped:	CONTIN

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Report Detail

Case Number: 87031

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Gender: F

Reported: 24/08/1993 ospitalisation:		Weight: Age: 73Y						
Onset Date: Outcome: Recovered			DOB: Causality: Causality probable					
eaction Detai				,	ausanty: (oausanty prob	aule	
Preferred Term	Seve	rity	Repor	t Descr	ption		Treatment	
Abdominal pain			•		•			
- Hyperhidrosis								
nsomnia								
Nausea								
Medicine Details:			2					
UREX (Other drug)		80.0 Milli	Reas	on: Daily				
3atch:	Star		gram	Daily	Stopped:			
SLOW-K (Other drug)			₹eas	on:				
		1.8 Gra	m	Daily				
3atch:	3tar	ted:			Stopped:			
TOLVON (Suspected)			₹eas					
		20.0 Milli		Daily				
3atch:	3tar	ted: 19/06/19	993		Stopped:	27/06/1993		
_aboratory Investigation		Date Tested	Result			Details	;	
Additional Information	:							
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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 87110 Seq: 1 Gender: M
Reported: 27/08/1993 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 18/08/1993
DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Detai

Preferred Term	Preferred Term Severity		Treatment
Agranulocytosis			

Medicine Details:

TOLVON (Suspected) Reason: Depression

10.0 Milligram Daily

3atch: **3tarted**: 04/08/1993 **3topped**:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Bone marrow				16/08/93 - bone marrow aspirate - normocellular marrow with a maturation arrest in granulopoiesis and (apart from the presence of a few ring sidero- blasts) no other abnormal features, are consistent with a drug induced neutro- penia although other mechanisms such as overwhelming infection or septicaemia may also produce this picture.
	Neutrophils				No neutrophils on blood film. confirmed on bone marrow
	Neutrophils	0.0 - 0.5	18/08/1993	0.0	
	White blood cells	4.0 - 11.0	18/08/1993	2.5	

Additional Information:

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 87319
 Seq:
 1
 Gender:
 M

 Reported:
 27/08/1993
 Weight:
 76.00

Hospitalisation: Age: 54

Onset Date: 23/07/1993 DOB: 31/08/1938
Outcome: Recovered Causality: Causality probable

Reaction Detai

Neaction Detai		_	
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			
Hyperhidrosis			
Malaise			

Medicine Details:

INDERAL (Other drug)	Reason:				
	0.0				
3atch:	Started:	L TERM	Stopped:		
ZANTAC (Other drug)		Reason:			
	0.0				
3atch:	Started:	L TERM	Stopped:		
TOLVON (Suspected)		Reason:	Depression		
Tablet	60.0 Mill	igram Daily	1	Oral	
3atch:	3tarted: 01/07/1	993	Stopped:	23/07/1993	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT	1 - 45 U/L	23/07/1993	304	
	AST = SGOT	1 - 45 U/L	12/08/1993	32	
	Bilirubin	1 - 24 UMOL/L	22/07/1993	19	
	Bilirubin	1 - 24 UMOL/L	12/08/1993	14	
	GGT = SGGT =	1 - 50 U/L	23/07/1993	640	
	GGT = SGGT =	1 - 50 U/L	12/08/1993	109	
	LDH	105 - 230 U/L	23/07/1993	403	

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Gender: M

Report Detail

Case Number: 87319 Seq: 1

Reported: 27/08/1993 Weight: 76.00 Hospitalisation: Age: 54

Onset Date: 23/07/1993 DOB: 31/08/1938

Outcome: Recovered Causality: Causality probable

Reaction Detai

Medicine Details:

INDERAL (Other drug)	Reason:				
	0.0				
3atch:	Started:	L TERM	Stopped:		
ZANTAC (Other drug)		Reason:			
	0.0				
3atch:	Started:	L TERM	Stopped:		
TOLVON (Suspected)		Reason:	Depression		
Tablet	60.0	Milligram Dail	y	Oral	
3atch:	3tarted: 01/0	7/1993	Stopped:	23/07/1993	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	LDH	105 - 230 U/L	12/08/1993	216	
	SAP = ALP	30 - 115 U/L	23/07/1993	331	
	SAP = ALP	30 - 115 U/L	12/08/1993	97	

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report	: Detail
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Case Number:87320Seq:1Gender:FReported:27/08/1993Weight:Hospitalisation:Age:48Y

Onset Date: 10/06/1993 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

		1	
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			
Nausea			
Vomiting			

Medicine Details:

PREMARIN (Suspected)		Reason:	Menopausal symptoms	
	0.0			
3atch:	Started:		Stopped:	
PROZAC (Suspected)		Reason:	Depression	
	40.0 Milligram	Daily		
3atch:	Started: 20/03/1993		Stopped:	
TOLVON (Suspected)		Reason:	Depression	
(
(**************************************	40.0 Milligram	Daily		
3atch:	40.0 Milligram 3tarted: 01/05/1989	Daily	Stopped:	
, , ,	· ·	Daily		
3atch:	· ·		Specific disorders of sleep	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Elevated alkaline phosphatase, ggt, alt, ast, ldh.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 87743
 Seq:
 1
 Gender:
 F

 Reported:
 13/09/1993
 Weight:
 45.00

 Hospitalisation:
 Age:
 68Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detail

Caction Betai			
Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			
Anorexia			
Diarrhoea			
Drug ineffective			
Dyspnoea			
Fatigue			
Hyperhidrosis			

Medicine Details:

TRYPTANOL (Suspected)		₹e	eason:	
		0.0		
3atch:	Started:	01/01/1973	Stopped:	28/06/1993
MYLANTA (Suspected)		₹e	eason:	
		0.0		
3atch:	Started:	01/08/1993	Stopped:	16/08/1993
DISPRIN (Suspected)		₹e	ason:	
		0.0	As necessary	
3atch:	Started:		Stopped:	16/08/1993
QUININE (Suspected)		₹e	ason: Pain in limb	
Oral application		1.0 Dose Unspecifie	ed As necessary	Oral
3atch:	Started:	01/01/1991	Stopped:	16/08/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Bone marrow				20/8/93 - bone marrow - early myeloid series.
	Neutrophils	2.00 - 7.50	16/08/1993	-	
	Neutrophils	2.00 - 7.50	22/08/1993	0.15	
	Neutrophils	2.00 - 7.50	24/08/1993	-	
	Neutrophils	2.00 - 7.50	27/08/1993	0.69	
	Neutrophils	2.00 - 7.50	26/08/1993	0.16	
	Neutrophils	2.00 - 7.50	25/08/1993	0.03	

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 87743 Seq: 1 Gender: F

Reported: 13/09/1993 Weight: 45.00
Hospitalisation: Age: 68Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

TOLVON (Suspected)	;	Reason: Depression		
Tablet	30.0 Milligram	Daily	Oral	
3atch:	Started: 01/06/1993	Stopped	17/08/1993	
CORTISONE (Suspected)	;	Reason:		
Ointment	1.0 Dose Unspeci	fied Daily	Topical	
3atch:	Started: 01/01/1983	Stopped	16/08/1993	
SULPHUR (Suspected)	;	Reason:		
Ointment	1.0 Dose Unspecif	fied Daily	Topical	
3atch:	Started: 01/01/1983	Stopped	16/08/1993	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	2.00 - 7.50	23/08/1993	0.18	
	White blood cells	4.0 - 11.0	16/08/1993	1.4	
	White blood cells	4.0 - 11.0	22/08/1993	1.5	
	White blood cells	4.0 - 11.0	23/08/1993	1.3	
	White blood cells	4.0 - 11.0	24/08/1993	2.2	
	White blood cells	4.0 - 11.0	25/08/1993	1.9	
	White blood cells	4.0 - 11.0	26/08/1993	2.1	

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 87743
 Seq:
 1
 Gender:
 F

 Reported:
 13/09/1993
 Weight:
 49

Reported: 13/09/1993 Weight: 45.00
Hospitalisation: Age: 68Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

TRYPTANOL (Suspected)		₹ea	son:	
		0.0		
Зatch:	Started:	01/01/1973	Stopped:	28/06/1993
MYLANTA (Suspected)		Rea	son:	
		0.0		
Зatch:	Started:	01/08/1993	Stopped:	16/08/1993
DISPRIN (Suspected)		Rea	son:	
		0.0	As necessary	
Зatch:	Started:		Stopped:	16/08/1993
QUININE (Suspected)		Rea	son: Pain in limb	
Oral application		1.0 Dose Unspecified	As necessary	Oral
3atch:	Started:	01/01/1991	Stopped:	16/08/1993

Laboratory Investigations:

					
Date	Туре	Range	Date Tested	Result	Details
	White blood cells	4.0 - 11.0	27/08/1993	2.1	

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 87743
 Seq:
 1
 Gender:
 F

 Reported:
 13/09/1993
 Weight:
 45.00

 Hospitalisation:
 Age:
 68Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

TOLVON (Suspected)	ŧ	eason:	Depression	
Tablet	30.0 Milligram	Daily		Oral
3atch:	Started: 01/06/1993		Stopped:	17/08/1993
CORTISONE (Suspected)	7	eason:		
Ointment	1.0 Dose Unspecif	ied Daily		Topical
3atch:	Started: 01/01/1983		Stopped:	16/08/1993
SULPHUR (Suspected)	Reason:			
Ointment	1.0 Dose Unspecif	ied Daily		Topical
3atch:	Started: 01/01/1983		Stopped:	16/08/1993

Laboratory Investigations:

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number:88519Seq:1Gender:FReported:16/10/1993Weight:56.00Hospitalisation:Admitted to hospitalAge:78Y

Onset Date: 31/08/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Candidiasis			
Renal impairment			

Medicine Details:

ZANTAC (Other drug)		Reason:	Other diseases of esophagus	3
	300.0 Milligram	Daily		
Заtch:	Started:		Stopped:	CONTIN
PREDNISOLONE (Suspected)		Reason:	Otr respiratory systm disease	es
	75.0 Milligram	Redu	ıcing	
Заtch:	3tarted: 20/08/1993		Stopped:	
LANOXIN (Suspected)		Reason:	Otr&nos disord of heart rhyth	m
	125.0 Microgram	Daily		
Заtch:	Started:		Stopped: 01/09/1993	
CAPOTEN (Suspected)		Reason:	Cardiomyopathy	
	100.0 Milligram	Daily		
Зatch:	Started: 01/01/1993		3topped: 01/09/1993	

Laboratory Investigations:

	J				
Date	Туре	Range	Date Tested	Result	Details
	Serum drug level	1 - 2.6 MMOL/L			Digoxin level trough 5.0 mmol/l

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Gender: F Case Number: 88519 Seq: 1 **Reported:** 16/10/1993 **Weight:** 56.00 Hospitalisation: Admitted to hospital **Age:** 78Y

Onset Date: 31/08/1993 DOB: Causality: Causality possible

Outcome: Recovered

Reaction Detai

Medicine Details:

FRUSEMIDE (Suspected)		Reason: Cardiomyopa	athy
	250.0 Milligram	Daily	
3atch:	Started:	Stopped:	01/09/1993
SPIRONOLACTONE (Suspected)		Reason:	
	100.0 Milligram	Daily	
3atch:	Started:	Stopped:	01/09/1993
TOLVON (Suspected)		Reason: Depression	
	10.0 Milligram	Daily	
3atch:	Started:	Stopped:	01/09/1993

Laboratory Investigations:

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 89180 Seq: 1 Gender: F

Reported: 09/11/1993 Weight: 60.00 Hospitalisation: Age: 46Y

Onset Date: 29/09/1992 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
	Coverity	' ' '	
Agranulocytosis			Isolation, supportive
Gingivitis			
Influenza like illness			

Medicine Details:

 ToLVON (Suspected)
 Reason:
 Headache

 Tablet
 90.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/08/1992
 \$topped:
 04/10/1992

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Bone marrow				Bone marrow aspiration report: agranulocytosis - probably drug
	Neutrophils	1.9 - 6.8	09/10/1993	-0.64	110 al. 10 a al
	Neutrophils	1.9 - 6.8	12/10/1993	3.92	
	White blood cells	4.0 - 10.5	04/10/1993	4.1	
	White blood cells	4.0 - 10.5	05/10/1993	5.2	
	White blood cells	4.0 - 10.5	06/10/1993	-2.9	
	White blood cells	4.0 - 10.5	09/10/1993	5.3	

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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 89180 Seq: 1 Gender: F

Reported: 09/11/1993 Weight: 60.00 Hospitalisation: Age: 46Y

Onset Date: 29/09/1992 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Medicine Details:

TOLVON (Suspected) Reason: Headache

Tablet 90.0 Milligram Daily Oral

3atch: 3tarted: 01/08/1992 3topped: 04/10/1992

Laboratory Investigations:

Data	Tuna	Danga	Data Tastad	Dogult	Detaile
Date	Туре	Range	Date Tested	Result	Details
	White blood cells	4.0 - 10.5	12/10/1993	8.7	

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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 89363 Seq: 1 Gender: F

Reported: 23/11/1993 Weight: 88.00 Hospitalisation: Age: 41Y

Onset Date: 13/11/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal			Observation, serial ecg's

Medicine Details:

TOLVON (Suspected)		Reason:	Depression	
Tablet	40.0 Milligram	Daily	Oral	
3atch:	Started: 01/02/1993		Stopped:	
IMDUR (Suspected)		Reason:	Angina pectoris w/o hyperten	
Tablet	60.0 Milligram	Daily	Oral	
3atch:	Started: 01/01/1993		Stopped:	
CAPOTEN (Suspected)		Reason:	Essential benign hypertension	
CAPOTEN (Suspected) Tablet	150.0 Milligram	Reason: Daily	Essential benign hypertension Oral	
, , ,	150.0 Milligram 3tarted: 01/01/1989		3 ,,	
Tablet	3 .		Oral	
Tablet 3atch:	3 .	Daily	Oral Stopped:	

Laboratory Investigations:

					
Date	Туре	Range	Date Tested	Result	Details
	Electrocardiograph				Prolonged qt internal 398 ms - 536 ms.

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 89602 Seq: 1 Gender: F

Reported: 01/12/1993 Weight:
Hospitalisation: Age: 63Y

Onset Date: 28/10/1993 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			

Medicine Details:

Modicino Botano:				
PARACETAMOL (Other drug)		Reason:	Pain	
Oral application	1.0 Gram	Daily		Oral
3atch:	Started: 22/10/1993		Stopped:	24/11/1993
MIANSERIN HYDROCHLORIDE (Sus	pected)	₹eason:	Depression	
Tablet	80.0 Milligram	Daily		Oral
3atch:	3tarted: 30/09/1993		Stopped:	02/11/1993
TRIFLUOPERAZINE HYDROCHLORI	DE (Suspected)	₹eason:	Depression	
	15.0 Milligram	Daily		
Batch:	Started:		Stopped:	02/11/1993

Laboratory Investigations:

Da	te	Туре	Range	Date Tested	Result	Details
		Bone marrow				Maturation arrest of granulocytes at the promyelocyte stage.

Additional Information:

Chronic schizophrenia on mianserin



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 90980 Seq: 1 Gender: M
Reported: 09/02/1994 Weight:
Hospitalisation: Age: 74Y

Onset Date: 20/01/1994 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspecte	d)	Reason:			
	20.0 Milligram	Daily			
3atch:	3tarted: 14/01/1994		Stopped:	24/01/1994	
DEPTRAN (Suspected)		Reason:			
	25.0 Milligram	Daily			
3atch:	3tarted: 10/01/1994		Stopped:	28/01/1994	
COLOXYL (Suspected)		Reason:			
COLOXYL (Suspected)	4.0 Dose Unspe				
COLOXYL (Suspected) 3atch:	4.0 Dose Unspe		}topped:	CONTIN	
	•		Stopped:	CONTIN	
3atch:	•	ecified Daily	Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		10/01/1994	15	
	ALT = SGPT		20/01/1994	44	
	ALT = SGPT		25/01/1994	16	
	ALT = SGPT		24/01/1994	18	
	ALT = SGPT		03/02/1994	14	
	AST = SGOT		10/01/1994	15	
	AST = SGOT		25/01/1994	16	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 90980
 Seq:
 1
 Gender:
 M

 Reported:
 09/02/1994
 Weight:

Hospitalisation: Age: 74Y
Onset Date: 20/01/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

ZANTAC (Suspected)	₹6	Reason:		
	150.0 Milligram	Daily		
3atch:	Started:	Stopped:	CONTIN	
PREPULSID (Suspected)	₹€	eason:		
PREPULSID (Suspected)	ર હ 15.0 Milligram	eason: Daily		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT		03/02/1994	17	
	AST = SGOT		24/01/1994	15	
	AST = SGOT		20/01/1994	32	
	Bilirubin		10/01/1994	7	
	Bilirubin		20/01/1994	8	
	Bilirubin		24/01/1994	7	
	Bilirubin		25/01/1994	4	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 90980
 Seq:
 1
 Gender:
 M

 Reported:
 09/02/1994
 Weight:

Hospitalisation: Age: 74Y
Onset Date: 20/01/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspecte	d)	Reason:		
	20.0 Milligram	Daily		
3atch:	3tarted: 14/01/1994		Stopped:	24/01/1994
DEPTRAN (Suspected)		Reason:		
	25.0 Milligram	Daily		
3atch:	3tarted: 10/01/1994		Stopped:	28/01/1994
COLOXYL (Suspected)		Reason:		
COLOXYL (Suspected)	4.0 Dose Unsp			
COLOXYL (Suspected) 3atch:	4.0 Dose Unsp		3topped:	CONTIN
, , ,	•		Stopped:	CONTIN
3atch:	•	ecified Daily	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin		03/02/1994	5	
	GGT = SGGT =		10/01/1994	80	
	GGT = SGGT =		25/01/1994	157	
	GGT = SGGT =		24/01/1994	168	
	GGT = SGGT =		20/01/1994	263	
	GGT = SGGT =		03/02/1994	100	
	SAP = ALP		10/01/1994	81	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

See Number 0						
ase Number: 9		Seq:	1		Gende	
Reported: 0 ospitalisation:	J9/UZ/ 1994				Weigh Aa	τ: e: 74Y
Onset Date: 2	20/01/1994				DO	
	Not yet recovered	l				y: Causality possible
action Detai	101 901 1000 1010	•			Jacount	y. Gaddanty poddibio
ledicine Detai	ile·					
CUICILE DELA						
				Reason:		
			150.0 Millig		ly	
		€ta	150.0 Milliç		ly Stopped:	CONTIN
ZANTAC (Suspected 3atch:	d)	3ta				CONTIN
ZANTAC (Suspected 3atch:	d)	Sta		gram Dai Reason:	Stopped:	CONTIN
ZANTAC (Suspected 3atch:	d)		rted:	gram Dai Reason:	Stopped:	CONTIN
ZANTAC (Suspected 3atch: PREPULSID (Suspected) 3atch:	cted)		rted: 15.0 Millig	gram Dai Reason:	Stopped:	
ZANTAC (Suspected 3atch: PREPULSID (Suspected) 3atch:	cted)	€ta	rted: 15.0 Millig rted:	gram Dai	Stopped:	CONTIN
3atch: PREPULSID (Suspected) 3atch:	cted) restigations: Type Range	€ta	rted: 15.0 Millig rted:	gram Dai	Stopped:	
3atch: PREPULSID (Suspected) 3atch:	vestigations: Type Range	€ta	rted: 15.0 Millig rted:	gram Dai	Stopped:	CONTIN
3atch: PREPULSID (Suspected) 3atch: PREPULSID (Suspected) 3atch: Date T SAP = A	restigations: Type Range ALP ALP ALP	€ta	nted: 15.0 Millig rted: Date Tested 20/01/1994	Result 137	Stopped:	CONTIN



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 91019 Seq: 1 Gender: M

Reported: 11/02/1994 Weight: 55.00 Hospitalisation: Age: 52

Onset Date: 21/01/1994 **DOB**: 31/08/1941

Outcome: Recovered Causality: Causality possible

Reaction Detai

		-	
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Benztroprine
Pyrexia			

Medicine Details:

MOCLOBEMIDE (Other drug) Reason: Depression

900.0 Milligram Daily

3atch: **3tarted**: 29/09/1993 **3topped**: 23/01/1994

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

80.0 Milligram Daily

3atch: Started: 06/01/1994 **Stopped:** 19/01/1994

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason: Depression

10.0 Milligram Daily

3atch: 3tarted: 09/12/1993 3topped: 20/01/1994

METHOHEXITONE SODIUM (Suspected) Reason: Other disturbance of sensation

Injection 70.0 Milligram Alternate days Intravenous

Started: 17/01/1994 Stopped: 07/02/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		21/01/1994	20	
	ALT = SGPT		23/01/1994	195	
	ALT = SGPT		25/01/1994	273	
	ALT = SGPT		08/02/1994	19	
	ALT = SGPT		01/03/1994	25	
	ALT = SGPT		31/01/1994	116	
	ALT = SGPT		27/01/1994	228	

Additional Information:

Moclobemide has been restarted at 300mg/bd without recurrence of adverse reaction .

Report Run 01/08/200 02:07PN Database: pusime ADRS004 Page 154 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 91019 Seq: 1 Gender: M

Reported: 11/02/1994 Weight: 55.00 Hospitalisation: Age: 52

Onset Date: 21/01/1994 **DOB**: 31/08/1941

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

SUXAMETHONIUM NOS (Suspected)

Injection

40.0 Milligram

Alternate days

Intravenous

3atch:

3tarted: 17/01/1994

3topped: 07/04/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT		21/01/1994	13	
	AST = SGOT		23/01/1994	212	
	AST = SGOT		25/01/1994	128	
	AST = SGOT		31/01/1994	33	
	AST = SGOT		01/03/1994	16	
	AST = SGOT		08/02/1994	10	
	AST = SGOT		27/01/1994	71	

Additional Information:

Moclobemide has been restarted at 300mg/bd without recurrence of adverse reaction .

Report Run 01/08/200 02:07PN Database: pusime ADRS004 Page 155 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 91019 Seq: 1 Gender: M

Reported: 11/02/1994 Weight: 55.00 Hospitalisation: Age: 52

Onset Date: 21/01/1994 **DOB:** 31/08/1941

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

MOCLOBEMIDE (Other drug) Reason: Depression

900.0 Milligram Daily

3atch: 3tarted: 29/09/1993 3topped: 23/01/1994

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

80.0 Milligram Daily

3atch: 3tarted: 06/01/1994 **3topped:** 19/01/1994

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason: Depression

10.0 Milligram Daily

3atch: 3tarted: 09/12/1993 3topped: 20/01/1994

METHOHEXITONE SODIUM (Suspected) Reason: Other disturbance of sensation

Injection 70.0 Milligram Alternate days Intravenous

3atch: 3tarted: 17/01/1994 3topped: 07/02/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin		21/01/1994	9	
	Bilirubin		23/01/1994	10	
	Bilirubin		25/01/1994	14	
	Bilirubin		31/01/1994	10	
	Bilirubin		01/03/1994	21	
	Bilirubin		08/02/1994	22	
	Bilirubin		27/01/1994	10	

Additional Information:

Moclobemide has been restarted at 300mg/bd without recurrence of adverse reaction .

