

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reported: 1	55702	Seq: 1		Gend	er: F
Nopolica.	26/08/1988			Weig	ht: 72.00
Hospitalisation:				Ąç	je : 33Y
Onset Date: 2	26/08/1988			DC	DB:
Outcome:	Recovered			Causali	ty: Causality possible
Reaction Detail	s:				
Preferre		Severity	Report De	scription	Treatment
Affect lability					
Dyspnoea					Phenergan 12.5mg given, complete resolution within 3 minutes. reaction occurred 5mins after droperidol given and 50mins after omnopon.
Tongue discoloura	ation				
Tongue oedema					
Medicine Deta			Reason:		
Injection	,	5.0 Mi		e Intrave	nous
Batch:		Started: 26/08/	•	Stopped:	
OMNOPON (Suspec	cted)		Reason:	Premedication	
Injection	•	20.0 Mi	Iligram 1 time	e Intram	uscular
Batch:		Started: 26/08/	1988	Stopped:	
Laboratory Inv		e Date Tested	Result		etails
	vestigations: Type Rang	e Date Tested	Result	D	etails
	Type Rang	e Date Tested	Result	D	etails

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 1 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 56929 Seq: 1 Gender: F

Reported: 13/10/1988 Weight: 57.00
Hospitalisation: Age: 52Y

Onset Date: 15/08/1988 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
	Neuroleptic malignant syndrome			

Medicine Details:

DROPERIDOL (Suspected) Reason:

Injection, intravenous infusion 10.0 Milligram Total Intravenous

Batch: Started: 14/08/1988 Stopped: 15/08/1988

PETHIDINE HYDROCHLORIDE (Suspected) Reason:

Injection, intravenous infusion 500.0 Milligram Total Intravenous

Batch: Started: 14/08/1988 Stopped: 15/08/1988

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 2 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 58196 Seq: 1 Gender: F

Reported: 25/01/1989 Weight: 57.00 Hospitalisation: Age: 34Y

Onset Date: 23/01/1989 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin & valium ivi

Medicine Details:

DROPERIDOL (Suspected) Reason: Nausea and vomiting

Injection 10.0 Milligram 1 time Intramuscular

Batch: Started: 23/01/1989 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 3 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

ospitalisatio Onset Da	ted: 17/03/198 on: ate: 14/03/198 ne: Recovered	9	1			c	DOB	: 49Y :	ality possibl	e
	eferred Term	Sev	erity	Repo	ort Descr	iption		7	Treatment	
)ysarthria)ystonia							21	ng coger	ntin	
Medicine I	Details:									
	L (Suspected)			Reas		usea and v				
DROPERIDOL Injecti Batch	ion	Star	75.0 Milli rted: 14/03/1	igram	son: Na Daily	usea and v	omiting Intraveno	us		
Injecti Batch	y Investigat	ions:	rted: 14/03/1	igram 989			Intraveno			
Injecti Batch	ion h:	ions:		igram						

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 4 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

Case Number: 59524 Seq: 1 Gender: F

Reported: 29/03/1989 Weight:
Hospitalisation: Age: 29Y

Onset Date: 13/02/1989 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaphylactoid reaction			Adrenaline 1:1000 1ml sc, hydrocortisone 100mg im, promethazine 25mg im

Medicine Details:

DIPRIVAN (Other drug)	F	Reason:	Other disturbance of sensation	
Injection	220.0 Milligram	Total	Intravenous	
Batch:	Started: 13/02/1989		Stopped:	
FENTANYL CITRATE (Other drug)	F	Reason:	Other disturbance of sensation	
Injection	50.0 Microgram	Total	Intravenous	
Batch:	Started: 13/02/1989		Stopped:	
SYNTOCINON (Other drug)	F	Reason:		
Injection	10.0 International Ur	nit Total	Intravenous	
Batch:	Started: 13/02/1989		Stopped:	
DROLEPTAN (Suspected)	F	Reason:	Other disturbance of sensation	
Injection	2.5 Milligram	Total	Intravenous	