Report Run 01/08/200 02:07PN Database: pusime ADRS004 Page 156 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 91019 Seq: 1 Gender: M

Reported: 11/02/1994 Weight: 55.00 Hospitalisation: Age: 52

Onset Date: 21/01/1994 **DOB**: 31/08/1941

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

SUXAMETHONIUM NOS (Suspected) Reason: Other disturbance of sensation

Injection 40.0 Milligram Alternate days Intravenous

3atch: 3tarted: 17/01/1994 3topped: 07/04/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Increased lfts's including rise in alk phos, ggt, ast & alt also
	GGT = SGGT =		21/01/1994	33	in and a different field of the
	GGT = SGGT =		23/01/1994	169	
	ĜĜŤ = SGGT =		27/01/1994	533	
	GGT = SGGT =		01/03/1994	58	
	ĜĜT = SGGT =		08/02/1994	152	
	GGT = SGGT =		31/01/1994	340	

Additional Information:

Moclobemide has been restarted at 300mg/bd without recurrence of adverse reaction .

Report Run 01/08/200 02:07PN Database: pusime ADRS004 Page 157 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 91019 Seq: 1 Gender: M

Reported: 11/02/1994 Weight: 55.00 Hospitalisation: Age: 52

Onset Date: 21/01/1994 **DOB**: 31/08/1941

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

MOCLOBEMIDE (Other drug) Reason: Depression

900.0 Milligram Daily

3atch: 3tarted: 29/09/1993 3topped: 23/01/1994

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

80.0 Milligram Daily

3atch: 3tarted: 06/01/1994 **3topped:** 19/01/1994

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason: Depression

10.0 Milligram Daily

3atch: 3tarted: 09/12/1993 3topped: 20/01/1994

METHOHEXITONE SODIUM (Suspected) Reason: Other disturbance of sensation

 Injection
 70.0 Milligram
 Alternate days
 Intravenous

 3atch:
 3tarted:
 17/01/1994
 3topped:
 07/02/1994

Laboratory Investigations:

<u> </u>	y mroonga				
Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =		25/01/1994	405	
	SAP = ALP		21/01/1994	63	
	SAP = ALP		23/01/1994	154	
	SAP = ALP		25/01/1994	378	
	SAP = ALP		27/01/1994	548	
	SAP = ALP		31/01/1994	331	
	SAP = ALP		08/02/1994	140	

Additional Information:

Moclobemide has been restarted at 300mg/bd without recurrence of adverse reaction .

Report Run 01/08/200 02:07PN Database: pusime ADRS004 Page 158 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 91019 Seq: 1 Gender: M

Reported: 11/02/1994 Weight: 55.00 Hospitalisation: Age: 52

Onset Date: 21/01/1994 **DOB**: 31/08/1941

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

SUXAMETHONIUM NOS (Suspected)

Injection

40.0 Milligram

Alternate days

Intravenous

3atch:

3tarted: 17/01/1994

3topped: 07/04/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP		10/02/1994	80	

Additional Information:

Moclobemide has been restarted at 300mg/bd without recurrence of adverse reaction .



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 91060 Seq: 1 Gender: F

 Reported:
 14/02/1994
 Weight:
 55.00

 Hospitalisation:
 Age:
 69Y

 Onset Date:
 29/01/1994
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			Phenergan, topical steriod

Medicine Details:

AMINOGLUTETHIMIDE (Suspected)		Reason:	Malignant ned	pplasm of breast
Tablet	250.0 Milligram	Daily		Oral
3atch:	Started: 01/01/1994		Stopped:	02/02/1994
CORTISONE ACETATE (Suspected)		Reason:		
Tablet	50.0 Milligram	Daily		Oral
Зatch:	Started: 01/01/1994		Stopped:	21/02/1994
DYAZIDE (Suspected)		Reason:	Essential ben	ign hypertension
DYAZIDE (Suspected) Tablet	1.0 Dose Unspe		Essential ben	ign hypertension Oral
	1.0 Dose Unspe		Essential ben	~ <i>;</i> ;
Tablet	•		3topped:	Oral
Tablet 3atch:	•	ecified Daily	3topped:	Oral 03/02/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of allergy to penicillin and aspirin - nausea the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Re	po	rt	D	et	ai	
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 Case Number:
 91060
 Seq:
 1
 Gender:
 F

 Reported:
 14/02/1994
 Weight:
 55.00

Hospitalisation: Age: 69Y
Onset Date: 29/01/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

MS CONTIN (Suspected)		Reason: Pain		
Tablet	40.0 Milligram	Daily	Oral	
3atch:	Started:	Stoppe	d:	
MIANSERIN HYDROCHLORIDE (S	uspected)	Reason: Depressio	n	
MIANSERIN HYDROCHLORIDE (S Tablet	uspected) 50.0 Milligram	Reason: Depression	n Oral	

Laboratory Investigations:

Additional Information:

History of allergy to penicillin and aspirin - nausea the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 91285 Seq: 1 Gender: F

Reported: 25/02/1994 Weight: 52.00
Hospitalisation: Age: 76Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
Anaemia	Severe		
Bone marrow failure			

Medicine Details:

LASIX (Other drug)		Rea	son:	Congestive he	eart failure
	40.0	Milligram	Daily		
3atch:	Started:	L TERM	1	Stopped:	
LANOXIN PG (Other drug)		Rea	son:	Congestive he	eart failure
	2.0	Dose Unspecified	Daily		
3atch:	Started:			Stopped:	
LOPID (Suspected)		Rea	son:	Othr&unspec	metabolic diseases
	1.2	Gram	Daily		
3atch:	Started:			Stopped:	20/01/1994
AURORIX (Suspected)		Rea	son:	Depression	
	450.0	Milligram	Daily		
Batch:	Started: 13	/01/1994		Stopped:	20/01/1994

Laboratory Investigations:

-		<u> </u>				
	Date	Туре	Range	Date Tested	Result	Details
	_	Haemoglobin				Hb 8.1

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Repor	t Detail
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 Case Number:
 91285
 Seq:
 1
 Gender:
 F

 Reported:
 25/02/1994
 Weight:
 52.00

 Hospitalisation:
 Age:
 76Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

Medicine Details.		
TOLVON (Suspected)		Reason: Depression
	40.0 Milligram	Daily
3atch:	Started: 01/12/1993	Stopped: 20/01/1994
RENITEC (Suspected)		Reason: Congestive heart failure
	20.0 Milligram	Daily
3atch:	Started:	3topped: 20/01/1994

Laboratory Investigations:

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 92176 Seq: 1 Gender: F

Reported: 13/04/1994 Weight: 61.00 Hospitalisation: Age: 43Y

Onset Date: 22/02/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Renal impairment			

Medicine Details:

TOLVON (Suspected)				₹easo	n:	Depression	
Tablet	10	0.0	Milligram		Daily		Oral
3atch:	Started:	18/0	02/1994			Stopped:	19/02/1994
TOLVON (Suspected)				₹easo	n:	Depression	
Tablet	30	0.0	Milligram		Daily		Oral
3atch:	Started:	20/0	02/1994			Stopped:	22/02/1994
CLONEA (Suspected)				₹easo	n:	Moniliasis	
Ointment	3	3.0	Dose Unspeci	ified	Daily		Topical
3atch:	Started:					Stopped:	23/02/1994
SODIUM BICARBONATE (Suspected)				Reaso	n:	Otr&unspec o	ral soft tissu dis
Mouthwash	4	1.0	Dose Unspeci	ified	Daily		Buccal
3atch:	Started:					Stopped:	23/02/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatinine		20/02/1994	87	
	Creatinine		22/02/1994	137	
	Creatinine		23/02/1994	144	
	Creatinine		24/02/1994	123	
	Creatinine		25/02/1994	105	
	Urea		20/02/1994	5.7	
	Urea		22/02/1994	10.1	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Re	po	rt	D	et	ai	
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Case Number: 92176 Seq: 1 Gender: F

Reported: 13/04/1994 Weight: 61.00 Hospitalisation: Age: 43Y

Onset Date: 22/02/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

FUNGILIN (Suspected)		Reason:	Otr&unspec or	ral soft tissu dis
Mouthwash	4.0 Millilitre	Daily		Buccal
3atch:	Started:		Stopped:	23/02/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Urea		23/02/1994	13.0	
	Urea		24/02/1994	11.9	
	Urea		25/02/1994	8.2	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 93133
 Seq:
 1
 Gender:
 M

 Reported:
 23/05/1994
 Weight:

Hospitalisation: Age: 62Y
Onset Date: 18/01/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

•	Caction Botal			
	Preferred Term	Severity	Report Description	Treatment
	Thrombocytopenia			

Medicine Details:

DIAZEPAM (Other drug)		Reason: Headache	
	5.0 Milligram	As necessary	
3atch:	Started:	Stopped:	
CAFERGOT (Other drug)		Reason: Migraine	
Suppository	0.0	As necessary Rectal	
3atch:	Started:	Stopped:	
STEMETIL (Other drug)		Reason: Migraine	
Suppository	0.0	As necessary Rectal	
3atch:	Started:	Stopped:	
PANADEINE FORTE (Other drug)		Reason: Migraine	
	0.0	As necessary	
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets		22/02/1993	51	
	Platelets		18/01/1994	58	



Report Detail

Case Number: 93133

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Gender: M

/1994 et recovered				С	Age: DOB: ausality:	62Y Causality possible
				С		Causality possible
et recovered				С	ausality:	Causality possible
			Reason: E	ssential beni	gn hypertens	sion
	100.0	Milligram	Daily			
	Started:			Stopped:		CONTIN
spected)			Reason:			
	300.0	Milligram	Weekly			
	Started:			Stopped:	17/02/1994	
			Reason:			
	80.0	Milligram	Daily			
	Started:			Stopped:		
			Reason:			
	0.5	Dose Unspec	ified Daily			
	Started:			Stopped:	18/01/1994	
gations:						
ation:						
	igations:	Started: 300.0 Started: 80.0 Started: 0.5 Started:	300.0 Milligram Started: 80.0 Milligram Started: 0.5 Dose Unspectorstarted: igations:	100.0 Milligram Daily Started: Spected) 300.0 Milligram Weekly Started: Reason: 80.0 Milligram Daily Started: Reason: 0.5 Dose Unspecified Daily Started:	100.0 Milligram Daily Started:	100.0 Milligram Daily Started: Stopped: Stopped: Started: Stopped: 17/02/1994 Started: Stopped: 17/02/1994 Started: Stopped: Stopped: Stopped: Stopped: Stopped: Started: Stopped: Started: Stopped: Started: Stopped: Started: Stopped: Started: Stopped:


Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Case Number:	93133	Seq: 1	Gender: M
Reported:	23/05/1994		Weight:
Hospitalisation:			Age: 62Y
Onset Date:	18/01/1994		DOB:
Outcome:	Not yet recovere	:d	Causality: Causality possible
Reaction Detai	i		
Marilla Dat	- • • -		
Medicine Det			Other control of the state of t
LIPEX (Suspected	1)	40.0	Reason: Othr&unspec metabolic diseases
		10.0 Milligram	Daily
3atch:		3tarted: 28/10/1993	Stopped: 22/02/1994
Laboratory In	nvestigations:		
•	3		
Additional In	formation:		
Additional iii	iorination.		
oport Pup 01/08/20/	0 02:07PN Data	phase: nusime	ADPS004 Dags 169 of 226

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report D)etail
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Case Number: 93203 Seq: 1 Gender: M

 Reported:
 26/05/1994
 Weight:
 74.00

 Hospitalisation:
 Age:
 73Y

 Onset Date:
 20/05/1994
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Rash		Rash on back, thighs, lower legs.	

Medicine Details:

TOLVON (Suspected) Reason: Depression

Tablet 20.0 Milligram Daily Oral

3atch: **3tarted**: 12/05/1994 **3topped**: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 93268 Seq: 1 Gender: F
Reported: 27/05/1994 Weight:
Hospitalisation: Age: 65Y

Onset Date: 10/05/1994 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Anorexia			
Back pain			
Chills			
Fatigue			
Hyperhidrosis			
Jaundice			
Nausea			
Pyrexia			

Medicine Details:

TOLVON (Suspected)			Reason:	Depression	
	0.0				
Заtch:	Started: 01	/04/1994		Stopped:	
PANAMAX (Suspected)			Reason:	Abdominal pain	
	0.0				
Зatch:	Started:		L TERM	Stopped:	
ENALAPRIL MALEATE (Suspected)			Reason:	Essential benign hypertension	
Tablet	10.0	Milligram	Daily	Oral	
Зatch:	Started:		L TERM	Stopped:	
TENORMIN (Suspected)			Reason:	Essential benign hypertension	
Tablet	25.0	Milligram	Daily	Oral	
Зatch:	Started:		L TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT		10/05/1994	280-385	
	Albumin		10/05/1994	23	
	Bilirubin		10/05/1994	40	
	GGT = SGGT =		10/05/1994	260-425	
	Protein		10/05/1994	56	
	SAP = ALP		10/05/1994	280-385	

Additional Information:

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



Report Detail

Case Number: 93268

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: F

Reported:	27/05/1994				Weigh	t:
Hospitalisation:					Age	e: 65Y
Onset Date:	10/05/1994				DO	3:
Outcome:	Not yet recovered				Causalit	y: Causality possible
Reaction Detai	,				•	,
todotion botai						
Madiaina Data	.!!a.					
Medicine Deta	IIIS:			2	Consensions beautifully as	
LASIX (Suspected)				Reason:	Congestive heart failure	
			Milligram	Daily		
3atch:		Started:	L	TERM	Stopped:	
Laboratory Inv	voetigations:					
Laboratory in	restigations.					
Additional Info						
Allergies to nsaids.	the dosage start date i	is not neces	sarily accu	rate but indic	ates that start occurre	ed sometime during the month.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 93646 Seq: 1 Gender: F

Reported: 14/06/1994 Weight: 79.00 Hospitalisation: Age: 37Y

Onset Date: 12/05/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hepatocellular damage			

Medicine Details:

DUCENE (Other drug)		Reason:	Anxiety neurosis	
	15.0 Milligram	Daily		
3atch:	Started:	L TERM	Stopped:	
MOXACIN (Other drug)		Reason:	Ac upr resp inf,mult,unsp stes	
	1.5 Gram	Daily		
3atch:	Started : 10/05/1994		Stopped:	
TOLVON (Suspected)		Reason:	Depression	
Tablet	50.0 Milligram	Daily	Oral	
3atch:	Started: 22/04/1994		Stopped: 18/05/1994	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT	<40 U/L	17/05/1994	175	
	AST = SGOT	<40 U/L	23/05/1994	113	
	AST = SGOT	<40 U/L	30/05/1994	54	
	AST = SGOT	<40 U/L	07/06/1994	37	
	Bilirubin	<20 UMOL/L	17/05/1994	13	
	Bilirubin	<20 UMOL/L	23/05/1994	6	
	Bilirubin	<20 UMOL/L	30/05/1994	9	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 93646 Seq: 1 Gender: F

Reported: 14/06/1994 Weight: 79.00 Hospitalisation: Age: 37Y

Onset Date: 12/05/1994 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Medicine Details:

vicaionic Details.				
DUCENE (Other drug)		Reason:	Anxiety neurosis	
	15.0 Milligram	Daily		
3atch:	Started:	L TERM	Stopped:	
MOXACIN (Other drug)		Reason:	Ac upr resp inf,mult,unsp stes	
	1.5 Gram	Daily		
3atch:	3tarted: 10/05/1994		Stopped:	
TOLVON (Suspected)		Reason:	Depression	
Tablet	50.0 Milligram	Daily	Oral	
3atch:	Started: 22/04/1994		Stopped: 18/05/1994	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	<20 UMOL/L	07/06/1994	7	
	GGT = SGGT =	<50 U/L	17/05/1994	235	
	GGT = SGGT =	<50 U/L	23/05/1994	159	
	GGT = SGGT =	<50 U/L	30/05/1994	99	
	GGT = SGGT =	<50 U/L	07/06/1994	62	
	SAP = ALP	30-120 U/L	17/05/1994	183	
	SAP = ALP	30-120 U/L	23/05/1994	112	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 93646 Seq: 1 Gender: F

Reported: 14/06/1994 Weight: 79.00 Hospitalisation: Age: 37Y

Onset Date: 12/05/1994 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Medicine Details:

DUCENE (Other drug)		Reason:	Anxiety neurosis	
	15.0 Milligram	Daily		
3atch:	Started:	L TERM	Stopped:	
MOXACIN (Other drug)		Reason:	Ac upr resp inf,mult,unsp stes	
	1.5 Gram	Daily		
3atch:	Started : 10/05/1994		Stopped:	
TOLVON (Suspected)		Reason:	Depression	
Tablet	50.0 Milligram	Daily	Oral	
3atch:	Started: 22/04/1994		Stopped: 18/05/1994	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	30-120 U/L	30/05/1994	88	
	SAP = ALP	30-120 U/L	07/06/1994	66	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 93735
 Seq:
 1
 Gender:
 F

 Reported:
 17/06/1994
 Weight:

Hospitalisation: Age: 50Y
Onset Date: 31/12/1992
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
Alopecia			
Hair colour changes			

Medicine Details:

CLONAZEPAM (Suspected)		Reason:	
	0.0		
Зatch:	Started:	Stopped:	CONTIN
DIAZEPAM (Suspected)		Reason:	
	0.0		
Зatch:	Started:	Stopped:	
SIMVASTATIN (Suspected)		Reason: Othr&unspec	metabolic diseases
Tablet	10.0 Milligram	Daily	Oral
Зatch:	Started: 01/05/1991	Stopped:	05/06/1994
CARBAMAZEPINE (Suspected)		Reason:	
	600.0 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 93735
 Seq:
 1
 Gender:
 F

 Reported:
 17/06/1994
 Weight:

Hospitalisation: Age: 50Y
Onset Date: 31/12/1992
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspecte	ed)	Reason:		
	30.0 Milligram	Daily		
3atch:	Started: 01/01/1990		Stopped:	CONTIN
MEDROXYPROGESTERONE ACETATE (S	Suspected)	Reason:		
	5.0 Milligram	Daily		
3atch:	Started: 01/01/1991		Stopped:	CONTIN
OESTROGENS CONJUGATED (Suspected	d)	Reason:		
OESTROGENS CONJUGATED (Suspected	d) 625.0 Microgram	Reason: Daily		
OESTROGENS CONJUGATED (Suspected Satch:	•		Stopped:	CONTIN
	625.0 Microgram		Stopped:	CONTIN
Satch:	625.0 Microgram	Daily	Stopped:	CONTIN

Laboratory Investigations:

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 93777 Seq: 1 Gender: F

Reported: 20/06/1994 Weight:
Hospitalisation: Age: 77Y

Onset Date: 31/05/1994 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Confusional state		Acute	
Nausea		Acute	

Medicine Details:

MADOPAR M (Other drug) Reason: Paralysis agitans

2.0 Dose Unspecified Daily

3atch: Started: L TERM Stopped: CONTIN

TOLVON (Suspected) Reason: Depression

20.0 Milligram 1 time

3atch: 31/05/1994 3topped: 31/05/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient developed acute bowel obstruction 01/06/94 - query relationship to mianserin.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

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UE	νv	יו ני	\boldsymbol{L}	τιa	

Case Number: 93938 Seq: 1 Gender: F

Reported: 24/06/1994 Weight:
Hospitalisation: Age: 67Y

Onset Date: 02/12/1993 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

VENTOLIN (Other drug)			₹eas	on:	Asthma		
	0	0.0		As ne	ecessary		
3atch:	Started:				Stopped:		
ATROVENT (Other drug)			Reas	on:	Asthma		
	0	0.0		As ne	ecessary		
3atch:	Started:				Stopped:		
BECLOFORTE (Other drug)			Reas	on:	Asthma		
Inhalation	6	6.0	Dose Unspecified	Daily		Inhalation	
3atch:	Started:				Stopped:		CONTIN
SLOW-K (Other drug)			Reas	on:	Essential beni	ign hypertension	
Tablet	1	1.2	Gram	Daily		Oral	
3atch:	Started:				Stopped:		CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Potassium				Potassium 3.1
	Sodium				Sodium 118.



Report Detail

Case Number: 93938

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Gender: F

93 ed			C	Age: DOB: Causality:	
			C		
ed			C	Causality:	Causality possible
		Reason:	Othr&unspec	metabolic dis	seases
30	0.0 Microgram	n Daily		Oral	
Started:			Stopped:		CONTIN
d)		Reason:			
	0.0				
Started:			Stopped:		
DE (Suspected)		Reason:			
	0.0				
Started:			Stopped:		1W
		₹eason:	Depression		
2	.0.0 Milligram	Daily		Oral	
			Stopped:	03/12/1993	3
tions:					
n:					
	Started: d) Started: DE (Suspected) Started:	Started: 0.0 Started: DE (Suspected) 0.0 Started: 20.0 Milligram Started: 02/12/1993 tions:	300.0 Microgram Daily Started: d) Reason: 0.0 Started: DE (Suspected) Reason: 20.0 Milligram Daily Started: 02/12/1993 tions:	300.0 Microgram Daily Started: Stopped: 0.0 Started: Stopped: DE (Suspected) 0.0 Started: Stopped: 20.0 Milligram Daily Started: 02/12/1993 Stopped: Topped: Stopped: 300.0 Microgram Daily Oral Started: Stopped: 0.0 Started: Stopped: DE (Suspected) Reason: 0.0 Started: Stopped: 20.0 Milligram Daily Oral Started: 02/12/1993 Stopped: 03/12/1993 tions:	



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: 9 Reported: 2 Hospitalisation: Onset Date: 0 Outcome: 9 Reaction Detai	24/06/1994 02/12/1993	Seq: 1				Gender: Weight: Age: DOB: Causality:	
Medicine Deta							
CHLOTRIDE (Suspe	ected)				son:	Essential benign hyperten	sion
Tablet			1.0	Dose Unspecified	Daily	Oral	
3atch:		Started:				Stopped:	
Laboratory Inv	vestigations.						
Additional Info	ormation:						



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report D)etail
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 Case Number:
 94270
 Seq:
 1
 Gender:
 M

 Reported:
 08/07/1994
 Weight:

Hospitalisation: Age: 80Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Visual disturbance			

Medicine Details:

AMPICILLIN (Suspected)		Reason:
Injection	4.0 Gram	Daily Intravenous
3atch:	Started:	Stopped:
VENTOLIN (Suspected)		Reason: Pneumonia,unspecified
Inhalation	4.0 Millilitre	Daily Inhalation
3atch:	Started:	Stopped:
ATROVENT (Suspected)		Reason: Pneumonia,unspecified
Inhalation	4.0 Millilitre	Daily Inhalation
3atch:	Started:	Stopped:
DIGOXIN (Suspected)		Reason: Congestive heart failure
	250.0 Microgram	n Daily
3atch:	Started:	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number:	3421U	Seq: 1			Gender:	IVI
Reported:	08/07/1994				Weight:	
Hospitalisation:					Age:	80Y
Onset Date:					DOB:	
Outcome:	Unknown					Causality possible
eaction Detai					Januarity	
caction betai						
Medicine Deta	aile.					
PREDNISOLONE (Reaso	on:		
(спороски,	5.0	Milligram	Daily		
3atch:		Started:	wiiiigram	Daily	Stopped:	
VIBRAMYCIN (Sus	nected)	Jui leu.	Reaso	n.	Alaphea.	
VIDRAWITCIN (SUS	pecieu)	400.0				
.			Milligram	Daily	Manage !	
3atch:		Started:			Stopped:	
TOLVON (Suspect	ea)		Reaso			
			Milligram	Daily		
3atch:		Started:			Stopped:	
DYAZIDE (Suspec	ted)		Reaso			
		1.0	Dose Unspecified	Daily		
3atch:		3tarted:			Stopped:	
Labandii						
Laboratory In	vestigations:					
Additional Inf	ormation:					
Additional Inf	formation:					
Additional Inf	ormation:					
Additional Inf	formation:					
Additional Inf	ormation:					
Additional Inf	formation:					



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail				
Case Number: 94270 Reported: 08/07/1994 Hospitalisation:	Seq: 1		Gender: Weight: Age:	80Y
Onset Date: Outcome: Unknown Reaction Detai			DOB: Causality:	Causality possible
Medicine Details:				
ASPIRIN (Suspected)	150.0 Milligram	Reason: Daily		
Batch:	Started:	Stopped	:	
Laboratory Investigations:				
Additional Information:				

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 94527 Seq: 1 Gender: F

Reported: 26/07/1994 Weight: 47.00 Hospitalisation: Age: 81Y

Onset Date: 15/07/1994 DOB:
Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

teaction Detai	a		
Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

Micaronic Details.					
TOLVON (Suspected)			Reason:	Depression	
Tablet	20.0	Milligram	Daily		Oral
3atch:	Started: 01	/01/1992		Stopped:	15/07/1994
ALPHAPRESS (Suspected)			Reason:	Essential beni	ign hypertension
Tablet	100.0	Milligram	Daily		Oral
3atch:	Started:	I	L TERM	Stopped:	15/07/1994
INDERAL (Suspected)			Reason:	Essential beni	ign hypertension
Tablet	80.0	Milligram	Daily		Oral
3atch:	Started:	I	L TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		15/07/1994	49%	
	White blood cells		15/07/1994	3.7	
	White blood cells		19/07/1994	3.1	

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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 94575 Seq: 1 Gender: F

Reported: 27/07/1994 Weight: 57.00 Hospitalisation: Age: 88Y

Onset Date: 07/07/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

AMOXIL (Other drug)		र	eason:	Otr&nos infec¶sit diseases	
Oral application	2.0	Gram	Daily	Oral	
3atch:	Started:			Stopped:	2W
DIGOXIN (Other drug)		5	eason:	Congestive heart failure	
Tablet	1.0	Dose Unspecifi	ed Daily	Oral	
3atch:	Started:	L TE	RM	Stopped:	
ZANTAC (Other drug)		3	eason:	Peptic ulcer nos w/o ment perf	
•					
Tablet	300.0	Milligram	Daily	Oral	
Tablet 3atch:	300.0 Started:	Milligram L TE	,	Oral Stopped:	
		L TE	,		
3atch:		L TE	RM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		26/05/1994	3.5	
	Neutrophils		07/06/1994	3.5	
	Neutrophils		07/07/1994	0.44	
	Neutrophils		18/07/1994	5.6	
	Neutrophils		13/07/1994	5.2	
	White blood cells		26/05/1994	5.6	
	White blood cells		07/06/1994	4.8	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 94575 Seq: 1 Gender: F

Reported: 27/07/1994 Weight: 57.00 Hospitalisation: Age: 88Y

Onset Date: 07/07/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Medicine Details:

NILSTAT (Other drug)		Reason:	Otr&unspec o	ral soft tissu dis	
Oral application	4.0 Millilitre	Daily		Oral	
3atch:	Started:		Stopped:		10D
MIANSERIN HYDROCHLORIDE (Suspected)	Reason:	Depression		
Tablet	60.0 Milligram	Daily		Oral	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells		07/07/1994	3.7	
	White blood cells		13/07/1994	6.4	
	White blood cells		18/07/1994	7.9	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 94873 Seq: 1 Gender: F

 Reported:
 05/08/1994
 Weight:
 74.00

 Hospitalisation:
 Age:
 73Y

 Onset Date:
 31/07/1994
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Nightmare Severe			

Medicine Details:

CAPOTEN (Other drug)		Reason:	Congestive heart failure
	50.0 Milligram	Daily	
3atch:	Started: 01/01/1990		Stopped:
LASIX (Other drug)		Reason:	Congestive heart failure
	40.0 Milligram	Daily	
3atch:	Started: 01/01/1990		Stopped:
DIL TIAZEM HVDDOCHI ODIDE (Othor dru		3	Angina paeteria w/a hypertan
DILTIAZEM HYDROCHLORIDE (Other drug	3)	Reason:	Angina pectoris w/o hyperten
DILTIAZEM HYDROCHLORIDE (Other dru	3) 360.0 Milligram	Reason: Daily	Angina pectoris w/o hyperten
3atch:	•		Stopped:
	360.0 Milligram		
Satch:	360.0 Milligram	Daily Reason:	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 94873
 Seq: 1
 Gender:
 F

 Reported:
 05/08/1994
 Weight:
 74.00

 Hospitalisation:
 Age: 73Y

Onset Date: 31/07/1994 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

licine I	

LUMIN (Suspected) Reason: Depression

3.0 Dose Unspecified Daily

3atch: 3tarted: 01/07/1994 **3topped:** 28/08/1994

Laboratory Investigations:

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 94968 Seq: 1 Gender: M

 Reported:
 10/08/1994
 Weight:
 63.00

 Hospitalisation:
 Age:
 72Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			
Insomnia			

Medicine Details:

Medicine Details:				
LITHIUM CARBONATE (Other drug)	Reason:			
	500.0 Milligram	Daily		
3atch:	Started: 01/01/1983		Stopped:	
MIANSERIN HYDROCHLORIDE (Suspec	ted)	Reason:	Depression	
Tablet	60.0 Milligram	Daily		Oral
3atch:	Started: 01/01/1989		Stopped:	25/06/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Numb	er: 96290	Seq:	1			Gender: F		
Report	ed: 04/10/199	_				Weight:		
lospitalisati	on:					Age: AE		
Onset Da	ate:					DOB:		
Outco	ne: Unknown				Ca	ausality: Caus	ality possi	ible
eaction D	etai							
Pref	erred Term	Sev	erity	Repor	t Description	Т	reatment	
Nightmare								
Medicine I	Details:							
LUMIN (Susp				₹eas	on:			
			0.0					
3atch	:	3ta	arted:		Stopped:			
Laborator	y Investigat	ions:						
Date	Туре	Range	Date Tested	Result		Details		
Additional	Informatio	n:						
eport Run 01/0	8/200 02:07PN	Database: p	usime	А	DRS004	P	age 190	of 336
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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 96334 Seq: 1 Gender: M

Reported: 07/10/1994 Weight: 83.00 Hospitalisation: Age: 75Y

Onset Date: 24/09/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

todotion botal		-	
Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Rash over trunk, back, palms/soles/face.	
Pruritus			

Medicine Details:

BECOTIDE (Other drug)		Reason:	Otr respiratory systm diseases
	0.0		
3atch:	Started:	L TERM	Stopped:
MAREVAN (Other drug)		Reason:	Acute,ill-def cerebrovascular disease w/o hyperte
	3.5	Milligram Dail	у
Batch:	Started:		Stopped:
ADALAT (Other drug)		Reason:	Essential benign hypertension
	80.0	Milligram Dail	у
3atch:	Started:	L TERM	Stopped:
RESPOLIN (Other drug)		Reason:	Otr respiratory systm diseases
Inhalation	8.0	Dose Unspecified Dail	y Inhalation
Зatch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Reported: 07/10/1994 Reported: 07/10/1994 Reported: 07/10/1994 Outcome: Recovered Outcome: Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Reson: Otr respiratory systm diseases Report Reson: Depression Reson: Depression Reson: Depression Reson: Depression Reson: Depression Reson: Depression Reson: Depression Reson: Depression Reson: Depression Reson: Depression Reson: Depression Reson: Depression Reson: Recovered Reson: Depression Reson: Recovered Reson: Depression Reson: Recovered Reson: Depression Reson: Recovered Reson: Depression Reson: Recovered Reson: Recovered Reson: Recovered Reson: Recovered Reson: Recovered Reson: Recovered Reson: Recovered Reson: Recovered Reson: Recovered Reson: Recovered Reson: Recovered Reson: Recovered Reson: Recovered Recovered Recovered Recovered Reson: Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Reson: Depression Reson: Recovered Recovered Recovered Recovered Recovered Recovered Recovered Reson: Depression Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Recovered Reson: Recovered Recove	eport Detail					
Action Details: LDECIN (Other drug) Spray 4.0 Dose Unspecified Daily 3atch: Started: LTERM 3topped: DLVON (Suspected) 60.0 Milligram 3atch: 3tarted: 15/09/1994 3topped: 26/09/1994 3topped: 26/09/1994 3topped: 50.0 Milligram Daily 3atch: \$topped: Reported: 07/10/1994 spitalisation: Onset Date: 24/09/1994	Seq: 1		С	Weight: Age: DOB:	83.00 75Y	
Spray 4.0 Dose Unspecified Daily Nasal Started: Started: L TERM Stopped: OLVON (Suspected) Started: 15/09/1994 Stopped: 26/09/1994 GRETOL (Suspected) Started: 11/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994	ction Detai				-	
Spray 4.0 Dose Unspecified Daily Nasal Started: Started: L TERM Stopped: OLVON (Suspected) Reason: Depression 60.0 Milligram Daily Started: Started: 15/09/1994 Stopped: 26/09/1994 EGRETOL (Suspected) Reason: Daily 3atch: Started: 11/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994						
Spray 4.0 Dose Unspecified Daily Nasal Started: Started: L TERM Stopped: OLVON (Suspected) Reason: Depression 60.0 Milligram Daily Started: Started: 15/09/1994 Stopped: 26/09/1994 EGRETOL (Suspected) Reason: Daily 3atch: Started: 11/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994						
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Spray 4.0 Dose Unspecified Daily Nasal Started: Started: L TERM Stopped: Depression 60.0 Milligram Daily 3atch: Started: 15/09/1994 Stopped: 26/09/1994 EGRETOL (Suspected) 3atch: Started: 11/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994						
Spray 4.0 Dose Unspecified Daily Nasal Started: Started: L TERM Stopped: Depression 60.0 Milligram Daily 3atch: Started: 15/09/1994 Stopped: 26/09/1994 GRETOL (Suspected) 3atch: Started: 11/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994						
Spray 4.0 Dose Unspecified Daily Nasal Started: Started: L TERM Stopped: OLVON (Suspected) Started: 15/09/1994 Stopped: 26/09/1994 GRETOL (Suspected) Started: 11/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994 Stopped: 15/09/1994	dicina Datails:					
Started: L TERM Stopped: Stopped: Started: L TERM Stopped: St			Reason:	Otr respiratory	systm disea	ases
Reason: Depression Go.0 Milligram Daily Stopped: 26/09/1994 Stopped: 26/09/199	Spray	4.0 Dose Unspe	ecified Daily		Nasal	
3atch: 3tarted: 15/09/1994 3topped: 26/09/1994 GRETOL (Suspected) Reason: 50.0 Milligram Daily 3atch: 3tarted: 11/09/1994 3topped: 15/09/1994 boratory Investigations:	Batch:	3tarted: L	TERM	Stopped:		
Started: 15/09/1994 3topped: 26/09/1994 3top	DLVON (Suspected)		Reason:	Depression		
Reason: 50.0 Milligram Daily 3atch: Started: 11/09/1994 Stopped: 15/09/1994 boratory Investigations:			Daily			
3atch: Started: 11/09/1994 Stopped: 15/09/1994 boratory Investigations:		Started: 15/09/1994	_	Stopped:	26/09/1994	1
Batch: Started: 11/09/1994 Stopped: 15/09/1994 boratory Investigations:	EGRETOL (Suspected)	50.0 M:10				
boratory Investigations:	2 otobo		Daily	\	45/00/4004	•
	satch:	Started: 11/09/1994		stoppea:	15/09/1994	•
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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Re	no	rt	D	eta	i	ı
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Case Number: 96913 Seq: 1 Gender: M

Reported: 03/11/1994 Weight: 75.00 Hospitalisation: Age: 30Y

Onset Date: 30/10/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

	Ť		
Preferred Term	Severity	Report Description	Treatment
Rash		Rash over face, lips and chest.	
Dizziness			
Malaise			
Pruritus			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

Tablet 20.0 Milligram 1 time Oral

3atch: 3tarted: 28/10/1994 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Allergy to penicillin=rash.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 98066 Seq: 1 Gender: M

Reported: 29/12/1994 Weight:
Hospitalisation: Age: 83Y

Onset Date: 25/09/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Fluid restriction

Medicine Details:

DONNATAB (Other drug)		Reason:	
	0.0		
3atch:	Started:	Stopped:	
RENITEC (Other drug)		Reason:	
	40.0 Milligram	Daily	
3atch:	Started: 21/02/1992	Stopped:	
ADALAT (Other drug)		Reason:	
	40.0 Milligram	Daily	
3atch:	40.0 Milligram	Daily Stopped:	
3atch: TOLVON (Suspected)	· ·	•	
	· ·	Stopped:	

Laboratory Investigations:

	<i>y</i> ga.				
Date	Туре	Range	Date Tested	Result	Details
	Sodium				Serum sodium improved from 124 mmol/l on admision to 133



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 98219 Seq: 1 Gender: F

Reported: 10/01/1995 Weight:
Hospitalisation: Age: 78Y

Onset Date: 14/12/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

UREX (Other drug)			Reason:		
	40.0	Milligram	Daily		
Зatch:	Started:			Stopped:	
ZANTAC (Other drug)			Reason:		
	300.0	Milligram	Daily		
Зatch:	Started:			Stopped:	
COUMADIN (Other drug)			Reason:		
	3.0	Milligram	Daily		
	0.0	wiiiigiaiii	Dally		
3atch:	Started:	wiiiigram	Dally	Stopped:	
3atch: KSR (Other drug)		- Willingram	Reason:	Stopped:	
	Started:	Gram	•	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		28/11/1994	5.10	
	Neutrophils		01/12/1994	3.93	
	Neutrophils		14/12/1994	2.36	
	Neutrophils		16/12/1994	2.53	
	Neutrophils		18/12/1994	2.88	
	Neutrophils		24/12/1994	3.48	
	White blood cells		28/11/1994	6.7	

Additional Information:

Therapy changed to aurorix.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 98219 Seq: 1 Gender: F

Reported: 10/01/1995 Weight:
Hospitalisation: Age: 78Y

Onset Date: 14/12/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Medicine Details:

TOLVON (Suspected) Reason: Depression

40.0 Milligram Daily

3atch: 3tarted: 3topped: 15/12/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells		01/12/1994	5.8	
	White blood cells		14/12/1994	4.0	
	White blood cells		16/12/1994	4.4	
	White blood cells		18/12/1994	4.7	
	White blood cells		24/12/1994	5.7	

Additional Information:

Therapy changed to aurorix.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 98301
 Seq: 1
 Gender: M

 Reported:
 12/01/1995
 Weight: 63.00

 Hospitalisation:
 Age: 77Y

Onset Date: 28/12/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

roadion Bota.			
Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Anorexia			
Hepatic function abnormal			
Nausea			
Prothrombin level decreased			

Medicine Details:

WARFARIN SODIUM (Other drug)		Reas	on:			
	0.0					
3atch:	Started: 25	5/11/1994		Stopped:		
ACETAZOLAMIDE (Other drug)		Reas	on:	Unspecified g	laucoma	
Tablet	250.0	Milligram	Daily		Oral	
3atch:	Started:	L TERM		Stopped:		
PROPINE (Other drug)		Reas	on:	Unspecified g	laucoma	
Eye Drops	2.0	Dose Unspecified	Daily		Ophthalmic	
3atch:	Started:	L TERM		Stopped:		
TIMOLOL MALEATE (Other drug)		Reas	on:	Unspecified g	laucoma	
Eye Drops	2.0	Dose Unspecified	Daily		Ophthalmic	
		L TERM		Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		29/12/1994	578	
	ALT = SGPT		03/01/1995	182	
	Albumin		29/12/1994	30	
	GGT = SGGT =		29/12/1994	1008	
	GGT = SGGT =		03/01/1995	568	
	SAP = ALP		29/12/1994	1006	
	SAP = ALP		03/01/1995	526	



Report Detail

Case Number: 98301

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: M

Reported:	12/01/1995							Weight:	63.00	
ospitalisation:								Age:	77Y	
Onset Date:	28/12/1994							DOB:		
Outcome:	Recovered						C	ausality:	Causality proba	able
action Detai										
ledicine Deta	aile:									
PILOCARPINE (Oti					Reaso	n:	Unspecified g	aucoma		
Eye Drops	O,		2.0	Dose Unsp			, ,	Ophthalmic		
3atch:		Starte			TERM	- ,	Stopped:			
MIANSERIN HYDR	OCHLORIDE (Su				Reaso	n:	Depression			
Tablet		ороской,	40.0	Milligram		Daily	Дор. 000.0	Oral		
3atch:		Starte		/12/1994		Dully	Stopped:	03/01/1995		
Jaten.		Jane	u. 21/	112/1334			noppeu.	03/01/1993		
aboratory In	vestigation	s:								
dditional Inf	ormation:									



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 99194 Seq: 1 Gender: M

Reported: 27/02/1995 Weight:
Hospitalisation: Age: 83Y

Onset Date: 22/02/1995 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Leukopenia			
Renal impairment			

Medicine Details:

3atch:

TOLVON (Suspected) Reason: Depression
Tablet 30.0 Milligram Daily Oral

Stopped:

22/02/1995

3tarted: 18/01/1995

Laboratory Investigations:

	y ilivestigat				
Date	Туре	Range	Date Tested	Result	Details
	Creatinine	0.06-0.12	22/02/1995	0.27	
	Neutrophils	2.0-7.5	22/02/1995	0.3	
	Neutrophils	2.0-7.5	06/03/1995	2.2	
	Urea	3.6-9.3 MMOL/L	22/02/1995	21.6	
	White blood cells	4.0-11.0	22/02/1995	1.6	
	White blood cells	4.0-11.0	06/03/1995	4.5	

Additional Information:

Patient has had no known previous allergies.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report D)etail
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Case Number: 99416 Seq: 1 Gender: M
Reported: 06/03/1995 Weight:

 Hospitalisation:
 Age: 83

 Onset Date: 22/02/1995
 DOB: 22/10/1911

Outcome: Unknown Causality: Causality probable

Reaction Detai

todotion Botai			
Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			
Confusional state			
Infection			
Neutropenia			
Pyrexia			

Medicine Details:

TOLVON (Suspected)		Reason:	Depression	
Oral application	60.0 Milligram	Daily		Oral
3atch:	Started: 18/01/1995		Stopped:	22/02/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		22/02/1995	17	
	White blood cells		22/02/1995	1.6	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 99684
 Seq: 1
 Gender: M

 Reported:
 20/03/1995
 Weight:

Hospitalisation: Age: 90Y
Onset Date: 30/11/1994
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			Ceftazidime
Anaemia			
Hyperhidrosis			
Pyrexia			

Medicine Details:

TOLVON (Other drug)		Reason:	
	70.0 Milligram	Daily	
Зatch:	Started: 30/11/1994	Stopped:	02/12/1994
NEULACTIL (Other drug)		Reason:	
	7.5 Milligram	Daily	
Зatch:	Started: 16/10/1994	Stopped:	CONTIN
AMOXIL (Other drug)		Reason: Othr diseases	of urinary tract
	250.0 Milligram	Daily	
Зatch:	Started:	Stopped:	CONTIN
TOLVON (Suspected)		Reason:	
	20.0 Milligram	Daily	
3atch:	Started: 25/10/1994	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin	135-180	26/11/1994	147	
	Haemoglobin	135-180	30/11/1994	129	
	Haemoglobin	135-180	01/12/1994	93	
	Haemoglobin	135-180	04/12/1994	105	
	Haemoglobin	135-180	12/12/1994	90	
	Haemoglobin	135-180	10/12/1994	94	
	Haemoglobin	135-180	06/12/1994	91	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 99684 Seq: 1 Gender: M

Reported: 20/03/1995 Weight:

Hospitalisation: Age: 90Y

Onset Date: 30/11/1994 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

Medicine Details.			
TOLVON (Suspected)		Reason:	,
	50.0 Milligram	Daily	
3atch:	Started: 09/11/1994	Stopped:	
DILANTIN (Suspected)		Reason: Other&unspecified epilepsy	
	100.0 Milligram	Daily	
3atch:	Started: 12/10/1994	Stopped: 02/12/1994	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin	135-180	05/12/1994	95	
	Neutrophils	1.7-8.2	26/11/1994	7.4	
	Neutrophils	1.7-8.2	30/11/1994	3.3	
	Neutrophils	1.7-8.2	01/12/1994	-	
	Neutrophils	1.7-8.2	04/12/1994	0.1	
	Neutrophils	1.7-8.2	12/12/1994	2.1	
	Neutrophils	1.7-8.2	10/12/1994	1.0	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 99684 Seq: 1 Gender: M

Reported: 20/03/1995 Weight:
Hospitalisation: Age: 90Y

Onset Date: 30/11/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

TOLVON (Other drug)

70.0 Milligram Daily

3atch: 3tarted: 30/11/1994 **3topped:** 02/12/1994

NEULACTIL (Other drug) Reason:

7.5 Milligram Daily

3atch: **3tarted**: 16/10/1994 **3topped**: CONTIN

AMOXIL (Other drug) Reason: Othr diseases of urinary tract

250.0 Milligram Daily

3atch: Started: Stopped: CONTIN

TOLVON (Suspected) Reason:

20.0 Milligram Daily

3atch: **3tarted**: 25/10/1994 **3topped**:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	1.7-8.2	06/12/1994	0.1	
	Neutrophils	1.7-8.2	05/12/1994	0.1	
	White blood cells	4-11	26/11/1994	9.4	
	White blood cells	4-11	30/11/1994	4.9	
	White blood cells	4-11	01/12/1994	1.0	
	White blood cells	4-11	04/12/1994	1.5	
	White blood cells	4-11	05/12/1994	1.4	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 99684
 Seq: 1
 Gender: M

 Reported:
 20/03/1995
 Weight:

Hospitalisation:
Onset Date: 30/11/1994
Age: 90Y
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

Medicine Details.			
TOLVON (Suspected)		Reason:	
	50.0 Milligram	Daily	
3atch:	Started: 09/11/1994	Stopped:	
DILANTIN (Suspected)		Reason: Other&unspecified epilepsy	
	100.0 Milligram	Daily	
3atch:	Started: 12/10/1994	3topped: 02/12/1994	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells	4-11	06/12/1994	1.9	
	White blood cells	4-11	10/12/1994	2.3	
	White blood cells	4-11	12/12/1994	4.2	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report	Detail
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Case Number: 100104 Seq: 1 Gender: F

Reported: 07/04/1995 Weight:
Hospitalisation: Age: 69Y

Onset Date: 03/04/1995 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Veaction Detai	action betain						
Preferred Term	Severity	Report Description	Treatment				
Paraesthesia		Crawling sensation in head					
	Required Specialist Consultation	Mild shooting pain across the head.					