Laboratory Investigations:

<u> </u>	i ji iii tootiga				
Date	Туре	Range	Date Tested	Result	Details
	Immunology				Skin testing performed on 29/3/89 positive for droperidol (droleptan)

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 5 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 61376 Seq: 1 Gender: F

Reported: 13/07/1989 Weight: 50.00 Hospitalisation: Age: 57Y

Onset Date: 05/07/1989 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Dotano			
Preferred Term	Severity	Report Description	Treatment
Dry mouth			I.m.i. cogentin
Dystonia			
Speech disorder			

Medicine Details:

DROPERIDOL (Suspected) Reason: Nausea and vomiting

Injection 5.0 Milligram Daily Intramuscular

Batch: Started: 04/07/1989 Stopped: 05/07/1989

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 6 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

R	Δ١	n	n	rt	ח	Δí	a	il	e	•
\mathbf{r}	CI	ш.	•	IL	ப	G I	a		3	

Case Number: 62150 Seq: 1 Gender: M

Reported: 28/08/1989 Weight:

Hospitalisation: Age: 53Y
Onset Date: 23/08/1989
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin iv/valium

Medicine Details:

DROPERIDOL (Suspected) Reason: Nausea and vomiting

Tablet 30.0 Milligram Daily Oral

Batch: Started: 22/08/1989 **Stopped:** 23/08/1989

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 7 of 254



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number: 62472 Seq: 1 Reported: 31/08/1989 Hospitalisation:			1	Gender: M Weight: Age: 53Y				
	on. Pate: 23/08/198	9				DOB:		
	me: Unknown				Cau	sality: Causality possible		
eaction D						,		
	eferred Term	Se	verity	Repo	ort Description	Treatment		
Dystonia					-			
Medicine DROPERIDO	Details: L (Suspected)		0.0	Rea	son:			
Bato	ch:	St	arted:		Stopped:			
Laborato	ry Investigat	ions:						
Date	Туре	Range	Date Tested	Result		Details		
Additiona	I Informatio	n:						
eport Run: 01/	06/2007 04:49PN	l Database: pu	sime02	A	DRS004	Page 8 of 254		

Rep



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

Report Details:

 Case Number:
 64103
 Seq: 1
 Gender: M

 Reported:
 25/10/1989
 Weight:

Hospitalisation: Age: 58Y
Onset Date: 26/09/1989
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Blood amylase increased			
Jaundice			

Medicine Details:

DIPRIVAN (Suspected) Reason: Other disturbance of sensation

0.0

Batch: Started: 26/09/1989 Stopped:

FENTANYL CITRATE (Suspected) Reason: Other disturbance of sensation

0.0

Batch: Started: 26/09/1989 Stopped:

DROPERIDOL (Suspected)Reason: Other disturbance of sensation

0.0

Batch: Started: 26/09/1989 Stopped:

ISOFLURANE (Suspected) Reason: Other disturbance of sensation

0.0

Batch: Started: 26/09/1989 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				30/8/89 26/9/89 27/9/89 28/9/89 16/10/89 ref range bili: 23 90 32 28 15 (0-20 umol/l) alk phos: 75 68 56 60 48 (35-115 u/l) ld: 176 718 572 467 252 (120-250 u/l) ast: 21 61 41 31 29 (0-40 u/l)
	Misclassified at				Amylase: - 283 - 77 101 (20-100 u/l)

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 9 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Re	po	rt	De	tai	ls:
	\sim		-	u	

Case Number: 64316 Seq: 1 Gender: F

Reported: 08/02/1990 Weight: 51.00 Hospitalisation: Age: 21Y

Onset Date: 07/02/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
Ocu	ulogyration			Benztropine 2 mg iv stat.