Medicine Details:

 TOLVON (Suspected)
 Reason:
 Depression

 Tablet
 10.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 03/04/1995
 3topped:
 05/04/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report D	Detai l
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Case Number: 100911 Seq: 1 Gender: M

Reported: 19/05/1995 Weight: 60.00 Hospitalisation: Age: 71Y

Onset Date: 16/05/1995 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

104011011 20141		-	
Preferred Term	Severity	Report Description	Treatment
Vertigo			

Medicine Details:

TOLVON (Suspected) Reason: Anxiety neurosis

20.0 Milligram Daily

3atch: 3tarted: 06/05/1995 3topped: 17/05/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 101218
 Seq:
 1
 Gender:
 F

 Reported:
 26/05/1995
 Weight:
 79.0

Reported: 26/05/1995 Weight: 79.00 Hospitalisation: Age: 63Y

Onset Date: 31/03/1995 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hypothyroidism	Severe		Thyroxine

Medicine Details:

LITHICARB (Suspected)		Reason:	Depression		
	500.0 Milligram	Daily			
3atch:	Started: 02/09/1994		Stopped:	26/04/1995	
AROPAX (Suspected)		Reason:	Depression		
Tablet	20.0 Milligram	Daily		Oral	
3atch:	3tarted: 06/01/1995		Stopped:		CONTIN
TOLVON (Suspected)		Reason:	Depression		
	20.0 Milligram	Daily			
3atch:	Started: 01/01/1993		Stopped:		CONTIN
MELLERIL (Suspected)		Reason:			
	25.0 Milligram	Daily			

Laboratory Investigations:

	<u> </u>				
Date	Туре	Range	Date Tested	Result	Details
_	Other data				Very high thyroid autoantibodies - tsh 100, t4 2.4.

Additional Information:

Patient is recovering. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not 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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 101806 Seq: 1 Gender: M
Reported: 20/06/1995 Weight:
Hospitalisation: Age: 74Y

Onset Date: 09/03/1995 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

touction betai			
Preferred Term	Severity	Report Description	Treatment
Dyspnoea			Prednisone
Eosinophilic pneumonia			
Headache			
Myalgia			

Medicine Details:

COGNEX (Suspected)		Reason:	Presenile dem	entia	
Capsule	80.0 Milligram	Daily		Oral	
3atch:	Started: 13/02/1995		Stopped:	12/03/1995	
TOLVON (Suspected)		Reason:	Depression		
Tablet	30.0 Milligram	Daily		Oral	
3atch:	Started: 21/12/1993		Stopped:		CONTIN
NAPROSYN (Suspected)		Reason:	Osteoarthritis		
Tablet	1.0 Gram	Daily		Oral	
3atch:	Started: 08/02/1995		Stopped:		CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Chest X-ray				Chest xray and ct lung scan -> honeycromb lung intersitial
	Lung biopsy				Lung biopsy 20/4/95-> eosinophic pneumonia.

Additional Information:

Report 101807 is a sequence to this report, the ultimate oucome was a fatal one.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

D D	
Report Deta	i

Case Number: 102862 Seq: 1 Gender: M

Reported: 14/08/1995 Weight: 63.00 Hospitalisation: Age: 79Y

Onset Date: 15/07/1995 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Gait disturbance			

Medicine Details:

PANADOL (Other drug)		Reas	on: Heada	ache
Oral application	1.0	Dose Unspecified	As necessar	y Oral
3atch:	Started:	L TERM	3to	ppped:
PANADEINE (Other drug)		₹eas	on: Heada	ache
Tablet	1.0	Dose Unspecified	As necessar	y Oral
3atch:	Started:	L TERM	Sto	ppped:
VALIUM (Other drug)		₹eas	on: Nervo	usness
VALIUM (Other drug) Tablet	5.0		on: Nervo Daily	ousness Oral
` "	5.0		Daily	
Tablet		Milligram	Daily	Oral
Tablet 3atch:	Started:	Milligram L TERM	Daily	Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: 1 Reported: 1 Hospitalisation: Onset Date: 1 Outcome: F Reaction Detai	14/08/1995 15/07/1995	Seq: 1			C	Gender: Weight: Age: DOB: ausality:	63.00	obable
Medicine Deta	ils:							
TOLVON (Suspected				Reason:	Nervousness			
Tablet			10.0 Milligram	Daily		Oral		
3atch:		Started:	: 14/07/1995		Stopped:	14/07/1995	5	
Laboratory Inv	vestigations:							
Additional Info	ormation:							

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 103457 Seq: 1 Gender: F

Reported: 11/09/1995 Weight: 58.00 Hospitalisation: Age: 77Y

Onset Date: 09/08/1995 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			

Medicine Details:

TEMAZEPAM (Other drug)		Reason:	Specific disor	ders of sleep
	10.0 Milligram	Daily	,	
3atch:	Started:	TERM	Stopped:	
MIANSERIN HYDROCHLORIDE (S	Suspected)	Reason:	Depression	
	10.0 Milligram	Daily	,	
3atch:	Started: 18/05/1995		Stopped:	22/05/1995
MIANSERIN HYDROCHLORIDE (\$	Suspected)	Reason:	Depression	
	20.0 Milligram	Daily	,	
3atch:	3tarted: 22/05/1995		Stopped:	26/05/1995
MIANSERIN HYDROCHLORIDE (S	Suspected)	Reason:	Depression	
	30.0 Milligram	Daily	,	
3atch:	Started: 26/05/1995		Stopped:	07/06/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin		16/06/1995	137	
	Haemoglobin		09/08/1995	121	
	Haemoglobin		15/08/1995	119	
	Haemoglobin		21/08/1995	114	
	Neutrophils		16/06/1995	7.4	
	Neutrophils		09/08/1995	1.6	
	Neutrophils		21/08/1995	4.46	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 103457 Seq: 1 Gender: F

Reported: 11/09/1995 Weight: 58.00 Hospitalisation: Age: 77Y

Onset Date: 09/08/1995 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 07/06/1995 **3topped:** 15/08/1995

TAMOXIFEN CITRATE (Suspected) Reason: Malignant neoplasm of breast

20.0 Milligram Daily

3atch: 3tarted: 04/05/1995 3topped: 15/08/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		15/08/1995	.2	
	White blood cells		16/06/1995	9.7	
	White blood cells		09/08/1995	4.2	
	White blood cells		15/08/1995	2.2	
	White blood cells		21/08/1995	7.2	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 103597 Seq: 1 Gender: F

Reported: 18/09/1995 Weight: 42.00 Hospitalisation: Age: 86Y

Onset Date: 04/09/1995 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

TENORMIN (Other drug)			Reason:	Essential ben	ign hypertension	
	25.0	Milligram	Daily			
Batch:	Started:	L	TERM	Stopped:		CONTIN
MIANSERIN HYDROCHLORIDE (Suspect	ed)		Reason:	Depression		
Tablet	40.0	Milligram	Daily		Oral	
3atch:	Started: 13	/07/1995		Stopped:	05/09/1995	
HALOPERIDOL (Suspected)			Reason:	Unspecified p	sychosis	
	500.0	Microgram	Daily			
3atch:	Started: 21	/08/1995		Stopped:	05/09/1995	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		01/09/1995	2.97	
	Neutrophils		08/09/1995	0.34	
	Neutrophils		04/09/1995	0.94	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 104437 Seq: 1 Gender: U
Reported: 03/11/1995 Weight:
Hospitalisation: Age:

Onset Date: 14/10/1995 **DOB**:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Pruritus			
Rash maculo-papular			

Medicine Details:

SOTALOL HYDROCHLORIDE (Suspected)			Reason:		
	160.0	Milligram	Daily		
3atch:	Started: 01	/07/1995		Stopped:	20/10/1995
SIMVASTATIN (Suspected)			Reason:		
	10.0	Milligram	Daily		
3atch:	Started:			Stopped:	
MIANSERIN HYDROCHLORIDE (Suspected	l)		Reason:		
MIANSERIN HYDROCHLORIDE (Suspected	l) 20.0	Milligram	Reason: Daily		
MIANSERIN HYDROCHLORIDE (Suspected Satch:	•	Milligram		Stopped:	
, ,	20.0	Milligram		Stopped:	
3atch:	20.0	Milligram Dose Unspec	Daily Reason:	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.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 104458 Seq: 1 Gender: F

Reported: 07/11/1995 Weight: 70.00 Hospitalisation: Age: 88Y

Onset Date: 29/10/1995 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Pruritus			
Rash maculo-papular			

Medicine Details:

IMDUR (Other drug)		Reason:	Chron isch heart dis no hyper	
Oral application	60.0 Milligram	Daily	Oral	
Зatch:	3tarted: 17/10/1995		Stopped:	CONTIN
LANOXIN PG (Other drug)		Reason:	Otr&nos disord of heart rhythr	n
Oral application	2.0 Dose Unspe	cified Daily	Oral	
3atch:	Started:		Stopped:	CONTIN
LASIX (Other drug)		Reason:	Congestive heart failure	
	40.0 Milligram	Daily		
3atch:	Started: 13/10/1995		Stopped:	CONTIN
ASPIRIN (Other drug)		Reason:	Chron isch heart dis no hyper	
Oral application	150.0 Milligram	Daily	Oral	
3atch:	Started: 13/10/1995		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Repo	ort D	etai
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Case Number: 104458 Seq: 1 Gender: F

Reported: 07/11/1995 Weight: 70.00 Hospitalisation: Age: 88Y

Onset Date: 29/10/1995 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspecte)	Reason:	Depression	
Oral application	10.0 Milligram	Daily		Oral
3atch:	Started: 27/10/1995		Stopped:	29/10/1995
METHYL SALICYLATE (Suspected)		Reason:		
Cream	3.0 Dose Unspe	ecified Daily		Topical
3atch:	Started: 27/10/1995		Stopped:	29/10/1995
RENITEC (Suspected)	Reason:			
	5.0 Milligram	Daily		
3atch:	3tarted: 16/10/1995		Stopped:	26/10/1995

Laboratory Investigations:

Additional Information:

See original report for other drugs.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 104952 Seq: 1 Gender: F

Reported: 29/11/1995 Weight:
Hospitalisation: Age: 47Y

Onset Date: 18/10/1995 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Arthralgia			
Arthritis			
Purpura			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

 Oral application
 100.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 03/12/1993
 3topped:
 27/11/1995

Laboratory Investigations:

	<u> </u>				
Date	Туре	Range	Date Tested	Result	Details
	Haematology				Hb, f.b.e., platelets, wbc normal 19/10/95.

Additional Information:

Dose depentant- disappeared in doses of mianserin below 40 mg daily, recurred above 80 mg daily.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Re	po	rt	D	et	ai∣
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Case Number:105607Seq:1Gender:FReported:02/01/1996Weight:Hospitalisation:Admitted to hospitalAge:82Y

Onset Date: 12/10/1995 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

ASCORBIC ACID (Other drug)		Reason:	
	0.0		
Зatch:	Started:	Stopped:	
PANAMAX (Other drug)		Reason:	
	0.0	As necessary	
Зatch:	Started:	Stopped:	
BETAMIN (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	
CARDIPRIN 100 (Other drug)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium		12/10/1995	124	
	Sodium		18/10/1995	136	



Case Number: 105607

Reported: 02/01/1996

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: F

Weight:

Hospitalisation: Onset Date:	Admitted to hospital 12/10/1995						Age: DOB:	82Y	
Outcome: eaction Detai						С	ausality:	Causality prob	able
Andinina Data	-!!								
Medicine Deta				Reason:	<u> </u>				
	9,	2.0	Dose Unspec						
3atch:		Started:				Stopped:			
METAMUCIL (Othe	r drug)			Reason:					
			Dose Unspec	cified Da	aily				
3atch:	(In any alarmon)	Started:		.		Stopped:			
NAPROSYN SR (O	ther drug)	750.0	Milliarom	Reason:			Oral		
3atch:		3tarted:	Milligram	Di	aily	Stopped:	12/10/1995		
TOLVON (Suspect	ed)	- Juli Cou		Reason:		жоррош	12/10/1000		
` .	•	0.0							
3atch:		Started:				Stopped:			
aboratory In	vestigations:								
aboratory in	vestigations.								
Additional Inf	ormation:								
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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

	105607	Seq:	1			Gender:	F	
Reported:	02/01/1996					Weight:		
	Admitted to hosp	ital				Age:	82Y	
Onset Date:	12/10/1995					DOB:		
Outcome:	Recovered					Causality:	Causality proba	able
action Detai								
edicine Deta								
AROPAX (Suspect	ed)				Depression			
Tablet		34	20.0 Milligram	Daily		Oral	4147	
3atch:		3tar	ted: 01/09/1995		Stopped:		4W	
					•			
aboratory In	vestigations:							
aboratory In	vestigations:							
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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

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 Case Number:
 105613
 Seq: 1
 Gender:
 F

 Reported:
 02/01/1996
 Weight:

Hospitalisation: Age: 82Y

Onset Date: 31/12/1995 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Anaemia			
Leukopenia			

Medicine Details:

CARDIPRIN 100 (Other drug)		Reas	on:		
Tablet	1.0	Dose Unspecified	Daily		Oral
3atch:	Started:	L TERM		Stopped:	
QUINATE (Other drug)		Reas	on:		
Tablet	1.0	Dose Unspecified	Daily		Oral
Batch:	Started:	L TERM		Stopped:	
ROHYPNOL (Other drug)		₹eas	on:		
ROHYPNOL (Other drug) Tablet	1.0				Oral
`	1.0 Started:		Daily	Stopped:	Oral
Tablet		Dose Unspecified	Daily	Stopped:	Oral
Tablet 3atch:	Started:	Dose Unspecified L TERM	Daily	• • • • • • • • • • • • • • • • • • • •	Oral Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin				Haemoglobin 9.4
	White blood cells				Wcc 3.6

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. 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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 106134 Seq: 1 Gender: M
Reported: 30/01/1996 Weight:
Hospitalisation: Age: 55Y

Onset Date: 16/11/1995 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

ENALAPRIL MALEATE (Other drug)		Reason:	Congestive heart	failure
	20.0 Milligram	Daily		
Зatch:	3tarted: 01/01/1990		Stopped:	CONTIN
AMIODARONE HYDROCHLORIDE (Su	ispected)	Reason:	Otr&nos disord of	heart rhythm
	200.0 Milligram	Daily		
Зatch:	Started: 01/01/1986		Stopped:	CONTIN
MIANSERIN HYDROCHLORIDE (Susp	ected)	Reason:	Depression	
	20.0 Milligram	Daily		
Зatch:	3tarted: 01/01/1990		Stopped: 12	2/01/1996
FRUSEMIDE (Suspected)		Reason:	Chron isch heart	dis no hyper
	40.0 Milligram	Daily		
1				

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	10 - 56	17/09/1995	33	
	ALT = SGPT	10 - 56	16/11/1995	72	
	ALT = SGPT	10 - 56	02/12/1995	76	
	ALT = SGPT	10 - 56	05/01/1996	88	
	ALT = SGPT	10 - 56	15/01/1996	86	
	ALT = SGPT	10 - 56	13/01/1996	66	
	ALT = SGPT	10 - 56	10/01/1996	101	

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 106134
 Seq: 1
 Gender: M

 Reported:
 30/01/1996
 Weight:

Hospitalisation: Age: 55Y
Onset Date: 16/11/1995
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

ISORDIL (Suspected) Reason:

30.0 Milligram Daily

3atch: **3tarted**: 01/01/1990 **3topped**: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	10 - 56	07/01/1996	115	
	GGT = SGGT =	10 - 69	17/09/1995	94	
	GGT = SGGT =	10 - 69	16/11/1995	379	
	ĜĜT = SGGT =	10 - 69	02/12/1995	857	
	GGT = SGGT =	10 - 69	05/01/1996	1107	
	GGT = SGGT =	10 - 69	15/01/1996	1346	
	GGT = SGGT =	10 - 69	13/01/1996	936	

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 106134
 Seq: 1
 Gender: M

 Reported:
 30/01/1996
 Weight:

Hospitalisation: Age: 55Y
Onset Date: 16/11/1995
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

ENALAPRIL MALEATE (Other drug)		Reason:	Congestive heart fa	ailure
	20.0 Milligram	Daily		
3atch:	Started: 01/01/1990		Stopped:	CONTIN
AMIODARONE HYDROCHLORIDE (Susp	pected)	Reason:	Otr&nos disord of h	eart rhythm
	200.0 Milligram	Daily		
Заtch:	3tarted: 01/01/1986		Stopped:	CONTIN
MIANSERIN HYDROCHLORIDE (Suspec	ted)	Reason:	Depression	
	20.0 Milligram	Daily		
Заtch:	Started: 01/01/1990		Stopped: 12/0	01/1996
FRUSEMIDE (Suspected)		Reason:	Chron isch heart di	s no hyper
	40.0 Milligram	Daily		
Зatch:	3tarted: 01/01/1990		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =	10 - 69	10/01/1996	1166	
	GGT = SGGT =	10 - 69	07/01/1996	1287	
	SAP = ALP	38 - 126	17/09/1995	113	
	SAP = ALP	38 - 126	16/11/1995	188	
	SAP = ALP	38 - 126	02/12/1995	296	
	SAP = ALP	38 - 126	05/01/1996	324	
	SAP = ALP	38 - 126	07/01/1996	391	

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 106134
 Seq: 1
 Gender: M

 Reported:
 30/01/1996
 Weight:

Hospitalisation: Age: 55Y
Onset Date: 16/11/1995
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

ISORDIL (Suspected) Reason:

30.0 Milligram Daily

3atch: **3tarted**: 01/01/1990 **3topped**: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	38 - 126	10/01/1996	308	
	SAP = ALP	38 - 126	13/01/1996	261	
	SAP = ALP	38 - 126	15/01/1996	342	

Additional Information:

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

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 108333 Seq: 1 Gender: F

Reported: 03/05/1996 Weight: 75.00 Hospitalisation: Age: 81Y

Onset Date: 05/04/1996 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Paranoia			

Medicine Details:

TOLVON (Suspected)

Tablet

2.0 Dose Unspecified Daily

Oral

Started:

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Tolvon recommenced on 10/4/96 resulting in same reaction occurring, see original report for other drugs.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 108963 Seq: 1 Gender: F

Reported: 05/06/1996 Weight: 100.00 Hospitalisation: Age: 62Y

Onset Date: 16/05/1996 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Leukopenia	Required Visit to Doctor		
Lymphopenia Neutropenia			

Medicine Details:

SERENACE (Other drug)			Reason:	Depression	
	1.5	Milligram	Daily		
3atch:	Started:	L	. TERM	Stopped:	
TOLVON (Suspected)			Reason:	Depression	
	100.0	Milligram	Daily		

3atch: **310/03/1996 3topped**: 18/05/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Lymphocytes	1.0-4.8	17/05/1996	0.86	
	Lymphocytes	1.0-4.8	27/05/1996	1.74	
	Neutrophils	1.80-7.50	17/05/1996	1.05	
	Neutrophils	1.80-7.50	27/05/1996	6.70	
	White blood cells	4.0-11.0	17/05/1996	2.46	
	White blood cells	4.0-11.0	27/05/1996	8.74	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 109144 Seq: 1 Gender: M

Reported: 17/06/1996 Weight: 70.00 Hospitalisation: Age: 67Y

Onset Date: 07/06/1996 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Leukopenia			
Neutropenia			

Medicine Details:

RANITIDINE (Other drug)		;	Reason:	Ulcer of duodenum	n w/o ment perf
	300.0	Milligram	Daily		
3atch:	Started:			Stopped:	CONTIN
COLOXYL WITH SENNA (Other drug)		;	Reason:	Constipation	
	2.0	Dose Unspecif	fied Daily		
3atch:	Started:			Stopped:	CONTIN
BENZTROPINE MESYLATE (Other drug)		;	Reason:		
	2.0	Milligram	Daily		
3atch:	Started:			Stopped:	CONTIN
TRIFLUOPERAZINE HYDROCHLORIDE (O	ther drug)	;	Reason:	Depression	
	6.0	Milligram	Daily		
3atch:	Started:			Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	2.0 - 7.5	25/04/1996	3.4	
	Neutrophils	2.0 - 7.5	07/06/1996	1.7	
	Neutrophils	2.0 - 7.5	08/06/1996	2.3	
	White blood cells	4.0 - 11.0	25/04/1996	5.1	
	White blood cells	4.0 - 11.0	07/06/1996	2.5	
	White blood cells	4.0 - 11.0	08/06/1996	3.9	



Case Number: 109144

Reported: 17/06/1996

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Gender: M

Weight: 70.00

spitalisation:				Age: DOB:	67Y	
Onset Date: 07/06/1996 Outcome: Recovered			•		Causality proba	ble
ction Detai				auounty i	Caddanty proba	
edicine Details:						
SORBITOL (Other drug)	40.0 1471777		Constipation			
2.4.1	40.0 Millilitre	Daily			CONTIN	
3atch:	Started:		Stopped:		CONTIN	
ISPERIDONE (Other drug)		Reason:				
	2.0 Milligram	Daily				
Зatch:	3tarted: 19/05/1996		Stopped:	28/05/1996		
IIANSERIN HYDROCHLORIDE (Suspect			Depression			
	140.0 Milligram	Daily				
3atch:	Started: 04/04/1996		Stopped:	03/06/1996		
	Started: 04/04/1996		Stopped:	03/06/1996		
aboratory Investigations:						
dditional Information:						
rt Run 01/08/200 02:08PN Databa	se: pusime	ADRS004	1		Page 229	of 33



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 109230
 Seq: 1
 Gender: M

 Reported:
 17/06/1996
 Weight:

Hospitalisation: Age: 71Y
Onset Date: 31/05/1996
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal		Marked functional decline/inability to dress	

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason:

100.0 Milligram Daily

3atch: 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.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 109835
 Seq: 1
 Gender:
 F

 Reported:
 08/07/1996
 Weight:

Hospitalisation: Admitted to hospital **Age**: 79Y **Onset Date**: 11/06/1996 **DOB**:

Outcome: Unknown Causality: Causality possible

Reaction Detai

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
Neutropenia			Antibiotics
Pyrexia			

Medicine Details:

SALBUTAMOL (Other drug)		Reas	on:	Otr respiratory systm diseases
Inhalation	0.0			Inhalation
3atch:	Started:			Stopped:
FLUTICASONE PROPIONATE (Other of	drug)	Reas	on:	Otr respiratory systm diseases
Inhalation	0.0			Inhalation
3atch:	Started:			Stopped:
GLIBENCLAMIDE (Other drug)		Reas	on:	Diabetes mellitus
	15.0	Milligram	Daily	
3atch:	Started:			Stopped:
DIABEX (Other drug)		Reas	on:	Diabetes mellitus
	1.0	Dose Unspecified	Daily	
3atch:	Started:			Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	1.9-7.6	11/06/1996	0.58	
	White blood cells	4-11	11/06/1996	2.24	

Additional Information:

In september 1994 possible quinidine-induced thrombocytopenia. see original report for other drugs. 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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

 Case Number:
 109835
 Seq:
 1
 Gender:
 F

 Reported:
 08/07/1996
 Weight:

Hospitalisation: Admitted to hospital Age: 79Y
Onset Date: 11/06/1996
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Medicine Details:

Medicine Details.			
RANITIDINE (Other drug)		Reason:	Peptic ulcer nos w/o ment perf
	300.0 Milligram	Daily	,
3atch:	Started:		Stopped:
MIANSERIN HYDROCHLORIDE (S	uspected)	Reason:	Depression
	40.0 Milligram	Daily	,
3atch:	Started: 01/04/1996		3topped: 11/06/1996

Laboratory Investigations:

Additional Information:

In september 1994 possible quinidine-induced thrombocytopenia. see original report for other drugs. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 110297
 Seq: 1
 Gender:
 F

 Reported:
 26/07/1996
 Weight:
 81.00

 Hospitalisation:
 Age: 32Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain from 65kg to 82kg over 2	

Medicine Details:

Modifile Botalie			
LOGYNON ED (Other drug)		Reason: Contraception	
	0.0		
Зatch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason: Specific disorders of sleep	
	2.0 Milligram	Daily	
Зatch:	Started:	Stopped:	
MIANSERIN HYDROCHLORIDE (S	uspected)	Reason: Depression	
Tablet	20.0 Milligram	Daily Oral	
3atch:	Started : 23/04/1996	Stopped : 24/06/1996	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient changed shape (lost fat mass) and lost 1 kg within 2 weeks of stopping the drug.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

	er: 11074 d: 13/08 n:		Seq:	1	Gender: F Weight: Age: 80Y DOB:				ght: .ge: 80Y	
Onset Date		et recover	ed					(lity: Causality possible
action Det	_	Ct recover	Ju						uusa	ity. Causanty possible
	rred Terr	n	Sev	verity		Report	Desc	ription		Treatment
Rash					xten	excoriations			es,	
ruritus						· P · · L				Paraffin, celestone cream, cotton seed oil baths daily, zantac changed to losec
ledicine De										
PANADEINE FO	JRIE (Oth	er drug)		0.0		Reaso		Headache		
3atch:			24	u.u tarted:			As nec	essary Stopped:		
DROXINE (Other	er drug)		- 1	arteu.		Reaso	nn.	Myxedema		
MOXINE (Othe	,i ulug,			125.0	Micro		Daily	Wyxcucina		
3atch:			St	arted:	IVIIOI	L TERM	Dully	Stopped:		
MIANSERIN HY	DROCHLO	ORIDE (Susp	ected)			Reaso	on:	Depression		
				60.0	Milliç	gram	Daily			
3atch:			3t	arted:		L TERM		Stopped:		
rEGRETOL (Su	spected)					Reaso	on:			
				200.0	Millig	gram	Daily			
3atch:			3t	arted:		L TERM		Stopped:	28/06	/1996
aboratory	Invest	igations								
	Туре		ange	Date Test	ed	Result				Details
Date				İ	\neg					



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: Reported: Hospitalisation: Onset Date:	13/08/1996	Seq:	1			Gender: Weight: Age: DOB:	80Y	ala
Outcome: Reaction Detai	Not yet recovered	1				Causality:	Causality possil	ole
Medicine Deta						 		
ZANTAC (Suspecte	ed)		300 0	Milligram	Reason: Da	nal pain		
3atch:		Sta	rted:		L TERM	ped: 27/06/1996	3	
Laboratory In	vestigations:							
Additional Inf	ormation:							
			_					



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

_	- 4	etai	•

 Case Number:
 110875
 Seq: 1
 Gender:
 F

 Reported:
 14/08/1996
 Weight:

Hospitalisation: Age: 41Y

Onset Date: 24/07/1996 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

todotion Dotal		E	
Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Absolute neutropenia		
Gingivitis	Swelling of gums.		
Mouth ulceration		Ulcers in oral cavity.	

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

Tablet 60.0 Milligram Daily Oral

3atch: 3tarted: 20/06/1996 3topped: 24/07/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Rep	00	rt	D	eta	il
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 Case Number:
 111606
 Seq:
 1
 Gender:
 F

 Reported:
 16/09/1996
 Weight:

Hospitalisation: Age: 87Y
Onset Date: 06/05/1996
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Veaction Detai	ā-		
Preferred Term	Severity	Report Description	Treatment
Rash			Diprosone, peanut cream and bath oil for washing

Medicine Details:

FRUSEMIDE (Other drug)			Reason:	Congestive heart failure
	60.0	Milligram	Daily	
3atch:	Started:			Stopped:
DIGOXIN (Other drug)			Reason:	Otr&nos disord of heart rhythm
	125.0	Microgram	Daily	
3atch:	Started:			Stopped:
LISINOPRIL (Other drug)			Reason:	Congestive heart failure
	20.0	Milligram	Daily	
3atch:	Started:			Stopped:
MIANSERIN HYDROCHLORIDE (Suspecte	d)		Reason:	Depression
	10.0	Milligram	Daily	
3atch:	Started: 28/	02/1996		3topped: 10/05/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail		
Case Number: 111606 Reported: 16/09/1996 Hospitalisation: Onset Date: 06/05/1996 Outcome: Unknown Reaction Detai	Seq: 1	Gender: F Weight: Age: 87Y DOB: Causality: Causality possible
Medicine Details: ASPIRIN (Suspected)	Reasc	on:
3atch:	150.0 Milligram Started:	Daily Stopped: 10/07/1996
Laboratory Investigations:		
Additional Information:		



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report D)etail
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Case Number: 112240 Seq: 1 Gender: F

Reported: 14/10/1996 Weight:
Hospitalisation: Age: 69Y

Onset Date: 10/10/1996 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Akathisia with restless legs and arms	

Medicine Details:

TOLVON (Suspected) Reason: Depression

Tablet 10.0 Milligram 1 time Oral

3atch: 3tarted: 10/10/1996 3topped: 11/10/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Repor		Seq:					
-	ted: 02/12/1996	3		Weight:			
spitalisat				Age : 59Y			
	ate: 29/10/1996					OOB:	
	me: Recovered	j			Causa	ality: Causality probable	
action D							
	ferred Term	Sev	rerity	Report	Description	Treatment	
thritis							
ladia!:aa	Deteile:						
MDUR (Othe	Details: er drug)			Reaso	on:		
,	- .		0.0				
3atcl	ո։	Sta	arted:		Stopped:		
ENORMIN (Other drug)			Reaso			
			0.0				
3atcl	ո։	Sta	arted:		Stopped:		
RENITEC (O	ther drug)			Reaso	on:		
			0.0				
3atcl		3ta	arted:		Stopped:		
A CDIDINI (O4	her drug)			Reaso	on:		
ASPIRIN (OU			0.0				
					\4		
3atcl	1:) Sta	arted:		Stopped:		
3atcl	ո։ ry Investigati				stopped:		
3atcl			Date Tested	Result	жоррей:	Details	



Case Number: 113589

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: M

Reported:	02/12/1996	;				Weight:		
lospitalisation:						Age:	59Y	
Onset Date:	29/10/1996	;				DOB:		
Outcome:	Recovered	ı			C	ausality:	Causality prob	able
eaction Detai								
Medicine Det	aile:							
NORVASC (Other				Reason:				
,	0 ,	0	0.0					
3atch:		Started:			Stopped:			
LUMIN (Suspected	1)			Reason:				
Tablet		20	.0 Milligram	Daily		Oral		
3atch:		Started:	07/10/1996		Stopped:	06/11/1996		
l abayataw <i>i</i> lw								
Laboratory In	vestigation	ons:						
Additional Inf	ormation	1:						



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report	: Detail
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 Case Number:
 114336
 Seq:
 1
 Gender:
 F

 Reported:
 06/01/1997
 Weight:

Hospitalisation: Age: 71

Onset Date: 24/11/1996 **DOB**: 05/12/1924

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal			Phenytoin withheld until within normal range and then
Gait disturbance			rectorica

Medicine Details:

MIANSERIN HYDROCHLORIDE (Interaction	n)		Reason:			
Oral application	10.0	Milligram	Daily		Oral	
3atch:	Started:	S	TERM	Stopped:		
PHENYTOIN SODIUM (Interaction)			Reason:			
Oral application	300.0	Milligram	Daily		Oral	
3atch:	Started:	S	TERM	Stopped:	25/11/1996	
PROMINAL (Other drug)			Reason:			
PROMINAL (Other drug) Tablet	180.0	Milligram	Reason:		Oral	
` "	180.0 Started:	ŭ		}topped:	Oral	CONTIN
Tablet		ŭ	Daily	Stopped:	Oral	CONTIN
Tablet 3atch:		S	Daily TERM	Stopped:	Oral Oral	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Case Number: 114336

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: F

Reported: 06/01/1997						Weight:	74	
lospitalisation: Onset Date: 24/11/1996						Age:	71 05/12/1924	
Outcome: Recovered					_			iblo
eaction Detai					C	ausanty.	Causality poss	ible
Medicine Details: THIAMINE (Other drug)	100.5	Maillan	Reaso			Oral		
Oral application		Milligram		Daily	Mannad.	Oral	CONITINI	
3atch: DIAZEPAM (Other drug)	Started:		S TERM	n.	Stopped:		CONTIN	
Oral application	5.0	Milligram		Daily		Oral		
Satch:	Started:		S TERM	Daily	Stopped:	22/11/1996		
₋aboratory Investigations	S :							
Additional Information:								



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 114642 Seq: 1 Gender: F

Reported: 21/01/1997 Weight:

Hospitalisation: Age: 73Y

Onset Date: 13/11/1996

Outcome: Recovered

Causality: Causality probable

Reaction Detai

104011011 20141		-	=
Preferred Term	Severity	Report Description	Treatment
Arthropathy		Inflam. arthropathy of	Hydrochlorothiazide,
Hepatic function abnormal			

Medicine Details:

DIGOXIN (Other drug)			Reason:	Otr&nos disord	d of heart rhythm
Tablet	62.5	Microgram	Daily		Oral
Зatch:	Started: 01	02/1996		Stopped:	
OXAZEPAM (Other drug)			Reason:	Specific disord	ders of sleep
Tablet	30.0	Milligram	Daily		Oral
Зatch:	Started:	L	. TERM	Stopped:	
MIANSERIN HYDROCHLORIDE (Sus	pected)		Reason:	Depression	
Tablet	60.0	Milligram	Daily		Oral
3atch:	Started: 23	10/1996		Stopped:	15/11/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		18/11/1996	90	
	GGT = SGGT =		18/11/1996	273	
	SAP = ALP		18/11/1996	203	

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: 116663

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: F

Reported: 10/04/	1997				W	eight:	
spitalisation:						Age: 92	
Onset Date:						DOB: 01/07/	1904
Outcome: Not ye	t recovered				Cau	sality: Causa	lity possible
action Detai Preferred Term	Seve	ority	Popol	t Desc	rintion	Tr	eatment
/pocalcaemia	364	city	Кери	l Desc	приоп	111	zauneni
edicine Details: YAZIDE (Suspected)		10 D	Reas				
3atch:	2ta	1.0 Do	ose Unspecified	Daily	Stopped:		
MIANSERIN HYDROCHLOI		. tou.	Reas	on:	Moppeu.		
	= (-40pooted)	30.0 Mi		Daily			
3atch:	Sta	rted:	•	,	Stopped:		
MOXYCILLIN-POTASSIUI	// CLAVULANATE (S	Suspected)	Reas	on:			
		3.0 Do	ose Unspecified	Daily			
Batch:	3ta	rted:			Stopped:		
aboratory Investig	gations: Range	Date Tested	Result			Details	
Additional Informa	tion:						
ort Run 01/08/200 02:0	8PN Database: pu	sime	A	DRS004	.	Pa	ge 245 of 33



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Gender: F Case Number: 118089 Seq: 1 Reported: 05/06/1997 Weight:

Hospitalisation: **Age:** 73

Onset Date: DOB: 29/08/1923

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Carbamazepine & paroxetine

Medicine Details:

TEGRETOL (Suspected)		Reason:	
Oral Liquid	200.0 Milligram	Daily	Oral
3atch:	3tarted: 19/04/1997	Stopped:	05/05/1997
PAROXETINE HYDROCHLORIDE (Su	spected)	Reason:	
	10.0 Milligram	Daily	
3atch:	Started: 29/04/1997	Stopped:	05/05/1997
MORPHINE NOS (Suspected)		Reason:	
MORPHINE NOS (Suspected) Oral Liquid	30.0 Milligram	Reason:	Oral
` . ,	30.0 Milligram Started: 27/04/1997		Oral
Oral Liquid	Started: 27/04/1997	Daily	Oral
Oral Liquid 3atch:	Started: 27/04/1997	Daily Stopped:	Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Reported: (pspitalisation: Onset Date: Outcome: (action Detai	05/06/1997	Seq: 1		C		3 9/08/1923 ausality possi	ble
ledicine Deta			Reason:				
ENALAFRIL MALEA	(Suspected)	10.0 Milligram	Reason: Daily				
3atch:		3tarted: 02/05/1997	Daily	Stopped:	04/05/1997		
IIANSERIN HYDRO	CHLORIDE (Susp		Reason:	· · · · · · · ·			
	(60.0 Milligram	Daily				
3atch:		Started:	- ,	Stopped:	14/04/1997		
aboratory Inv	vestigations:	:					
dditional Info	ormation:						
ort Run 01/08/200	02:08PN Data	abase: pusime	ADRS004			Page 247	of 226



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 118092
 Seq:
 1
 Gender:
 F

 Reported:
 05/06/1997
 Weight:
 50.00

Hospitalisation: Age:
Onset Date: 11/05/1997
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Veaction Detai			
Preferred Term	Severity	Report Description	Treatment
Paranoia		Paranoid delusions	
Agitation			Phenergan given
Rash maculo-papular			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspecte	d)		Reason:		
	40.0	Milligram	Daily		
Зatch:	Started: 08	/05/1997		Stopped:	11/05/1997
ENALAPRIL MALEATE (Suspected)			Reason:		
	5.0	Milligram	Daily		
3atch:	Started:			Stopped:	
SALBUTAMOL (Suspected)			Reason:		
SALBUTAMOL (Suspected)	30.0	Milligram	Reason:		
SALBUTAMOL (Suspected) 3atch:	30.0 Started:	Milligram		Stopped:	
		Milligram		Stopped:	
3atch:		Milligram Dose Unspe	Daily Reason:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Case Number:	118092	Seq: 1				Gender:	F	
Reported:	05/06/1997	•				Weight:	50.00	
Hospitalisation:						Age:		
Onset Date:	11/05/1997					DOB:		
Outcome:	Not yet recovered	d			C	ausality:	Causality poss	ible
Reaction Detai	i							
Medicine Det								
COLOXYL WITH S	SENNA (Suspected)		0.0 Dana Harr	Reason:				
Jatah.		Mantad	2.0 Dose Unsp	ecified Daily	\			
3atch:	DILIM (Cooperated)	Started	: 03/05/1997	2000000	Stopped:			
CEFOTAXIME SOI	JIUM (Suspected)		2.0 Crom	Reason:				
Zotob.		Stantad	2.0 Gram	Daily	Mannadi	10/05/1007		
3atch:		Started	: 06/05/1997		Stopped:	12/05/1997		
Laboratory In	vestigations:							
Additional In	formations							
Additional in	formation:							
	0 00.0051 5 11			ABB000:				
eport Run 01/08/200	0 02:08PN Datab	base: pusime	J.	ADRS004			Page 249	01.336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 118106 Seq: 1 Gender: M
Reported: 05/06/1997 Weight:
Hospitalisation: Age: 58Y

Onset Date: 20/05/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Arthralgia		Arthralgia affecting hands, knees and	Nsaid given and mianserin

Medicine Details:

PARACETAMOL (Other drug)			Reason:	
	4.0	Gram	Daily	
Зatch:	Started:	L	_ TERM	Stopped:
ALPRAZOLAM (Other drug)			Reason:	
	2.0	Milligram	Daily	
3atch:	Started:	L	TERM	Stopped:
RANITIDINE (Other drug)			Reason:	
RANITIDINE (Other drug)	300.0	Milligram	Reason:	
RANITIDINE (Other drug) 3atch:	300.0 Started:	Ū		Stopped:
, .	Started:	Ū	Daily	Stopped:
3atch:	Started:	Ū	Daily _ TERM	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Case Number: 118106

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Gender: M

Reported:	05/06/1997					Weight:		
ospitalisation:						Age:	58Y	
Onset Date:	20/05/1997					DOB:		
Outcome:	Not yet recovered					Causality:	Causality poss	ible
action Detai								
<u>ledicine Deta</u>								
NITRAZEPAM (Oth	er drug)			Reason:				
			Milligram	Daily				
3atch:		Started:		L TERM	Stopped:			
MIANSERIN HYDR	OCHLORIDE (Suspected	(t		Reason:	Depression			
Tablet		40.0	Milligram	Daily		Oral		
3atch:		Started: 08	/05/1997		Stopped:	22/05/1997		
Laboratory In	vestigations:							
Additional Inf	ormation:							
oort Run 01/08/200) 02:08PN Database	e: pusime		ADRS00	04		Page 251	of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 118161
 Seq: 1
 Gender:
 F

 Reported:
 10/06/1997
 Weight:
 53.00

 Hospitalisation:
 Age: 86Y

Onset Date: 22/05/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			

Medicine Details:

FAMOTIDINE (Other drug)		Reason:		
Tablet	40.0 Milligram	Daily		Oral
3atch:	Started:		Stopped:	CONTIN
MIANSERIN HYDROCHLORIDE (Suspe	ected)	Reason:	Depression	
Tablet	120.0 Milligram	Daily		Oral
3atch:	Started: 28/03/1997		Stopped:	22/05/1997
ENALAPRIL MALEATE (Suspected)		Reason:	Essential ben	ign hypertension
Tablet	5.0 Milligram	Daily		Oral
3atch:	Started:		Stopped:	22/05/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatinine		15/05/1997	264	
	Creatinine		22/05/1997	223	
	Haematocrit	(0.32 - 0.46)	15/05/1997	0.237	
	Haematocrit	(0.32 - 0.46)	22/05/1997	0.231	
	Haemoglobin	(115 -165)	15/05/1997	81	
	Haemoglobin	(115 -165)	22/05/1997	77	
	Neutrophils	(1.8 - 7.7)	15/05/1997	2.7	

Additional Information:

Previous adverse reaction (akathisia) to sertraline requiring change to mianserin



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 118161
 Seq: 1
 Gender:
 F

 Reported:
 10/06/1997
 Weight:
 53.00

 Hospitalisation:
 Age: 86Y

Onset Date: 22/05/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

FAMOTIDINE (Other drug)		Reason:		
Tablet	40.0 Milligram	Daily		Oral
3atch:	Started:		Stopped:	CONTIN
MIANSERIN HYDROCHLORIDE (Suspe	cted)	Reason:	Depression	
Tablet	120.0 Milligram	Daily		Oral
3atch:	Started: 28/03/1997		Stopped:	22/05/1997
ENALAPRIL MALEATE (Suspected)		Reason:	Essential ben	ign hypertension
Tablet	5.0 Milligram	Daily		Oral
Зatch:	Started:		Stopped:	22/05/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	(1.8 - 7.7)	22/05/1997	0.1	
	leucocytes	(4-11)	15/05/1997	5.3	
	leucocytes	(4-11)	22/05/1997	1.4	

Additional Information:

Previous adverse reaction (akathisia) to sertraline requiring change to mianserin



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 118795 Seq: 1 Gender: M
Reported: 03/07/1997 Weight:
Hospitalisation: Age: 54Y

Onset Date: DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			Caverject, andriol, papaverine, testosterone.
Libido decreased			

Medicine Details:

EFEXOR (Suspected)			Reason:	Depression	
Tablet	137.5	Milligram	Daily	Oral	
3atch:	Started: 06	/12/1996		Stopped:	CONTIN
TOLVON (Suspected)			Reason:	Depression	
	20.0	Milligram	Daily		
3atch:	Started: 26	/07/1996		Stopped:	CONTIN
TRITACE (Suspected)			Reason:	Essential benign hypertension	1
	2.5	Milligram	Daily		
3atch:	Started:		L TERM	Stopped:	
ISOPTIN SR (Suspected)			Reason:	Essential benign hypertension	1
	240.0	Milligram	Daily		
3atch:	Started:		L TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Type 11 diabetes-diet controlled.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 120674
 Seq: 1
 Gender: M

 Reported:
 10/09/1997
 Weight:

Hospitalisation: Age: 71

Onset Date: DOB: 28/10/1925

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Hallucination			

Medicine Details:

SINEMET (Other drug) Reason:

1.0 Dose Unspecified 1 time

3atch: 3tarted: 13/07/1997 3topped:

SINEMET CR (Other drug) Reason:

4.0 Dose Unspecified Daily

3atch: 3tarted: 13/07/1997 3topped:

MIANSERIN HYDROCHLORIDE (Suspected) Reason:

20.0 Milligram Daily

3atch: 3tarted: 27/07/1997 3topped: 29/07/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient previously reacted in a similar way to sertraline.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: 121178	Seq: 1		Gen	der: F	
Reported: 29/09/1997				ight:	
ospitalisation:				Age : 84Y	
Onset Date:				OB:	
Outcome: Unknown			Causa	ality: Causality possible	
action Detai				1	
Preferred Term	Severity	Repor	t Description	Treatment	
onstipation					
nistipation					
dicina Dataila.					
edicine Details: DLVON (Suspected)		Reas			
	0.0	(eas			
Tablet 0.0			Oral		
3atch:	Started:		Stopped:		
boratory Investigatio	ns:				
Date Type	Range Date Tes	sted Result		Details	
7.	<u> </u>				
Iditional Information:					
t Run 01/08/200 02:08PN	Database: pusime	A	DRS004	Page 256 of 336	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 121479
 Seq:
 1
 Gender:
 F

 Reported:
 10/10/1997
 Weight:

Hospitalisation: Age:
Onset Date: 26/08/1997
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

			=
Preferred Term	Severity	Report Description	Treatment
Neutropenia			Withdraw mianserin.
Pneumonia			

Medicine Details:

LITHIUM CARBONATE (Other drug) Reason: Depression

0.0

3atch: 3tarted: 01/06/1997 3topped:

SALBUTAMOL (Other drug) Reason: Bronchitis,unqualified

Inhalation 4.0 Dose Unspecified Daily Inhalation

3atch: Started: Stopped:

IPRATROPIUM BROMIDE (Other drug) Reason: Bronchitis,unqualified

Inhalation 4.0 Dose Unspecified Daily Inhalation

3atch: Started: Stopped:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

0.0

3atch: 3tarted: 01/06/1997 3topped: 28/08/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Onset Date: Outcome: Recovered eaction Detai Preferred Term Severity enthralgia Medicine Details: PREMARIN (Other drug)	Rea		Gender: F Weight: 67.00 Age: 67Y DOB: ausality: Causality probab Treatment
Reported: 24/11/1997 ospitalisation: Onset Date: Outcome: Recovered eaction Detai Preferred Term Severity orthralgia Medicine Details: PREMARIN (Other drug)	Rea	C	Weight: 67.00 Age: 67Y DOB: ausality: Causality probab
Onset Date: Outcome: Recovered eaction Detai Preferred Term Severity Arthralgia Medicine Details: PREMARIN (Other drug)	Rea		Age: 67Y DOB: ausality: Causality probab
Onset Date: Outcome: Recovered Paction Detai Preferred Term Severity Arthralgia Medicine Details: PREMARIN (Other drug)	Rea		DOB: ausality: Causality probab
Outcome: Recovered Paction Detai Preferred Term Severity Arthralgia Medicine Details: PREMARIN (Other drug)	Rea		ausality: Causality probab
Preferred Term Severity Arthralgia Medicine Details: PREMARIN (Other drug)	Rea		
Preferred Term Severity Arthralgia Medicine Details: PREMARIN (Other drug)	Rea	ort Description	Treatment
Medicine Details: PREMARIN (Other drug)	Rea	•	
Medicine Details: PREMARIN (Other drug)			
PREMARIN (Other drug)			
PREMARIN (Other drug)			
PREMARIN (Other drug)			
PREMARIN (Other drug)			
PREMARIN (Other drug)			
PREMARIN (Other drug)			
PREMARIN (Other drug)			
PREMARIN (Other drug)			
PREMARIN (Other drug)			
PREMARIN (Other drug)			
		son: Menopausal sy	vmptoms
0.	.3 Milligram	Daily	, ,
3atch: Started:	L TERM	-	
PROVERA (Other drug)	Rea	son: Menopausal sy	ymptoms
5.	.0 Milligram	Daily	
3atch: Started:	L TERM	∕l 3topped:	
TOLVON (Suspected)		son:	
0.	.0		
3atch: Started:		Stopped:	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 125024 Seq: 1 Gender: F

Reported: 16/02/1998 Weight:
Hospitalisation: Age: 61Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

104011011 20141		-	-
Preferred Term	Severity	Report Description	Treatment
Convulsion		Full body spasms - patient had no control.	
Somnolence		Very drowsy.	Patient stopped taking lumin.