Medicine Details:

DROPERIDOL (Suspected)Reason: Otr intestne&peritoneum dsease

Injection 15.0 Milligram Total Intramuscular

Batch: Started: 06/02/1990 Stopped: 07/02/1990

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 10 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 64696 Seq: 1 Gender: F

Reported: 02/03/1990 Weight: 56.00 Hospitalisation: Age: 34Y

Onset Date: 02/03/1990 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			

Medicine Details:

DROPERIDOL (Suspected) Reason: Nausea and vomiting

Injection 10.0 Milligram As necessary Intramuscular Batch: Started: 01/03/1990 Stopped: 02/03/1990

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 11 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reported	65043	Seq	: 1				Gender: F
. topo. tou	: 04/04/199	90				,	Weight:
spitalisation:	i i						Age: 46Y
Onset Date	: 03/04/199	90					DOB:
Outcome:	Recovere	:d				Ca	ausality: Causality possible
action Deta							
	red Term	S	everity	Repo	ort Des	cription	Treatment
ruritus							Ceased omnopon infusion pethidine 100 mg im was used.
ash							
ledicine De							
OMNOPON (Susp		f t	400.0 14:11				ace of sensation
-	intravenous int		100.0 Mill		Total		Intravenous
Batch:	ODULIN (O		Started: 03/04/1			Stopped:	04/04/1990
THIOPENTONE S	ODIUM (Susp	sectea)	200 0 Mill		son:		
D-4-b-		,	300.0 Mill	ligram	Daily	04	
Batch: /ECURONIUM BI	POMIDE (Suc		Started:	Pos	son:	Stopped:	
VECORONION BI	YOMIDE (Sus	pecteu)	6.0 Mill		Daily		
Batch:		ç	Started:	iigiaiii	Daily	Stopped:	
MORPHINE NOS	(Suspected)		Jiai leu.	Rea	son:	Эторрец.	
	(Gaspeotea)		5.0 Mill		Daily		
Batch:		ç	Started:	iigraiii	Daily	Stopped:	
			otarioa.			оторроц.	
	nvoetiaat	ions:	T	T			
aboratory I							
aboratory I	Type	Range	Date Tested	Result			Details

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 12 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:				
Case Number: 65043 Reported: 04/04/1990 Hospitalisation: Onset Date: 03/04/1990 Outcome: Recovered Reaction Details:	Seq: 1		Gender: Weight: Age: DOB: Causality:	46Y
Medicine Details: DROPERIDOL (Suspected)		Reason:		
Batch:	4.0 Milligram Started:	Daily	Stopped:	
Laboratory Investigations:				
Additional Information:				

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 13 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

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

Case Number: 65534 Seq: 1 Gender: M

Reported: 17/05/1990 Weight: 60.00 Hospitalisation: Age: 18Y

Onset Date: 16/05/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			lv benztropine 2mg

Medicine Details:

PANADEINE (Other drug) Reason: Pain

2.0 Dose Unspecified As necessary

Batch: Started: 14/05/1990 Stopped:

FLOXAPEN (Other drug) Reason: Otr&nos infec¶sit diseases

Injection 4.0 Gram Daily Intravenous

Batch: Started: 14/05/1990 Stopped:

PENICILLIN NOS (Other drug)

Reason: Otr&nos infec¶sit diseases

Injection 4.0 Dose Unspecified Daily Intravenous

Batch: Started: 14/05/1990 Stopped:

DROLEPTAN (Suspected) Reason: Nausea and vomiting

Injection10.0MilligramDailyIntravenousBatch:Started: 15/05/1990Stopped: 16/05/1990

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 14 of 254



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reported: spitalisation: Onset Date: Outcome: action Detail	17/05/1990 16/05/1990 Recovered	Seq. 1		Weight: 60.00 Age: 18Y DOB: Causality: Causal	ty possible
ction Betain	3.				
edicine Deta			Reason:	Neurosa and vamiting	
Injection	tea)	50.0 Milligram	Daily	Nausea and vomiting Intramuscular	
Batch:		Started: 15/05/1990	Duny	Stopped:	
AXOLON (Suspe	cted)		Reason:	Nausea and vomiting	
Injection		40.0 Milligram	Daily	Intramuscular	
Batch:		Started: 15/05/1990		Stopped:	
boratory In	vestigations:				
lditional Inf	ormation:				
ort Pup : 01/06/200	7 04·49PM Data	ahasa: nusiman?	ADRS00	M D	age 15 of 2

ADRS004 Page 15 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Numb							
_	Der : 65964	Seq:	1			Gender:	
-	ted: 07/06/1990					Weight:	
ospitalisati						Age:	
Onset Da	ate: ne: Recovered					DOB:	
						Causanty:	Causality possible
eaction De	etans: eferred Term	Sev	verity	Renor	t Description		Treatment
ot flush	sierreu reini	361	verity	Перы	t Description		rreaument
Palpitations							
Tremor							
Medicine I							
TEMAZEPAM	(Suspected)			Reaso	,	eurosis	
		.		e Unspecified	-		
Batch	n: YDROCHLORIDE (Sus		arted: 04/06/19	990 Reaso	Stopp Other dist	ed: urbance of sens	ation
Injecti		specieu	10.0 Milli		As necessary	Intramuscu	
Batch		Sta	arted: 04/06/19	_	Stopp		ilai
PANADEINE (Reaso		urbance of sens	ation
	,		2.0 Dos	e Unspecified	As necessary		
	h:	Sta	arted: 04/06/19	990	Stopp	ed:	
Batch				Reaso	n: Nausea a	nd vomiting	
Batch DROPERIDOL	_ (Suspected)						
			1.0 Milli	gram ,	As necessary	Intravenou	s
DROPERIDOL	ion	Sta	1.0 Milli arted: 05/06/19	_	-	Intravenou ed: 05/06/1990	
DROPERIDOL Injecti Batch	ion h:			_	-		
DROPERIDOL Injecti Batch	on h: y Investigation	ns:		_	-		

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 16 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number: 65964 Reported: 07/06/1990 Hospitalisation: Onset Date: Outcome: Recovered Reaction Details:	Seq: 1	Gender: Weight: Age: DOB: Causality:	59.00
Medicine Details:	Passani	Other consulation defeats	
HEPARIN SODIUM (Suspected) Injection	Reason: 10.0 Thousand Internal Daily	Other coagulation defects Subcutaneo	ue.
Batch:	Started: 04/06/1990	Stopped:	us
Laboratory Investigations:			
Additional Information:			

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 17 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 66411 Seq: 1 Gender: F

Reported: 27/06/1990 Weight: 57.00 Hospitalisation: Age: 24Y

Onset Date: 26/06/1990 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

caction Details.				_
Preferred Term	Severity	Report Description	Treatment	
Myalgia				1
Oculogyration			Benztropine img iv	

Medicine Details:

DROPERIDOL (Suspected) Reason: Nausea and vomiting

Injection 4.0 Milligram Total Intravenous

Batch: Started: 25/06/1990 Stopped: 26/06/1990

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 18 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 67715 Seq: 1 Gender: F

 Reported:
 02/10/1990
 Weight:
 60.00

 Hospitalisation:
 Age:
 45Y

 Onset Date:
 25/06/1990
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Injection site reaction			Dmso, vitamin e cream.	

Medicine Details:

EPIRUBICIN HYDROCHLORIDE (Suspec	ted)	Reason: Malignar	nt neoplasm of ovary	
Injection	100.0 Milligram	1 time	Intravenous	
Batch:	Started: 25/06/1990	Stop	ped:	
CYCLOPHOSPHAMIDE (Suspected)		Reason: Malignar	nt neoplasm of ovary	
Injection	1.2 Gram	1 time	Intravenous	
Batch:	Started: 25/06/1990	Stop	ped:	
DEXAMETHASONE (Suspected)		Reason: Malignar	nt neoplasm of ovary	
Injection	10.0 Milligram	1 time	Intravenous	
Batch:	Started: 25/06/1990	Stop	ped:	
PROCHLORPERAZINE MALEATE (Suspe	ected)	Reason: Malignar	nt neoplasm of ovary	
Injection	12.0 Milligram	1 time	Intravenous	
Batch:	Started: 25/06/1990	Stop	ped:	