Medicine Details:

 LUMIN (Suspected)
 Reason:
 Specific disorders of sleep

 Tablet
 10.0 Milligram
 1 time
 Oral

 3atch:
 3tarted:
 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has no history of allergies. patient is reluctant to see her doctor.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 125034 Seq: 1 Gender: F

Reported: 16/02/1998 **Weight:** 51.00

Hospitalisation: Age:
Onset Date: 19/11/1997
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Neutropenia			
Pancytopenia			Cessation of mianserin

Medicine Details:

RISPERIDONE (Other drug)		Reason:	Manic depressive psycho	, depre
Oral application	1.0 Millig	gram Daily	Oral	
3atch:	Started:		Stopped:	6W
MOCLOBEMIDE (Other drug)		Reason:	Depression	
Tablet	900.0 Millig	gram Daily	Oral	
3atch:	Started:		Stopped:	CONTIN
TRIMETHOPRIM (Other drug)		Reason:	Othr diseases of urinary t	ract
Tablet	300.0 Millig	gram Daily	Oral	
3atch:				
Salcii.	Started:		Stopped:	4D
PARACETAMOL (Other drug)	Started:	Reason:	Stopped: Pyrexia of unknown origin	
	started: 4.0 Gran		Pyrexia of unknown origin	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Case Number:	125034	Seq: 1				Gender:	F	
Reported:	16/02/1998					Weight:	51.00	
Hospitalisation:						Age:		
Onset Date:	19/11/1997					DOB:		
Outcome:	Recovered					Causality:	Causality proba	able
Reaction Detai								
Medicine Deta								
LUMIN (Suspected	1)			Reason:	Depression			
Tablet			Milligram	Daily		Oral	000	
3atch:		Started:			Stopped		26D	
Laboratory In	vestigations:							
	and the second s							
Additional Inf	ormation:							
oport Pup 01/08/200	0.02:08PN Datah	ases: pusimo		ADDS00	. 4		Dogg 201	of 220

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 126143 Seq: 1 Gender: M

Reported: 25/03/1998 Weight: 70.00 Hospitalisation: Age: 76Y

Onset Date: 20/02/1998

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic			

Medicine Details:

TRITACE (Other drug)		Reason:	Congestive heart failure
Tablet	2.5 Milligram	Daily	Oral
3atch:	Started: 01/11/1994		Stopped:
BETAMIN (Other drug)		Reason:	Congestive heart failure
Tablet	200.0 Milligram	Daily	Oral
Batch:	3tarted: 01/01/1990		Stopped:
CARDIPRIN 100 (Other drug)		Reason:	Acute myocard infarc,no hypert
CARDIPRIN 100 (Other drug) Tablet	100.0 Milligram	Reason: Daily	Acute myocard infarc,no hypert Oral
, , , , , , , , , , , , , , , , , , , ,	100.0 Milligram Started: 01/01/1981		, ,,
Tablet	· ·		Oral
Tablet 3atch:	· ·	Daily	Oral Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		20/02/1998	145	
	ALT = SGPT		16/03/1998	13	
	AST = SGOT		20/02/1998	122	
	AST = SGOT		16/03/1998	21	
	Bilirubin		20/02/1998	113	
	Bilirubin		16/03/1998	13	
	GGT = SGGT =		20/02/1998	521	

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 accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 126143 Seq: 1 Gender: M

Reported: 25/03/1998 Weight: 70.00 Hospitalisation: Age: 76Y

Onset Date: 20/02/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

ORUVAIL SR (Suspected)
Capsule
200.0 Milligram
Daily
Oral

3atch: \$tarted: 14/07/1997
\$topped: 25/02/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =		16/03/1998	95	
	SAP = ALP		20/02/1998	626	
	SAP = ALP		16/03/1998	168	

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 accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 126760
 Seq: 1
 Gender:
 F

 Reported:
 17/04/1998
 Weight:

Hospitalisation: Admitted to hospital Age: 80

Onset Date: 05/03/1998 DOB: 25/07/1917

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

100000000000000000000000000000000000000		-	-
Preferred Term	Severity	Report Description	Treatment
Sepsis		Speudomonas septicaemia	
Agranulocytosis			Treatment: neupogen ceased

Medicine Details:

Medicine Details.					
NATRILIX (Other drug)	Reason:				
	2.5 Milligram	Daily			
3atch:	Started:	Stopped:			
TOLVON (Suspected)		leason:			
	30.0 Milligram	Daily			
3atch:	Started: 01/09/1997	Stopped : 05/03/1998			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Lymphocytes		09/03/1998	0.4	
	Neutrophils		09/03/1998	0.00	
	Other data				Bone marrow aspirate suggestive of idiosyncratic drug reaction.

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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

	Re	oa	rt	D	eta	i	ı
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 Case Number:
 127129
 Seq:
 1
 Gender:
 F

 Reported:
 04/05/1998
 Weight:

Hospitalisation: Age: 56Y
Onset Date: 08/04/1998
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

reaction Detai			
Preferred Term	Severity	Report Description	Treatment
Abscess		Dental and sinus septic abscesses.	
Hepatic function abnormal			
Lymphocytosis			
Neutropenia			

Medicine Details:

<u>Medicine Details.</u>			
DIAZEPAM (Other drug)		Reason:	
Oral application	6.0 Milligram	Daily	Oral
3atch:	Started: 25/02/1998	Stopped:	
MIANSERIN HYDROCHLORIDE (S	uspected)	Reason: Anxiety neuro	osis
Tablet	60.0 Milligram	Daily	Oral
3atch:	Started: 27/02/1998	Stopped:	08/04/1998

Laboratory Investigations:

					
Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		08/04/1998	0.11	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 127154
 Seq:
 1
 Gender:
 M

 Reported:
 05/05/1998
 Weight:
 70.00

 Hospitalisation:
 Age:
 81Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Headache	Severe	Severe pain over I eyebrow & into I temple	Tolvon ceased
Dizziness	Severe		

Medicine Details:

NORMISON (Other drug)		Reason:	Specific disorde	ers of sleep	
	10.0 Milligram	Daily			
Зatch:	3tarted: 03/03/1998		Stopped:		
POLY-TEARS (Other drug)		Reason:			
	5.0 Dose Uns	specified Daily			
3atch:	Started: 01/09/1997		Stopped:		
SODIUM BICARBONATE (Other drug)		Reason:			
SODIUM BICARBONATE (Other drug)	3.0 Gram	Reason: Daily			
SODIUM BICARBONATE (Other drug) 3atch:	3.0 Gram		Stopped:		
, ,					
3atch:		Daily	Stopped: Depression		

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.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 127165 Seq: 1 Gender: F

Reported: 05/05/1998 Weight: 51.00 Hospitalisation: Age: 66Y

Onset Date: 19/11/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Pancytopenia			

Medicine Details:

RISPERDAL (Other drug) Reason: Depression

1.0 Milligram Daily

3atch: 3tarted: 23/10/1997 **3topped:** 08/12/1997

AURORIX (Other drug) Reason: Depression

900.0 Milligram Daily

3atch: 3tarted: 27/10/1997 3topped:

DISPRIN (Other drug) Reason: Transient cereb isch no hypert

150.0 Milligram Daily

 3atch:
 3tarted:
 14/11/1997
 3topped:
 08/12/1997

PANADOL (Other drug) Reason: Pyrexia of unknown origin

4.0 Gram Daily

3atch: 3tarted: 17/11/1997 3topped: 27/11/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Case Number:	127165	Seq: 1			Gender:	F	
Reported:	05/05/1998				Weight:	51.00	
Hospitalisation:					Age:	66Y	
Onset Date:	19/11/1997				DOB:		
Outcome:	Recovered			Ca	ausality:	Causality possi	ible
Reaction Detai	İ						
Medicine Det	ails:						
LUMIN (Suspected			Reason:	Depression			
		40.0 Milligram	Daily				
3atch:		Started: 21/10/1997		Stopped:	19/11/1997		
ALPRIM (Suspecte	ed)		Reason:	Othr diseases	of urinary tra	ct	
		300.0 Milligram	Daily				
3atch:		Started: 16/11/1997		Stopped:	19/11/1997		
Laboratory In	vestigations:						
-	_						
Additional Inf	formation:						
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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 128287
 Seq:
 1
 Gender:
 M

 Reported:
 11/06/1998
 Weight:
 135.00

 Hospitalisation:
 Age:
 47Y

Onset Date: 24/05/1998 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dysgeusia		Bad taste in mouth	
Flatulence		Bloated	
Hypertension		Bp 160/110	
Depersonalisation		Feels spaced out, coldness around heart	
Myalgia		Leg pains	
Dizziness			
Fatigue			
Headache			
Nausea			
Nightmare			

Medicine Details:

PANADEINE FORTE (Other drug)			Reaso	n:	Headache	
Tablet	4.0	Dose Unsp	ecified	Daily		Oral
Зatch:	Started:	I	TERM		Stopped:	
AROPAX (Other drug)			₹easc	n:		
Tablet	20.0	Milligram		Daily		Oral
Зatch:	Started: 01	/06/1997			Stopped:	
INDERAL (Other drug)			Reaso	n:		
Tablet	80.0	Milligram		Daily		Oral
Зatch:	Started:	I	TERM		Stopped:	
LUMIN (Suspected)			Reaso	n:	Depression	
Tablet	20.0	Milligram		Daily		Oral
3atch:	Started: 23	/05/1998			Stopped:	25/05/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 128981
 Seq: 1
 Gender:
 F

 Reported:
 08/07/1998
 Weight:

Hospitalisation:
Onset Date: 23/06/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Ceased medication

Medicine Details:

RANITIDINE (Suspected) Reason: Ulcer of stomach w/o ment perf

300.0 Milligram Daily

3atch: 3tarted: 09/02/1998 **3topped:** 23/06/1998

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

30.0 Milligram Daily

3atch: 3tarted: 01/04/1998 3topped: 25/06/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	6-31	23/06/1998	94	
	GGT = SGGT =	10-35	23/06/1998	465	
	SAP = ALP	35-120	23/06/1998	622	

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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 129311 Seq: 1 Gender: F

Reported: 20/07/1998 Weight: 70.00 Hospitalisation: Age: 47Y

Onset Date: 31/10/1997 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Menstrual disorder			

Medicine Details:

TOLVON (Suspected) Reason: Depression

60.0 Milligram Daily

3atch: 3tarted: 01/04/1997 3topped: 28/10/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage 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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 130166 Seq: 1 Gender: M

Reported: 11/08/1998 Weight: 90.00 Hospitalisation: Age: 57Y

Onset Date: 25/05/1998 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

		-	-
Preferred Term	Severity	Report Description	Treatment
Myalgia		Myalgia of biceps and forearms	Ceased tolvon
Arthralgia		Pain & stiffness in small joints of hands &	

Medicine Details:

 TOLVON (Suspected)
 Reason:
 Depression

 Tablet
 10.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 11/05/1998
 \$topped:
 22/07/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Gradual onset of pain and stiffness in small joints of hands and knees with myalgia of biceps and forearms, two weeks after commencing tolvon 10 mg per day. all relevent pathology normal. arthralgia and myalgia resolved within 1 week of cessation of tolvon. no history or family history of arthritis.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 130555 Seq: 1 Gender: F
Reported: 28/08/1998 Weight:
Hospitalisation: Age: 57Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Fatigue			
Hepatic function abnormal			
Myalgia			
Neutropenia			Both amoxil and mianserin
Pain			
Pharyngitis			
Pyrexia			

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Oral application	2.0 Milligram	Daily	Oral
3atch:	Started:	Stopped	:
PROGYNOVA (Other drug)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Зatch:	Started:	Stopped	:
PROVERA (Other drug)	Reason:		
	10.0 Milligram	Daily	
3atch:	3tarted:	Stopped	:
3atch: AMOXIL (Suspected)	Started:		inf,mult,unsp stes
	Started:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	(<40)	15/04/1998	293	
	ALT = SGPT	(<40)	16/04/1998	139	
	ALT = SGPT	(<40)	20/04/1998	85	
	ALT = SGPT	(<40)	20/04/1998	67	
	ALT = SGPT	(<40)	17/04/1998	92	
	AST = SGOT		15/04/1998	139	
	AST = SGOT		17/04/1998	-	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 130555
 Seq: 1
 Gender:
 F

 Reported:
 28/08/1998
 Weight:

Hospitalisation:
Onset Date:
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected)

Tablet

40.0 Milligram

Daily

Oral

3atch:

\$topped: 12/04/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT		20/04/1998	59	
	AST = SGOT		16/04/1998	-	
	GGT = SGGT =		15/04/1998	680	
	GGT = SGGT =		16/04/1998	-	
	GGT = SGGT =		17/04/1998	-	
	GGT = SGGT =		20/04/1998	-	
	LDH		15/04/1998	153	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

 Report Detail

 Case Number:
 130555
 Seq:
 1
 Gender:
 F

 Reported:
 28/08/1998
 Weight:

Hospitalisation: Age: 57Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

DIAZEPAM (Other drug)		Reason:		
Oral application	2.0 Milli	igram Daily	,	Oral
Зatch:	Started:		Stopped:	
PROGYNOVA (Other drug)		Reason:		
Tablet	2.0 Milli	igram Daily	,	Oral
3atch:	Started:		Stopped:	
PROVERA (Other drug)		Reason:		
	10.0 Milli	igram Daily	,	
3atch:	Started:		Stopped:	
AMOXIL (Suspected)		Reason:	Ac upr resp ir	ıf,mult,unsp stes
Tablet	0.0			Oral
3atch:	Started:		Stopped:	12/04/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	LDH		16/04/1998	-	
	LDH		17/04/1998	-	
	LDH		20/04/1998	-	
	SAP = ALP		15/04/1998	880	
	SAP = ALP		16/04/1998	641	
	SAP = ALP		17/04/1998	584	
	SAP = ALP		20/04/1998	607	



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number:	130555	Seq:	1				Gender:	F	
Reported:	28/08/1998						Weight:		
Hospitalisation:							Age:	57Y	
Onset Date:							DOB:		
Outcome:	Not yet recovered	I					Causality:	Causality possible	
Reaction Detai									
Medicine Deta	aile:								
	OCHLORIDE (Suspec	ted)			Reason:	Depression			
Tablet			40.0	Milligram	Daily	·	Oral		
3atch:		€ta	rted:	-	·	Stopped:		3	
									.
I oborotomy In	vootigationa								
Laboratory In	vestigations.								
A .1.1141 1.1.6									
Additional Inf	ormation:								



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

	Re	oa	rt	D	eta	i	ı
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Case Number: 134438 Seq: 1 Gender: M

Reported: 18/12/1998 Weight: 73.00 Hospitalisation: Age: 38Y

Onset Date: 03/12/1998 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

todotion botal		-	=
Preferred Term	Severity	Report Description	Treatment
Nightmare		Severe lucid nightmares	
Insomnia			

Medicine Details:

CIPRAMIL (Other drug) Reason: Depression

40.0 Milligram Daily

3atch: 3tarted: 3topped: 27/11/1998

TOLVON (Suspected) Reason: Depression

30.0 Milligram Daily

3atch: 3tarted: 03/12/1998 3topped: 16/12/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 137968 Seq: 1 Gender: M

Reported: 30/03/1999 Weight: 94.00 Hospitalisation: Age: 19Y

Onset Date: 12/03/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agitation		Panic secondary to symptoms	
Headache	Severe	Sensation of head rush then severe	Penicillin 8mg prn (up to 32mg/day) for 4 days then 16mg/day for 2-3 days + codeine phosphate imi when pethidine failed imi
Hypertonia			
Hyperventilation			
Paraesthesia			

Medicine Details:

ANAFRANIL (Suspected)		Reason:	
	50.0 Milligram	1 time	
3atch:	Started: 11/03/1999	Stopped:	12/03/1999
AROPAX (Suspected)		Reason:	
Tablet	20.0 Milligram	As necessary	Oral
3atch:	Started: 25/02/1999	Stopped:	04/03/1999
LUMIN (Suspected)		Reason: Specific disor	ders of sleep
Tablet	40.0 Milligram	Daily	Oral
3atch:	Started: 06/11/1998	Stopped:	12/03/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reactions not reversed by rebreathing. suspected drugs given for severe ptsd. see original report for details of other drugs - neulactil, mogadon, normison.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 141446 Seq: 1 Gender: M
Reported: 12/07/1999 Weight:

Reported: 12/07/1999 Weight:
Hospitalisation: Age: 74

Onset Date: 21/04/1999 **DOB**: 11/07/1924

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Jaundice			Ceased mianserin

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

Tablet 30.0 Milligram Daily Oral

3atch: 3tarted: 14/04/1999 3topped: 18/04/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		12/04/1999	65	
	ALT = SGPT		22/04/1999	282	
	AST = SGOT		12/04/1999	64	
	AST = SGOT		22/04/1999	291	
	Bilirubin		12/04/1999	26	
	Bilirubin		22/04/1999	185	
	Bilirubin		22/04/1999	165	

Additional Information:

Please see original report for details of other drugs - flixotide, ventolin, diazepam, ms contin, maxolon, ordine, nilstat.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 141446
 Seq: 1
 Gender: M

 Reported:
 12/07/1999
 Weight:

Hospitalisation: Age: 74

Onset Date: 21/04/1999 **DOB**: 11/07/1924

Outcome: Unknown Causality: Causality possible

Reaction Detai

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected)

Tablet

30.0 Milligram

Daily

Oral

3atch: 3tarted: 14/04/1999 3topped: 18/04/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT = GGT = SGGT = Other data		12/04/1999 22/04/1999	108 624	21/04/1999 usua - no mets seen in liver, dilated ducts.

Additional Information:

Please see original report for details of other drugs - flixotide, ventolin, diazepam, ms contin, maxolon, ordine, nilstat.

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Report Detail

Case Number: 142546

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: F

Reporto Iospitalisatio Onset Da		9				Weight: Age: DOB:	
	ne: Not yet re	covered			C	ausality: Causality po	ssible
eaction De							
	erred Term	Sev	erity	Repor	t Description	Treatme	
lveolitis alle						Ceased mianserin	
ulmonary fit	010313	l					
Medicine E	Details:						
	YDROCHLORIDE	(Suspected)		Reas	on:		
			100.0 Millig		Daily		
3atch:		3ta	arted:	L TERM	Stopped:		
aboratory	/ Investigat	ions:					
Date	Туре	Range	Date Tested	Result		Details	
Additional	Informatio	n:					
ort Run 01/08	3/200 02:08PN	Database: pi	usime	Δ	DRS004	Page 29	21 of 226
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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 142712 Seq: 1 Gender: F

Reported: 17/08/1999 Weight: 45.00 Hospitalisation: Age: 70Y

Onset Date: 26/07/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			
Neutropenia			

Medicine Details:

HALOPERIDOL (Other drug) Reason: Unspecified psychosis

2.0 Milligram Daily

3atch: 3tarted: 31/05/1999 3topped:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

60.0 Milligram Daily

3atch: 3tarted: 03/06/1999 3topped: 26/07/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details	
	Haematology				Wc = 1.7; neutrophils = 0.08	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 142848
 Seq: 1
 Gender: M

 Reported:
 23/08/1999
 Weight:

Hospitalisation: Age: 58Y
Onset Date: 31/07/1999
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Dotai		<u> -</u>	
Preferred Term	Severity	Report Description	Treatment
Libido decreased		Patient experienced loss of libido.	
Weight increased		Patient experienced weight gain.	

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason:

Tablet 100.0 Milligram Daily Oral

3atch: 3tarted: 26/03/1997 3topped: 13/12/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 143637 Seq: 1 Gender: F

Reported: 13/09/1999 Weight: 56.00 Hospitalisation: Age: 83Y

Onset Date: 10/08/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

Micarchic Betaris.					
LUMIN (Suspected)		Reason:	Depression		
	10.0 Milligram	Daily			
3atch:	Started: 09/07/1999		Stopped:	23/07/1999	
LUMIN (Suspected)		Reason:	Depression		
	20.0 Milligram	Daily			
3atch:	Started : 23/07/1999		Stopped:	09/08/1999	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		10/08/1999	796	
	AST = SGOT		10/08/1999	453	
	GGT = SGGT =		10/08/1999	187	
	Low density		10/08/1999	450	
	SAP = ALP		10/08/1999	265	

Additional Information:

See original report for other drug details: ranitidine & thyroxine. patient has had no previous exposure to mianserin.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 143997 Seq: 1 Gender: M

 Reported:
 07/09/1999
 Weight:
 81.00

 Hospitalisation:
 Age:
 53Y

Onset Date: 31/08/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Paraesthesia			Prepulsid and pravachol therapy ceased.
Neuropathy			

Medicine Details:

PREPULSID (Suspected)	Reason:						
Tablet	10.0 Milligram	As necess	sary Oral				
3atch:	Started: 01/10/1998		Stopped: 28/08/	1999			
TOLVON (Suspected)		Reason: Dep	pression				
Tablet	50.0 Milligram	Daily	Oral				
3atch:	Started: 01/01/1979		Stopped:	CONTIN			
PRAVACHOL (Suspected)		Reason: Oth	nr&unspec metaboli	ic diseases			
Tablet	20.0 Milligram	Daily	Oral				
3atch:	Started: 01/01/1997		3topped: 28/08/	1999			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drug. coloxyl and senna. patient is currently being investigated for neuropathy and other possible causes. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop 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 month. the dosage start date is not 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 month.