Laboratory Investigations:

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

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 19 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number: 67715 Reported: 02/10/1990 Hospitalisation: Onset Date: 25/06/1990 Outcome: Recovered Reaction Details:	Seq: 1	Gender: Weight: Age: DOB: Causality:	60.00 45Y
Medicine Details: DROPERIDOL (Suspected)		Reason: Malignant neoplasm of ov	onv
Injection	10.0 Milligram	Reason: Malignant neoplasm of ov 1 time Intravenou	
Batch:	Started: 25/06/1990	Stopped:	
Laboratory Investigations:			
Additional Information:			

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 20 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reported: 09/01/19	Seq: 1		Gende Weight	
ospitalisation:			_	: 6M
Onset Date:			DOE	
Outcome: Recovere	ed		Causality	: Causality possible
eaction Details: Preferred Term	Severity	Report De	escription	Treatment
Oculogyration	Ocverty	Troport Dr		Cogentin 0.02mg/kg 1gm
Medicine Details: DROLEPTAN (Suspected) Injection Ratch:		Reason: Milligram Daily		cular
Batch:	Started:		Stopped:	
MORPHINE NOS (Suspected)		Reason:	Premedication	oular
Injection Batch:		Milligram Daily		Cuidi
ATROPINE (Suspected)	Started:	Reason:	Stopped: Premedication	
Injection	1 20	Milligram Daily		cular
Batch:	Started:	g. 2011)	Stopped:	
<u>aboratory Investiga</u>	ations: Range Date Teste	ed Result	Det	ails
Date I IVUE	90 Date 10010			

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 21 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:		
Case Number: 69072	Seq: 1	Gender: M
Reported: 09/01/1991		Weight: 8.00

Hospitalisation: Age: 7M
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Cogentin 0.02mg/kg, 1gm

Medicine Details:

DROLEPTAN (Suspected)			Reason:	Premedication	
Injection	1.0	Milligram	Daily		Intramuscular
Batch:	Started:			Stopped:	
MORPHINE NOS (Suspected)			Reason:	Premedication	
Injection	1.0	Milligram	Daily		Intramuscular
Batch:	Started:			Stopped:	
ATROPINE (Suspected)			Reason:	Premedication	
Injection	0.1	Milligram	Daily		Intramuscular
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 22 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

ase Number:	69738	Seq: 1				Gender	: F
Reported:		4.				Weight:	
pitalisation:						_	: 28Y
Onset Date:	21/02/1991					DOB	
Outcome:	Recovered				Ca	ausality	: Causality probable
action Detai	ls:					-	
Preferre		Severity	F	Report Des	cription		Treatment
allucination							
ninking abnorma							
sual disturbanc	e					In	ni cogentin 2mg
edicine Deta	ails:						
ROPERIDOL (Sus				Reason:	Other disturbar	nce of sen	sation
Injection		2.0	Milligram	Total		Intraveno	us
Batch:		Started: 21/0)2/1991		Stopped:		
					Сиррин		
aboratory In	vestigations	:					
-aboratory In		ange Date Test	ed Result	t		Deta	ails

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 23 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 69739 Seq: 1 Gender: M

Reported: 26/02/1991 Weight:
Hospitalisation: Age: 19Y

Onset Date: 26/02/1991 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Opisthotonus			lmi cogentin 2mg.

Medicine Details:

DROPERIDOL (Suspected) Reason: Other disturbance of sensation

Injection 2.5 Milligram Total Intravenous

Batch: Started: 26/02/1991 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 24 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

eport Details:	0 4		0	L F
Case Number: 69935	Seq: 1			ler: F
Reported: 08/02/1991 spitalisation:	Į.		Weig	nt: ge: 26Y
Onset Date: 31/12/1990	1			ge. 201 OB:
Outcome: Recovered				ity: Causality possible
action Details:			Causan	ity. Causanty possible
Preferred Term	Severity	Report De	escription	Treatment
rand mal convulsion		'	•	
uscle twitching				
ausea				
edicine Details:				
edicine Details:		Reason:		
	0.0	Reason:	Oral	
ORAZEPAM (Suspected) Tablet Batch:	0.0 Started:	Reason:	Oral Stopped:	
ORAZEPAM (Suspected) Tablet Batch: DIAZEPAM (Suspected)	Started:	Reason:	Stopped:	
Tablet Batch: DIAZEPAM (Suspected) Tablet	Started:		Stopped:	
.ORAZEPAM (Suspected)	Started:	Reason:	Stopped: Oral Stopped:	
Tablet Batch: DIAZEPAM (Suspected) Tablet	Started: 0.0 Started:		Stopped:	sensation
Tablet Batch: DIAZEPAM (Suspected) Tablet Batch: DIAZEPAM (Suspected) Tablet Batch: DMNOPON (Suspected)	Started: 0.0 Started: 0.0	Reason:	Stopped: Oral Stopped: Other disturbance of s	sensation
Tablet Batch: DIAZEPAM (Suspected) Tablet Batch: DIAZEPAM (Suspected) Tablet Batch: DMNOPON (Suspected)	Started: 0.0 Started:	Reason: Reason:	Stopped: Oral Stopped: Other disturbance of s Stopped:	
Tablet Batch: DIAZEPAM (Suspected) Tablet Batch: DIAZEPAM (Suspected) Tablet Batch: DMNOPON (Suspected)	Started: 0.0 Started: 0.0 Started:	Reason:	Stopped: Oral Stopped: Other disturbance of s	
Tablet Batch: DIAZEPAM (Suspected) Tablet Batch: DIAZEPAM (Suspected) Tablet Batch: DMNOPON (Suspected) Batch: DROPERIDOL (Suspected)	0.0 Started: 0.0 Started: 0.0 Started:	Reason: Reason:	Stopped: Oral Stopped: Other disturbance of s Stopped: Other disturbance of s	
Tablet Batch: DIAZEPAM (Suspected) Tablet Batch: DIAZEPAM (Suspected) Tablet Batch: DMNOPON (Suspected)	Started: 0.0 Started: 0.0 Started:	Reason: Reason:	Stopped: Oral Stopped: Other disturbance of s Stopped:	
Tablet Batch: DIAZEPAM (Suspected) Tablet Batch: DIAZEPAM (Suspected) Tablet Batch: DMNOPON (Suspected) Batch: DROPERIDOL (Suspected)	0.0 Started: 0.0 Started: 0.0 Started:	Reason: Reason:	Stopped: Oral Stopped: Other disturbance of s Stopped: Other disturbance of s Stopped:	

Additional Information:

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

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 25 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	69935	Seq: 1		Gender:	F
Reported:	08/02/1991			Weight:	
Hospitalisation:				Age:	26Y
Onset Date:	31/12/1990			DOB:	
Outcome:	Recovered			Causality:	Causality possible
Reaction Detai	ils:				
Medicine Det	ails:				
MIDAZOLAM (Sus			Reason:	Other disturbance of sensa	ation
·		0.0			
Batch:		Started:		Stopped:	
PROPOFOL (Susp	ected)		Reason:	Other disturbance of sensa	ation
		120.0 Milligran	n Daily		
Batch:		Started:		Stopped:	
					_
l abaratarı in	waatigatiana				
Laboratory III	vestigations:				
Additional In					
- the date of onse	t is not accurate but	indicates that onset occ	urred sometime	e during the year.	

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 26 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

 Case Number:
 70325
 Seq: 1
 Gender:
 F

 Reported:
 10/12/1990
 Weight:

Hospitalisation: Age: 17

Onset Date: 08/07/1988 **DOB**: 19/09/1970

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash			Promethazine commenced, cephalothin ceased.