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Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: 145880 Reported: 12/11/1999 Iospitalisation: Onset Date: Outcome: Unknown	Seq : 1	Gender: U Weight: Age: 72Y DOB: Causality: Causality possible		
eaction Detai Preferred Term	Severity	Report Description	Treatment	
Photosensitivity reaction		otoxic reaction - rash	Trodunone	
Madiaina Datailas				
Medicine Details: TOLVON (Suspected)		Reason:		
, , ,	0.0			
3atch:	Started:	Stopped:		
_aboratory Investigatio	ons:			
Date Type	Range Date Tested	Result	Details	
Additional Information	ı:			
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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 147656 Seq: 1 Gender: F

Reported: 05/01/2000 Weight: 50.00 Hospitalisation: Age: 77Y

Onset Date: 17/09/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			
Hepatic function abnormal			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

 Oral application
 80.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 16/08/1999
 3topped:
 17/09/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		17/09/1999	0.3	
	White blood cells		17/09/1999	1.6	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 150591
 Seq: 1
 Gender:
 F

 Reported:
 21/03/2000
 Weight:

Hospitalisation: Age: 66Y

Onset Date: 07/03/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Dotal		_	
Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular Pruritus		Papul.sev rash including palms of	

Medicine Details:

TOLVON (Suspected) Reason: Depression
Tablet 40.0 Milligram Daily Oral

3atch: 3tarted: 04/02/2000 3topped: 08/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No previous drug allergies.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 151030 Seq: 1 Gender: F

Reported: 28/03/2000 Weight: 55.00 Hospitalisation: Admitted to hospital Age: 84

Onset Date: 21/12/1999

Outcome: Unknown

DOB: 12/09/1915

Causality: Causality certain

Reaction Detai

100000000000000000000000000000000000000			-
Preferred Term	Severity	Report Description	Treatment
Angina pectoris			Digoxin with held.
Bradycardia			

Medicine Details:

Medicine Details.					
DILTIAZEM HYDROCHLORIDE (Interaction	on)		Reason:		
	240.0	Milligram	Daily		
Заtch:	Started:			Stopped:	
DIGOXIN (Interaction)			Reason:		
	125.0	Microgram	Daily		
Batch:	Started:			Stopped:	21/02/2000
MIANSERIN HYDROCHLORIDE (Interacti	on)		Reason:		
	20.0	Milligram	Daily		
Зatch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking aspirin, calcitriol and famotidine.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 151288 Seq: 1 Gender: M

Reported: 06/04/2000 Weight:
Hospitalisation: Age: 74Y

Onset Date: 20/01/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Leukopenia			
Neutropenia			

Medicine Details:

TOLVON (Suspected)		Reason:	Depression	
Tablet	160.0 Milligram	Daily		Oral
Зatch:	Started: 31/12/1999		Stopped:	16/02/2000
MELLERIL (Suspected)		Reason:	Otr spec symp	psychopathol nec
MELLERIL (Suspected) Tablet	40.0 Milligram	Reason: Daily	Otr spec symp	psychopathol nec Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		29/12/1999	4.2	
	Neutrophils		17/02/2000	0.7	
	White blood cells		29/12/1999	5.2	
	White blood cells		17/02/2000	1.7	

Additional Information:

Patint was also taking coversyl, lipitor. allergic to aspirin.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 151780
 Seq:
 1
 Gender:
 F

 Reported:
 10/04/2000
 Weight:

Hospitalisation: Age: 25Y
Onset Date: 10/08/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

104041011 20441			
Preferred Term	Severity	Report Description	Treatment
Speech disorder		Slurred speech	
Coordination abnormal			
Polydipsia			
Polyuria			

Medicine Details:

QUILONUM SR (Suspected) Reason:

0.0

3atch: 3tarted: 27/07/1999 3topped: 12/09/1999

MIANSERIN HYDROCHLORIDE (Suspected) Reason:

20.0 Milligram Daily

3atch: 3tarted: 03/08/1999 3topped: 12/09/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Serum drug level		09/08/1999	0.5	Quilonum level
	Serum drug level		11/08/1999	0.7	Quilonum level
	Serum drug level		14/08/1999	1.7	Quilonum level

Additional Information:

Patient also taking zyprexa, efexor.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 151911 Seq: 1 Gender: F
Reported: 20/04/2000 Weight:
Hospitalisation: Age: 50

Onset Date: DOB: 13/01/1950

Outcome: Recovered Causality: Causality possible

Reaction Detai

Addion Dotal							
Preferred Term	Severity	Report Description	Treatment				
Fatigue							
Hepatic function abnormal							
Jaundice							
Nausea							
Pruritus							

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason:

0.0

3atch: 3tarted: 22/12/1999 3topped: 27/01/2000

Laboratory Investigations:

	. <u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		24/01/2000	287 U/L	
	ALT = SGPT		08/06/2000	88	
	AST = SGOT		24/01/2000	114 U/L	
	AST = SGOT		08/06/2000	41	
	Bilirubin		24/01/2000	111 UMOL/L	
	Bilirubin		08/06/2000	21	
	GGT = SGGT =		24/01/2000	746 U/L	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 151911
 Seq: 1
 Gender:
 F

 Reported:
 20/04/2000
 Weight:

Hospitalisation: Age: 50

Onset Date: DOB: 13/01/1950

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason:

0.0

3atch: 3tarted: 22/12/1999 3topped: 27/01/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT = Histology	- 3	08/06/2000	249	Liver histology was reported as indicating bridging fibrosis (between portal tracts) with lymphocytic (occasional plasma cell) infiltration of portal tracts and mild piecemeal necrosis. there was no steatosis nor mallorv's hvaline Negative serology for cmv, human parvovirus, negative hbsag, hbsab and anti- hcv. positive total hepatitis a antibody consistent
	SAP = ALP		24/01/2000	739 U/L	with previous infection, positive ebv igg (neg ebv igm) consistent with previous infection



Report Detail

Case Number: 151911

Reported: 20/04/2000

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: F

Reported:	20/04/2000			Weight:		
ospitalisation:				Age:	50	
Onset Date:					13/01/1950	
Outcome:	Recovered				Causality poss	ible
action Detai				•		
edicine Det	aile					
	alis. ROCHLORIDE (Suspe	ected)	Reason:			
MANOEKIN III DI	CONLONIDE (Ouspe	0.0	(ed30ii.			
3atch:		3tarted: 22/12/19	000	Stopped: 27/01/2000	1	
Jaicii.		Starteu. ZZ/1Z/18	799	3topped. 27/01/2000	,	
aboratory In	vestigations:					
Date		nge Date Tested	Result	Deta	ils	
SAP :	= ALP	08/06/2000	235			
SAP :	= ALP	08/06/2000	235			
al alisti	.					
dditional In	formation:					
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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 152401 Seq: 1 Gender: M

Reported: 08/05/2000 **Weight:** 130.00

Hospitalisation: Age: 48Y
Onset Date: 23/04/2000 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Somnolence	Severe	Severe sedation lasting 3 days.	

Medicine Details:

TOLVON (Suspected) Reason: Depression

 Tablet
 20.0 Milligram
 1 time
 Oral

 3atch:
 3tarted:
 23/04/2000
 3topped:
 24/04/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Various adverse reactions to asociated antidepressants.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 156288
 Seq: 1
 Gender:
 F

 Reported:
 14/08/2000
 Weight:
 50.00

 Hospitalisation:
 Age: 71Y

Onset Date: 12/07/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
Purpura		Ecchymoses over legs and feet.	
Face oedema		Sudden onset of swelling of face and body.	

Medicine Details:

MIANSERIN HYDROCHLORIDE (Sus	spected)	Reason:	Depression		
	10.0 Milligram	Daily			
3atch:	Started: 11/07/2000		Stopped:	12/07/2000	
HALOPERIDOL (Suspected)		Reason:	Depression		
	0.5 Milligram	Daily			
3atch:	Started: 11/07/2000		Stopped:	12/07/2000	
IMOVANE (Suspected)		Reason:	Specific disor	ders of sleep	
	3.7 Milligram	Daily			
3atch:	Started: 11/07/2000		Stopped:	12/07/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking fentanyl patch, maxolon, coloxyl with senna and losec. patient suffers from multiple myeloma / dementia.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 156511 Seq: 1 Gender: M
Reported: 18/08/2000 Weight:

 Hospitalisation:
 Age: 58

 Onset Date: 31/10/1998
 DOB: 22/02/1940

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Neuropathy peripheral		Both feet and legs.	

Medicine Details:

Modicino Botano.				
TOLVON (Suspected)	:	Reason:	Depression	
Tablet	80.0 Milligram	Daily		Oral
3atch:	Started: 11/08/1994		Stopped:	18/08/2000
ATORVASTATIN (Suspected)		Reason:	Othr&unspec	metabolic diseases
	1.0 Dose Unspeci	fied Daily		
3atch:	Started: 22/07/1998		Stopped:	
CARTIA (Suspected)		Reason:		
Tablet	100.0 Milligram	Daily		Oral
3atch:	Started: 05/09/1998		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 158451
 Seq: 1
 Gender:
 F

 Reported:
 09/10/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 81Y

Onset Date: 25/07/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

		-	
Preferred Term	Severity	Report Description	Treatment
Syncope		Fall.	
Dizziness			Admitted to hospital.

Medicine Details:

TOLVON (Suspected) Reason: Depression

20.0 Milligram Daily

3atch: 3tarted: 25/07/2000 **3topped:** 25/07/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reactions occurred 40-50 minutes after tolvon taken. patient also taking irbesartan and thyroxine. sequelae: fractured ankle as a result. treated with pain killers prn and plaster on ankle.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 159560 Seq: 1 Gender: M

Reported: 27/11/2000 Weight: 118.00 pitalisation: Age: 37Y

Hospitalisation: Age: 3
Onset Date: 25/12/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Stiffness/rigidity.	
Agitation			
Confusional state			
Hypertension			Benztropine , midazolam, haloperidol, clonazepam, phenergan. ceased timentin, mianserin, tramadol
Tachycardia			miangenn framanni
Tremor			

Medicine Details:

Medicine Details.				
TRAMADOL HYDROCHLORIDE (Suspecte	d)	Reason:		
	20.0 Millig	gram As nec	essary	
Зatch:	Started: 07/12/19	99	Stopped:	25/12/1999
MIANSERIN HYDROCHLORIDE (Suspecte	d)	Reason:		
Tablet	50.0 Millig	ıram Daily		Oral
Зatch:	Started:	L TERM	Stopped:	26/12/1999
METOCLOPRAMIDE HYDROCHLORIDE (S	uspected)	Reason:		
	40.0 Millig	ıram Daily		
Зatch:	3tarted: 01/10/19	99	Stopped:	26/12/1999

Laboratory Investigations:

	,	The confidence of the confiden							
Date	Туре	Range	Date Tested	Result	Details				
	Electroencephalog				Eeg showed status epilepticus (non convulsive).				

Additional Information:

Patient was also taking paracetamol, heparin, nystatin, vancomycin, timentin, droperidol, ranitidine, fefol, zinc, loperamide, mulvitamin, vitamin c, magnesium, ms contin. patient had reaction to stemetil->tardive dyskinesia. 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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Rep	00	rt	D	eta	il
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 Case Number:
 159973
 Seq: 1
 Gender: M

 Reported:
 14/12/2000
 Weight:
 80.00

Hospitalisation: Age: 41

Onset Date: 24/11/2000 **DOB**: 11/02/1959

Outcome: Recovered Causality: Causality probable

Reaction Detai

10404011 20441			
Preferred Term	Severity	Report Description	Treatment
Nausea			Required a visit to doctor. date of recovery 04/12/00. therapy

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

20.0 Milligram Daily

3atch: 3tarted: 24/11/2000 3topped: 27/11/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 160012 Seq: 1 Gender: M

Reported: 18/12/2000 Weight: 100.00 Hospitalisation: Age: 53

Onset Date: DOB: 05/04/1947

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Apnoea		Worsening of sleep apnoea	Ceased mianserin.

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Specific disorders of sleep

 Tablet
 10.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 18/08/2000
 3topped:
 28/11/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking cipramil, losec. patient drinks 6-8 mid strength stubbies beer nightly for years-wont reduce. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 162027 Seq: 1 Gender: F

Reported: 28/02/2001 Weight: 70.00 Hospitalisation: Age: 76

Onset Date: 31/01/2001 DOB: 08/12/1924

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Botal								
Preferred Term	Severity	Report Description	Treatment					
Fatigue								
Jaundice								
Nausea			Withdrawn tolvon and celebrex therapy. required a visit to					
Pruritus			doctor					

Medicine Details:

TOLVON (Suspected) Reason: Depression

0.0

3atch: 3tarted: 02/01/2001 3topped: 02/02/2001

CELEBREX (Suspected) Reason: Unspecified arthritis

0.0

3atch: Started: 01/07/2000 Stopped: 02/02/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Bilirubin 85, alt 600, alp 226.
	Other data				Viral and liver desease test negative. biopsy not done.

Additional Information:

Patient also taking - normison and multivitamins. - 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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Rep	00	rt	D	eta	il
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 Case Number:
 163160
 Seq: 1
 Gender: M

 Reported:
 30/03/2001
 Weight:
 70.00

 Hospitalisation:
 Age: 41

Onset Date: 21/03/2001 **DOB:** 10/12/1959

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Cachon Detai			
Preferred Term	Severity	Report Description	Treatment
Agitation			Largactil. required a visit to
Insomnia			
Neurosis			

	ed					

MIANSERIN HYDROCHLORIDE (Suspected)

0.0

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Prozac ceased immediately prior to commencing mianserin.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 169083 Seq: 1 Gender: U

Reported: 15/10/2001 Weight: 76.00 Hospitalisation: Age: 82

Onset Date: 28/09/2001 DOB: 15/09/1919

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Flatulence			
Nausea			

Medicine Details:

Medicine Details.					
LAMISIL (Suspected)	Reason:				
	250.0 Milligram	Daily			
3atch:	Started:	Stopped:	11D		
TOLVON (Suspected)		Reason: Dermatophytosis			
	110.0 Milligram	Daily			
3atch:	Started: 01/09/2001	Stopped:	11D		

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 tolvon is not necessarily accurate but indicates tolvon was started sometime in the month.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 169606
 Seq: 1
 Gender:
 F

 Reported:
 02/11/2001
 Weight:

Hospitalisation: Admitted to hospital **Age**: 80

Onset Date: 23/10/2001 **DOB**: 17/10/1921

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Patient hospitalised. given csf, antibiotics. date of recovery
Sepsis			DE/10/01

Medicine Details:

ALLOPURINOL (Other drug)		Reason:	Gout		
	100.0 Milligram	Daily	,		
3atch:	Started:		Stopped:	CONTIN	
ADALAT (Other drug)		Reason:	Essential benign hyp	ertension	
	60.0 Milligram	Daily	•		
3atch:	Started:		Stopped:	CONTIN	
CARDIPRIN 100 (Other drug)		Reason:	Chron isch heart dis	no hyper	
	100.0 Milligram	Daily	•		
3atch:	Started:		Stopped:	CONTIN	
HYGROTON (Other drug)		Reason:	Essential benign hyp	ertension	
	25.0 Milligram	Daily	,		
3atch:	Started:		Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number:169606Seq: 1Gender:FReported:02/11/2001Weight:Hospitalisation:Admitted to hospitalAge: 80

Onset Date: 23/10/2001 DOB: 17/10/1921

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

MINAX (Other drug)		Reason:	Essential benign hypertension	
	100.0 Millig	gram Daily		
3atch:	Started:		Stopped:	CONTIN
EXELON (Other drug)		Reason:	Osteoarthritis	
	4.5 Milli	gram Daily		
Batch:	Started:		Stopped:	CONTIN
LIPITOR (Other drug)		Reason:	Othr&unspec metabolic diseas	es
	10.0 Milli	gram Daily		
3atch:	Started:		Stopped:	CONTIN
MIANSERIN HYDROCHLORIDE (Suspecto	ed)	Reason:		
	40.0 Millig	gram Daily		

Laboratory Investigations:



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 170135
 Seq: 1
 Gender:
 F

 Reported:
 20/11/2001
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 30/06/2000
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Pyrexia		38.5	
Tachycardia		Hr 120 bpm.	
Speech disorder		Mutism	
Coordination abnormal			
Faecal incontinence			
Hypertonia			
Hypokinesia			
Leukocytosis			
Neuroleptic malignant syndrome			Patient was hospitalised. tolvon, risperidone, benztropine, lithium carbonate

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:				
	750.0 Milligram	Daily			
Зatch:	Started: 31/12/1999	Sto	oped: 06/07/2000		
ALPRAZOLAM (Other drug)		Reason:			
	500.0 Microgram	Daily			
Заtch:	Started: 31/12/1999	Sto	oped:		
ASPIRIN (Other drug)		Reason:			
	150.0 Milligram	Daily			
	S .	•			
3atch:	Started: 31/12/1999) Sto	oped:		
3atch: TOLVON (Suspected)	Started: 31/12/1999	Reason:	pped:		
	3tarted: 31/12/1999		pped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 170135 Seq: 1 Gender: F

Reported: 20/11/2001 Weight:
Hospitalisation: Admitted to hospital Age: 73Y

Onset Date: 30/06/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			

Medicine Details:

RISPERIDONE (Suspected) Reason: 3.0 Milligram Daily 31/12/1999 06/07/2001 3atch: Stopped: **BENZTROPINE MESYLATE (Suspected)** Reason: 2.0 Milligram Daily 3atch: 31/12/1999 Stopped: 06/07/2000

Laboratory Investigations:

Additional Information:

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Rep	00	rt	D	eta	il
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 Case Number:
 171947
 Seq: 1
 Gender: F

 Reported:
 30/11/2001
 Weight:

Hospitalisation: Age: 31

Onset Date: 15/02/1995 **DOB:** 06/09/1963

Outcome: Unknown Causality: Causality possible

Reaction Detai

104011011 20141		<u>-</u>	
Preferred Term	Severity	Report Description	Treatment
Brain neoplasm benign		Dysembryoplastic neuroepithelial tumor in	
Neonatal disorder			

Medicine Details:

TOLVON (Suspected)

Oral application

40.0 Milligram

Daily

Oral

3atch: \$tarted: 30/06/1992

\$topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 172112
 Seq:
 1
 Gender:
 M

 Reported:
 02/01/2002
 Weight:
 80.00

 Hospitalisation:
 Age:
 72

Onset Date: 28/10/2001 **DOB**: 20/01/1929

Outcome: Recovered Causality: Causality possible

Reaction Detai

74041011 20441							
Preferred Term	Severity	Report Description	Treatment				
Extrasystoles			Ceased more than a multi. date of recovery 4.10.01. required a visit to doctor.				
Palpitations							

Medicine Details:

MIANSERIN HYDROCHLORIDE (Interaction	Reason:			
	0.0			
3atch:	Started:		Stopped:	
MORE THAN A MULTI (Interaction)		Reason:		
Tablet	1.0 Dos	se Unspecified Daily	Oral	
3atch:	3tarted: 01/10/2	001	Stopped: 04/10/2001	
LUMIN (Other drug)		Reason:	Specific disorders of sleep	
	60.0 Milli	igram Daily		
3atch:	Started:		Stopped:	
TRITACE (Other drug)		Reason:	Essential benign hypertension	
	10.0 Milli	igram Daily		
Зatch:	Started:		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.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Rei	port	: Det	tail
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 Case Number:
 172112
 Seq: 1
 Gender: M

 Reported:
 02/01/2002
 Weight: 80.00

 Hospitalisation:
 Age: 72

 Onset Date: 28/10/2001
 DOB: 20/01/1929

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

MEGICINE DELANS.					
PROSCAR (Other drug)			Reason:	Hyperplasia of prostate	
	5.0	Milligram	Daily		
3atch:	Started:	L	TERM	Stopped:	
CELEBREX (Other drug)			Reason:	Osteoarthritis	
	200.0	Milligram	Daily		
3atch:	Started:	L	TERM	Stopped:	

Laboratory Investigations:

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

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UE	νv	יו ני	\boldsymbol{L}	τιa	

 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 Causality: Causality possible

Reaction Detai

			E
Preferred Term	Severity	Report Description	Treatment
Delirium		Acute delerium.	Date of recovery: 17/7/02.
Confusional state			

Medicine Details:

ASPIRIN (Other drug)			Reason:	
	150.0	Milligram	Daily	
3atch:	Started:		Stopped:	CONTIN
CYPROTERONE ACETATE (Other drug)			Reason:	
	300.0	Milligram	Daily	
3atch:	Started:		Stopped:	CONTIN
MIANSERIN HYDROCHLORIDE (Suspected)				
MIANSERIN HYDROCHLORIDE (Suspected	d)		Reason:	
MIANSERIN HYDROCHLORIDE (Suspected	d) 20.0	Milligram	Reason: As necessary	
MIANSERIN HYDROCHLORIDE (Suspected Satch:	•	Milligram		05/07/2002
, .	20.0	Milligram	As necessary	05/07/2002
3atch:	20.0		As necessary Stopped :	05/07/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Reported: 22/07/2002 spitalisation: Onset Date: 08/07/2002 Outcome: Recovered action Detai	Seq: 1			c		
edicine Details: ANITIDINE (Suspected) 3atch: MAGNESIUM PLUS (Suspected)	300.0 Started:	Milligram	son: Daily son:	Stopped:	15/07/2002	
Batch:	1.0 Started:	Dose Unspecified		Stopped:	11/07/2002	
aboratory Investigation	ıs:					



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 180653
 Seq: 1
 Gender:
 F

 Reported:
 13/11/2002
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 61

Onset Date: DOB: 26/08/1941

Outcome: Recovered Causality: Causality possible

Reaction Detai

•	teaction Detai	-		
	Preferred Term	Severity	Report Description	Treatment
	Dystonia		Oro-buccal dyskinesia, dystonia of upper right arm and left toes.	

Medicine Details:

Medicine Details.				
TEMAZEPAM (Other drug)		Reason:	Specific disor	ders of sleep
	0.0	Daily		Oral
3atch:	Started:	L TERM	Stopped:	
TOLVON (Suspected)		Reason:	Depression	
Tablet	10.0 Milligra	am Daily		Oral
3atch:	Started: 01/03/199	4	Stopped:	28/03/1998

Laboratory Investigations:

	<u> </u>				
Date	Туре	Range	Date Tested	Result	Details
17/12/2002	Other data				Relevant tests: huntington disease gene testing (2002), and screening for both friedreich's ataxia and spinocerebellar ataxia showed no significant results.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 183034
 Seq: 1
 Gender:
 F

 Reported:
 18/02/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 78Y

Onset Date: 14/07/2002 **DOB**:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Delirium			Digoxin withheld for the level to fall, mianserin and indapamide
Dehydration			
Orthostatic hypotension			
Therapeutic agent toxicity			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Interaction	1)			Reason:			
Tablet	10	0.0	Milligram	Daily		Oral	
3atch:	Started:				Stopped:	14/07/2002	
INDAPAMIDE HEMIHYDRATE (Interaction)				Reason:			
Tablet	2	2.5	Milligram	Daily		Oral	
3atch:	Started:				Stopped:	14/07/2002	
DIGOXIN (Interaction)				Reason:	Otr&nos disord	d of heart rhythm	
Tablet	187	7.0	Microgram	Daily		Oral	
Зatch:	Started:				Stopped:	14/07/2002	
ENOXAPARIN (Other drug)				Reason:	Otr&nos disord	d of heart rhythm	
Injection	70	0.0	Milligram	Daily			
3atch:	Started:		07/2002		Stopped:		contin

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
18/02/2003	Pharmacokinetics				



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: 183034 Reported: 18/02/2003 Hospitalisation: Onset Date: 14/07/2002 Outcome: Unknown Reaction Detai	Seq: 1	Gender: F Weight: 0.00 Age: 78Y DOB: Causality: Causality possible
Medicine Details:		
WARFARIN SODIUM (Other drug)		Reason: Otr&nos disord of heart rhythm
Tablet 3atch:	Started:	Daily Oral Stopped:
Laboratory Investigatio	ns:	
Additional Information:		

Report Run 01/08/200 02:09PN Database: pusime ADRS004 Page 316 of 336



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 186555
 Seq: 1
 Gender: M

 Reported:
 03/06/2003
 Weight:
 51.00

Hospitalisation: Age: 79

Onset Date: 15/05/2003 DOB: 28/10/1923
Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
		Generalised papular rash,exanthematous appearance.	