Medicine Details:

ENFLURANE (Suspected)		Reason:	Surgery	
Inhalation	0.0			Inhalation
Batch:	Started: 08/07/1988		Stopped:	
THIOPENTONE SODIUM (Suspected)		Reason:	Surgery	
Injection	0.0			Intravenous
Batch:	Started: 08/07/1988		Stopped:	
SUXAMETHONIUM BROMIDE (Suspected)		Reason:	Surgery	
Injection	100.0 Milligram	Total		Intravenous
Batch:	Started: 08/07/1988		Stopped:	
PANCURONIUM BROMIDE (Suspected)		Reason:	Surgery	
Injection	6.0 Milligram	Total		Intravenous
Batch:	Started: 08/07/1988		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 27 of 254



Case Number: 70325

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

			Weight:	
			Age:	17
			_	19/09/1970
		С	ausality:	Causality possible
	Reason:	Surgery		
15.0 Milligram	Total		Intravenous	
Started: 08/07/1988		Stopped:		
	Reason:	Surgery		
10.0 Milligram	Total		Intravenous	
Started: 08/07/1988		Stopped:		
	Reason:			
4.0 Gram	Daily		Intravenous	
Started: 08/07/1988		Stopped:	08/07/1988	
	10.0 Milligram Started: 08/07/1988 4.0 Gram	15.0 Milligram Total Started: 08/07/1988 Reason: 10.0 Milligram Total Started: 08/07/1988 Reason: 4.0 Gram Daily	Reason: Surgery Total Started: 08/07/1988 Stopped: Started: 08/07/1988 Stopped: Started: 08/07/1988 Stopped: Started: 08/07/1988 Stopped: Reason: Surgery Total Started: 08/07/1988 Stopped: Reason: 4.0 Gram Daily	Reason: Surgery 15.0 Milligram Total Intravenous Started: 08/07/1988 Stopped: Reason: Surgery 10.0 Milligram Total Intravenous Started: 08/07/1988 Stopped: Reason: Surgery 10.0 Milligram Total Intravenous Started: 08/07/1988 Stopped: Reason: A.0 Gram Daily Intravenous

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 28 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reported			: 1		Ger	
-	: 15/05/199	91			Wei	ight:
spitalisation						Age : 36Y
Onset Date						DOB:
	: Recovere	ed			Caus	ality: Causality possible
action Deta		<u>, </u>				
	red Term	S	everity	Repo	rt Description	Treatment
pnoea						
aralysis						
ledicine De						
PROPOFOL (Sus	pected)			Reas	on: Other disturbance of	f sensation
			0.0			
Batch:			Started:		Stopped:	
SUXAMETHONIU	IM NOS (Susp	pected)		Reas	on: Other disturbance o	f sensation
		_	0.0		•	
Batch:	DOMIDE (Oct		Started:	Desir	Stopped:	facaction
VECURONIUM B	KUMIDE (Sus	spectea)	0.0	Reas	on: Other disturbance o	or sensation
			0.0 Started:		Stopped:	
Datah.					ətoppea:	
Batch:	(Suspected)	•	Janteu.	Pose		of sensation
	(Suspected)			Reas		f sensation
NITROUS OXIDE	(Suspected)		0.0	Reas	on: Other disturbance o	f sensation
NITROUS OXIDE Batch:		;		Reas		f sensation
NITROUS OXIDE		;	0.0	Reas Result	on: Other disturbance o	f sensation Details



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Hospitalisation: Onset Date:	15/05/1991 07/11/1990 Recovered	Seq: 1		Gender: Weight: Age: DOB: Causality:	36Y
Medicine Det					
FENTANYL CITRA	TE (Suspected)		Reason:	Other disturbance of sensa	ation
		0.0			
Batch:		Started:	_	Stopped:	
DROPERIDOL (Su	spected)	0.0	Reason:	Other disturbance of sensa	ation
Batch:		Started:		Stopped:	
ENFLURANE (Sus	nected)	Starteu.	Reason:	Other disturbance of sensa	ation
EN EUNANE (Ous	pectedy	0.0	Neason.	Office disturbance of series	ation
Batch:		Started:		Stopped:	
TEMAZEPAM (Sus	spected)		Reason:	Premedication	
		20.0 Milligram	1 time)	
Batch:		Started: 07/11/1990		Stopped:	
Laboratory In	vestigations:				
Additional Inf	formation:				