Medicine Details:

LIPITOR (Other drug)			Reason:	Othr&unspec	metabolic diseas	es
Tablet	10.0	Milligram	Daily		Oral	
Зatch:	Started:	l	TERM	Stopped:		contin
LUMIN (Suspected)			Reason:	Depression		
Tablet	80.0	Milligram	Daily		Oral	
3atch:	Started: 16/	/04/2003		Stopped:	22/05/2003	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 198337
 Seq: 1
 Gender:
 F

 Reported:
 21/06/2004
 Weight:
 0.00

 Hospitalisation:
 Age: 34Y

Onset Date: 15/03/2004 **DOB:**

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

teaction betai			
Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		Serotonin syndrome; shivering, agitation, panic attacks, highly stimulated, problems with abnormal vision watching TV screen 'flickers'.	Lovan ceased.
Agitation	Required Specialist Consultation		
Chills	Required Specialist Consultation		

Medicine Details:

LUMIN (Suspected)	र	Reason:					
Tablet	140.0 Milligram	Daily	Oral				
3atch:	Started: 01/03/2004	Stopped:					
LOVAN (Suspected)	र	Reason:					
	20.0 Milligram	Daily					
3atch:	Started: 01/03/2004	Stopped:	31/03/2004				

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Rivotril, Xanax and Stilnox.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 198337
 Seq: 1
 Gender:
 F

 Reported:
 21/06/2004
 Weight:
 0.00

 Hospitalisation:
 Age: 34Y

Onset Date: 15/03/2004 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Neaction Detai			
Preferred Term	Severity	Report Description	Treatment
Panic attack	Required Specialist Consultation		
Psychomotor hyperactivity	Required Specialist Consultation		
Visual disturbance	Required Specialist Consultation		

Medicine Details:

LUMIN (Suspected)	3	Reason:					
Tablet	140.0 Milligram	Daily	Oral				
3atch:	Started: 01/03/2004	Stopped:	Stopped:				
		Reason:					
LOVAN (Suspected)	\$	eason:					
LOVAN (Suspected)	و 20.0 Milligram	eason: Daily					

Laboratory Investigations:

Additional Information:

Patient also taking Rivotril, Xanax and Stilnox.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Case Number:	200190	Seq:	1			Gei	nder: M		
Reported:	20/08/200)4				We	ight: 0.0	00	
lospitalisation:	Admitted	to hospital					Age: 80)	
Onset Date:	01/08/200)4				I	OOB:		
Outcome:	: Unknown					Caus	ality: Ca	ausality poss	ible
eaction Deta	ı <u>i</u>								
Preferr	ed Term	Seve	erity	Rep	ort Descrip	tion		Treatment	
Epilepsy		Caused prolong inpatien hospital	ed ir nt h	Patient develop ncreased agita ad a high alco wo epileptic fits	tion and agg hol intake an	ression. He d experienced		ceased.	
Aggression		Caused prolong inpatien hospital	ed nt						
Agitation		Caused prolong inpatien hospital	ed nt						
Medicine De		•	•				•		
ALCOHOL (Susp	ected)			₹e	ason:				
						Ora	I		
3atch:		Sta .	rted:			Stopped:			
TOLVON (Suspec	itea)			₹e	ason:	0			
Tablet		240	uta di			Ora	l		
3atch: TEMAZEPAM (Su	spected)	Sta	rted:	30	ason:	Stopped:			
TEMAZEI AM (Ou	эрестец			10	a3011.	Ora	ı		
3atch:		Sta	rted: 01/0	08/2004		Stopped:	•		
ARICEPT (Suspe	cted)					senile dementia			
Tablet	,		5.0	Milligram	Daily	Ora	I		
3atch:		Sta	rted: 09/0	_	·	Stopped:			
-1		•							
			Data Tost	tod Bosult	1		Dotaile		
Date	туре	Kange	Date Test	leu Result			Details		
3atch: Laboratory II Date	nvestigat ^{Type}		Date Test			Stopped:	Details		
Additional In	formatio	n:							
oort Run 01/08/20)O 02·00PA	- Datahase: nu	ısime		ADRS004			Page 320	of 226



Report Detail

Case Number: 200190

Reported: 20/08/2004

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: M

Weight: 0.00

Hospitalisation: Admitted to hospital Age: 80				
Onset Date: 01/08/2004		DOB:		
Outcome: Unknown		Ca	ausality: Causality possible	
eaction Detai Preferred Term	Severity	Report Description	Treatment	
Hallucination	Caused or prolonged inpatient hospitalisation	Troport 2 company	T. Gallano III	
nsomnia	Caused or prolonged inpatient hospitalisation			
Medicine Details: AMITRIPTYLINE HYDROCHLORI	DE (Suspected)	Reason:		
Tablet	25.0 Milligram		Oral	
3atch:	Started:	Stopped:		
Laboratory Investigatio	ons:			
Additional Information	:			
port Run 01/08/200 02:09PN	Database: pusime	ADRS004	Page 321 of 336	



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Rep	oort	Det	ail
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Case Number: 202520 Seq: 1 Gender: F

Reported: 12/11/2004 Weight: 58.00 Hospitalisation: Age: 55

Onset Date: 01/03/2004 **DOB**: 08/09/1948

Outcome: Recovered 01/07/2004 **Causality**: Causality probable

Reaction Detai

Cachon Detai		-	
Preferred Term	Severity	Report Description	Treatment
Leukopenia	Treated in outpatient department		Ordered to stop taking Lumin immediately

Medicine Details:

LUMIN (Suspected) Reason:

10.0 Milligram Daily Oral

3atch: 3tarted: 01/03/2004 3topped: 01/04/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Reported: 18/11/2004 ospitalisation: Onset Date: Outcome: Unknown action Detai Preferred Term uicidal ideation	Severity Su	Report De	Aq DC Causali	ht: 0.00 ge: 86 ps: 12/06/1918 ty: Causality possi	ble
Onset Date: Outcome: Unknown action Detai Preferred Term		·	DC Causali	DB : 12/06/1918	ble
Outcome: Unknown action Detai Preferred Term		·	Causali		ible
action Detai Preferred Term		·		ty: Causality possi	ible
Preferred Term		·			
		·			
uicidal ideation	Su		scription	Treatment	
		icidal ideation.			
edicine Details:					
OLVON (Suspected)		Reason:			
Tablet			Oral		
3atch: Started:			Stopped:		
aboratory Investigation Date Type	Range Date Teste	d Result	Г	Details	
Date Type	Range Date reste	u Result	L	retails	
dditional Information:					
ort Run 01/08/200 02:09PN [Database: pusime	ADRS	004	Page 323	of 334



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

 Case Number:
 211373
 Seq:
 1
 Gender:
 M

 Reported:
 05/09/2005
 Weight:
 0.00

 Hospitalisation:
 Age:
 58Y

Onset Date: 01/05/2005 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

todotion Dotai	-		
Preferred Term	Severity	Report Description	Treatment
Myalgia		Patient experienced generalised myalgias, severe arthralgias in wrists, hips, knees and ankles and groin pain.	Ceased Lipitor and Efexor.
Arthralgia			

							• •	
n	$^{\prime\prime}$	a.	\sim 1	nn		eta	116	٠.
	/15	u		116	ப	cia	112	• -

EPILIM (Other drug)		Reason:		
Зatch:	Started:		Stopped:	
IMOVANE (Other drug)		Reason:		
3atch:	Started:		Stopped:	
BRICANYL TURBUHALER (Other drug)		Reason:		
3atch:				
-4.5	Started:		Stopped:	
CALTRATE (Other drug)	Started:	Reason:	Stopped:	
	Started:	Reason:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
05/09/2005	ALT = SGPT		04/05/2005	127	
05/09/2005	ALT = SGPT		06/05/2005	93	
05/09/2005	ALT = SGPT		12/05/2005	50	
05/09/2005	ALT = SGPT		20/05/2005	47	
05/09/2005	ALT = SGPT		15/06/2005	35	
05/09/2005	Creatine		04/05/2005	1451	
05/09/2005	Creatine		06/05/2005	646	

Additional Information:

Patient was on Lopid since at least 2001 until July 2003 when it was ceased due to myalgia. Anafranil and Prothiaden caused some agitation.



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

-	etail						
Case Num	ber: 211373	Seq:	1			Gender:	M
Repor	ted: 05/09/200	05				Weight:	0.00
spitalisat	tion:					Age:	58Y
Onset D	ate: 01/05/200	05				DOB:	
Outco	me: Recovere	ed			C	ausality:	Causality possible
action D)etai					-	
	Details: FORTE (Other dru	ıg)		Reaso	n:		
	FORTE (Other dru		arted:	Reaso	n: Stopped:		
CODALGIN F	FORTE (Other dru h:		arted:	Reasc	Stopped:		
CODALGIN F	FORTE (Other dru h:		arted:		Stopped:		
CODALGIN F	FORTE (Other dru h: her drug)	Sta	arted: arted:		Stopped:		
3atch BEXIUM (Oth 3atch	FORTE (Other dru h: her drug) h:	Sta			Stopped:		
CODALGIN F 3atch IEXIUM (Oth 3atch	FORTE (Other dru h: her drug) h:	Sta		Reasc	Stopped:		
ODALGIN F 3atch EXIUM (Oth	FORTE (Other dru h: her drug) h: Other drug)	Sta Sta		Reasc	Stopped:		
3atch BORVASC (C	FORTE (Other dru h: her drug) h: Other drug)	Sta Sta	arted:	Reasc	Stopped: n: Stopped: n:		
3atch BORVASC (C	FORTE (Other dru h: her drug) h: Other drug)	Sta Sta	arted:	₹easc ₹easc	Stopped: n: Stopped: n:		
3atch BORVASC (C	FORTE (Other dru h: her drug) h: Other drug) h: er drug)	Sta Sta	arted:	₹easc ₹easc	Stopped: n: Stopped: n: Stopped: n:		
ODALGIN F 3atch ORVASC (C 3atch OTEN (Other	FORTE (Other dru h: her drug) h: Other drug) h: er drug)	Sta Sta Sta	arted: arted:	₹easc ₹easc	Stopped: n: Stopped: n:		
3atch BOTEN (Other 3atch BOTEN (Other 3atch	h: her drug) h: Other drug) h: er drug)	Sta Sta Sta Sta	arted: arted: arted:	Reason Reason	Stopped: n: Stopped: n: Stopped: n:		
ODALGIN F 3atch CRVASC (C 3atch OTEN (Other 3atch borator Date	h: her drug) h: Other drug) h: er drug) h: Type	Sta Sta Sta	arted: arted: arted:	Result	Stopped: n: Stopped: n: Stopped: n:	Deta	ils
ODALGIN F 3atch EXIUM (Oth 3atch ORVASC (O 3atch OTEN (Othe 3atch borator Date 5/09/2005	h: her drug) h: Other drug) h: er drug) h: Type Creatine	Sta Sta Sta Sta	arted: arted: Date Tested 12/05/2005	Result	Stopped: n: Stopped: n: Stopped: n:	Deta	ils
3atch BORVASC (C) 3atch ORVASC (C) 3atch OTEN (Other Aborator Date 5/09/2005 5/09/2005	h: her drug) h: Other drug) h: er drug) h: ry Investigat Type Creatine Creatine	Sta Sta Sta Sta	arted: arted: Date Tested 12/05/2005 20/05/2005	Result 90 1299	Stopped: n: Stopped: n: Stopped: n:	Deta	ils
3atch BORVASC (C 3atch BORVASC (C 3atch BOTEN (Other Both Borator Date 5/09/2005 5/09/2005 5/09/2005	h: h: hcr drug) h: Other drug) h: er drug) h: ry Investigat Type Creatine Creatine Creatine Creatine	Sta Sta Sta Sta	Date Tested 12/05/2005 20/05/2005 23/05/2005	Result 90 1299 298	Stopped: n: Stopped: n: Stopped: n:	Deta	ils
3atch IEXIUM (Oth 3atch IORVASC (C 3atch IOTEN (Othe 3atch IOTEN (Othe 5/09/2005 5/09/2005 5/09/2005 5/09/2005	h: h: hcr drug) h: Other drug) h: er drug) h: cr drug) Creatine Creatine Creatine Creatine Creatine	Sta Sta Sta Sta	Date Tested 12/05/2005 20/05/2005 23/05/2005 26/05/2005	Result 90 1299 298 241	Stopped: n: Stopped: n: Stopped: n:	Deta	ils
3atch NEXIUM (Oth 3atch NORVASC (C 3atch NOTEN (Other 3atch 25/09/2005 05/09/2005 05/09/2005 05/09/2005 05/09/2005	h: h: hcr drug) h: Other drug) h: er drug) h: ry Investigat Type Creatine Creatine Creatine Creatine	Sta Sta Sta Sta	Date Tested 12/05/2005 20/05/2005 23/05/2005	Result 90 1299 298	Stopped: n: Stopped: n: Stopped: n:	Deta	ils



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: 211373 Reported: 05/09/2005 Hospitalisation: Onset Date: 01/05/2005	Seq: 1	Gender: Weight: Age: DOB:	0.00 58Y
Outcome: Recovered		Causality:	Causality possible
Reaction Detai			
Medicine Details:			
QUINATE (Other drug)		Reason:	
Зatch:	Started:	Stopped:	
RECTOGESIC (Other drug)		Reason:	
Batch:	Stantado	Mannadi	
Seretide 250/50 Accuhaler (Other drug)	Started:	Stopped:	
3atch:	Started:	Stopped:	
VOLTAREN (Other drug)		Reason:	
3atch:	Started:	Stopped:	
Laboratory Investigations:			_
Laboratory invoctigations.			
Additional Information: Patient was on Lopid since at least 20 some agitation.	01 until July 2003 when it wa	ns ceased due to myalgia. Anafrani	and Prothiaden caused

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Report Detail

Case Number: 211373 Seq: 1 Gender: M

Reported: 05/09/2005 Weight: 0.00 Hospitalisation: Age: 58Y

Onset Date: 01/05/2005 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LIPITOR (Suspected)			Reason:		
Tablet	80.0	Milligram	Daily	Oral	
3atch:	Started:			Stopped:	
EFEXOR (Suspected)			₹eason:		
Tablet	150.0	Milligram	Daily	Oral	
3atch:	Started:			Stopped:	
TOLVON (Suspected)			₹eason:		
Tablet	40.0	Milligram	Daily	Oral	
3atch:	Started:			Stopped:	

Laboratory Investigations:

Additional Information:

Patient was on Lopid since at least 2001 until July 2003 when it was ceased due to myalgia. Anafranil and Prothiaden caused some agitation.

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

 Case Number:
 212299
 Seq:
 1
 Gender:
 U

 Reported:
 07/10/2005
 Weight:
 0.00

 Hospitalisation:
 Age:
 49Y

Onset Date: 08/04/2004 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome		Patient experienced restlessness in sleep with irritable legs, arthralgia, myalgia, increased tinnitus, ulcerated mouth-FBC taken	
Arthralgia			
Mouth ulceration			
Myalgia			
Tinnitus			

Medicine Details:

EPILIM (Other drug)		Reason:	Otr&unsp forms neural	g&neurit
	600.0	Milligram Daily	1	
Batch:	Started:	L TERM	Stopped:	
LANOXIN (Other drug)		Reason:	Otr&nos disord of hear	rhythm
Tablet	250.0	Milligram Daily	Oral	
Batch:	3tarted: 15/0	2/2004	Stopped:	
TOLVON (Suspected)		Reason:	Depression	
Tablet	10.0	Milligram Daily	Oral	
3atch:	3tarted: 06/0	4/2004	3topped: 13/04/2	004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 215385 Seq: 1 Gender: M

Reported: 30/01/2006 Weight: 0.00 Hospitalisation: Age: 74Y

Onset Date: 05/12/2005 DOB:

Outcome: Recovered 09/12/2005 Causality: Causality possible

Reaction Detai

todotion Botal		_	
Preferred Term	Severity	Report Description	Treatment
Nightmare Coordination abnormal		The patient was "terrified all night" and wanted to get up, but couldn't. The next day his lips felt numb, his cheeks were tingly and he had blurred vision	Lumin, Imovane and Lexapro
Paraesthesia			
Vision blurred			

Medicine Details:

BLACKMORES BIO MAGNESIUM (Other d	rug)		Reason:	Constipation	
	2.0	Dose Unspe	ecified		
3atch:	Started:			Stopped:	
ZANTAC (Other drug)			Reason:		
	300.0	Milligram	Daily		
3atch:	Started:	L	TERM	Stopped:	
ZYLOPRIM (Other drug)			Reason:		
	200.0	Milligram	Daily		
3atch:	200.0 Started :	ŭ	Daily TERM	Stopped:	
3atch: LUMIN (Suspected)		ŭ	,	Stopped:	
	Started:	ŭ	TERM	Stopped:	Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Case Number: 215385

Reported: 30/01/2006

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Gender: M

Weight: 0.00

ospitalisation:			Age	: 74Y	
Onset Date: 05/12/2005			DOB		
Outcome: Recovered	09	/12/2005	Causality	: Causality possible	
ection Detai					
edicine Details:	_				
exapro (Suspected)	10.0 Milligra	Reason: am Daily	Oral		
3atch:	Started:	iiii Daiiy	Stopped:	0	
MOVANE (Suspected)		Reason:	лоррош.		
Tablet	1.0 Dose l	Jnspecified Daily	Oral		
3atch:	Started: 05/12/2005		Stopped:	0	
			••		
boratory Investigations	:				
	•				
dditional Information:					
ort Run 01/08/200 02:09PN Data	abase: pusime	ADRS004		Page 330 of 33	36



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report D)etail
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Case Number: 216706 Seq: 1 Gender: F

Reported: 28/03/2006 Weight: 83.00 Hospitalisation: Age: 50

Onset Date: 28/02/2006 DOB: 21/04/1955

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Transaminases increased		Raised Transaminase levels.	Nil

Medicine Details:

COVERSYL (Other drug) Reason: Essential benign hypertension

1.0 Dose Unspecified

3atch: Started: Stopped:

TAMOXIFEN CITRATE (Other drug) Reason: Malignant neoplasm of breast

3atch: Started: Stopped:

GLUCOSAMINE SULPHATE (Other drug) Reason: Unspecified arthritis

3atch: Started: Stopped: 0

SOMAC (Other drug) Reason: Other diseases of esophagus

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN, MIANSERIN HYDROCHLORIDE, TOLVON

Case Number:	216706	Seq:	1			Gender:	F	
Reported:	28/03/2006					Weight:	83.00	
Hospitalisation:						Age:	50	
Onset Date:	28/02/2006					DOB:	21/04/1955	
Outcome:	Not yet recovered	i				Causality:	Causality poss	ible
Reaction Detai								
Medicine Deta								
TOLVON (Suspect	ted)			Reason:	Depression			
			30.0 Milligram	Daily				
3atch:		3ta	rted: 06/12/2005		3topped	:		
Laboratory In	voetigatione:							
Laboratory in	ivestigations.							
Additional Inf	formation:							
aport Pup 01/08/200) 02:00PN Datah	aco: nu	oimo	ADDS00	nα		Daga 222	of 226

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

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Case Number: 219998 Seq: 1 Gender: M

Reported: 13/07/2006 Weight: 70.00 Hospitalisation: Age: 29

Onset Date: 23/06/2006 **DOB**: 22/07/1976

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Patient experienced increased liver blood	

Medicine Details:

Medicine Details.					
EFEXOR (Other drug)		Reason:	Depression		
3atch:	Started:		Stopped:		
TOLVON (Suspected)		Reason:	Depression		
Tablet				Oral	
3atch:	Started: 19/06/2006		Stopped:	26/06/2006	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Report Detail

Case Number: 220030 Seq: 1 Gender: M
Reported: 14/07/2006 Weight: 0.00
Hospitalisation: Age: 79Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

104041011 20441		-	-
Preferred Term	Severity	Report Description	Treatment
Skin reaction			Zyprexa and Tolvon ceased. Given salt tablets 1800mg/bd.

Medicine Details:

DEPTRAN (Other drug)		Reason:	
	50.0 Milligram	n Oral	
3atch:	Started:	Stopped:	
NORMISON (Other drug)		Reason:	
	10.0 Milligram	n Oral	
3atch:	Started:	Stopped:	
LIPITOR (Other drug)		Reason:	
Tablet	10.0 Milligram	n Oral	
3atch:	Started:	Stopped:	
3atch: ZYPREXA (Suspected)	· ·		
	· ·	Reason:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
14/07/2006	Sodium		04/04/2006	137	
14/07/2006	Sodium		11/04/2006	134	
14/07/2006	Sodium		18/04/2006	133	
14/07/2006	Sodium		26/04/2006	129	
14/07/2006	Sodium		14/06/2006	136	
14/07/2006	Sodium		28/06/2006	136	



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	14/07/2006 Unknown	Seq: 1			Gender: Weight: Age: DOB: Causality:	0.00	
Medicine Deta							
TOLVON (Suspecte	ed)			Reason:	•		
Tablet 3atch:		40.0 Started:	Milligram	Daily	Oral Stopped:		
		2 2001 200 201			жеррен.		
Laboratory In	vestigations:						
Additional Inf	ormation:						



Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: LUMIN,MIANSERIN HYDROCHLORIDE,TOLVON

	Re	oa	rt	D	eta	i	ı
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 Case Number:
 226053
 Seq: 1
 Gender:
 F

 Reported:
 22/02/2007
 Weight:
 0.00

Hospitalisation: Weight: 0.00

Onset Date: 17/12/2006 DOB: 01/01/1974

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
, , , , , ,	Caused or prolonged inpatient hospitalisation		Tramadol ceased.

Medicine Details:

TRAMADOL HYDROCHLORIDE (Suspe	Reason:	Otr&unsp vertebrogen pain synd		
Tablet	200.0 Milligram	Daily		Oral
3atch:	3tarted: 10/12/2006		Stopped:	17/12/2006
MIANSERIN HYDROCHLORIDE (Suspe	cted)	Reason:		
MIANSERIN HYDROCHLORIDE (Suspen	c ted) 120.0 Milligram	Reason: Daily		Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details