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 30 of 254



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	72219	Seq:	1			Gende	er: M	
Reported:	09/08/1991					Weigh	nt: 63.00	
Hospitalisation:						Ag	e: 19Y	
Onset Date:	29/07/1991					DO	B:	
Outcome:	Not yet reco	overed				Causali	ty: Causality poss	ible
<u>leaction Detai</u>	ls:							
Preferre	ed Term	Sev	verity	Rep	ort Descri	iption	Treatmer	nt
Agitation								
Fatigue								
Insomnia								
Medicine Deta								
DROPERIDOL (Su	spected)					ner disturbance of se		
Injection Batch:		•	2.5 Milli arted: 29/07/1	-	1 time	Intraver Stopped:	nous	
Laboratory In	vestigatio	ons:						
Date	Туре		Date Tested	Result		De	etails	
Additional Inf	formation	:						
eport Run: 01/06/200	07 04:49PM	Database: pus	sime02		ADRS004		Page 31	of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

Case Number: 72472 Seq: 1 Gender: M

Reported: 07/08/1991 **Weight:** 65.00

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

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			
Preferred Term		Severity	Report Description	Treatment
	Dystonia	Severe	Dystonic reaction affecting mouth/tongue	Settled with 6 mg cogentin
	Tremor		Whole body tremors	

Medicine Details:

NILSTAT (Other drug)		Reason:	
Mouthwash	40.0 Millilitre	Buccal	
Batch:	Started:	Stopped:	
ZANTAC (Other drug)		Reason: Other diseases of esophagus	
Tablet	300.0 Milligram	Oral	
Batch:	Started: 12/06/1991	Stopped:	
LASIX (Other drug)		Reason:	
Injection	20.0 Milligram	As necessary Intravenous	
Batch:	Started: 11/06/1991	Stopped: 17/06/1991	
ZOFRAN (Other drug)		Reason: Nausea and vomiting	
Oral application	24.0 Milligram	Daily Oral	
Batch:	Started: 12/06/1991	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 32 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detail	07/08/1991 16/06/1991 Recovered Is:	Seq: 1	Gender: Weight: Age: DOB: Causality:	65.00
Medicine Deta				
DROLEPTAN (Susp	pected)		Reason: Nausea and vomiting	
		1.0 Milligram	Per hour	
Batch:		Started: 15/06/1991	Stopped: 16/06/199	
Laboratory In	vestigations:			
Additional Inf	ormation:			

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 33 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Re	ро	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 74464 Seq: 1 Gender: M

Reported: 27/11/1991 Weight: 88.00 Hospitalisation: Age: 31Y

Onset Date: 22/11/1991 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin
Torticollis			

Medicine Details:

DROPERIDOL (Suspected)
Injection
Reason: Nausea and vomiting
3 times Intramuscular

Batch: Started: 21/11/1991 **Stopped:** 22/11/1991

OMNOPON (Suspected) Reason:

 Injection
 20.0 Milligram
 1 time
 Intramuscular

 Batch:
 Started: 21/11/1991
 Stopped: 22/11/1991

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 34 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 74501 Seq: 1 Gender: F

Reported: 02/12/1991 Weight: 80.00 Hospitalisation: Age: 46Y

Onset Date: 29/11/1991 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest		Cardiac asystole.	

Medicine Details:

DROPERIDOL (Suspected) Reason: Premedication

Injection 10.0 Milligram 1 time Intramuscular

Batch: Started: 29/11/1991 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient history: diazepam - dystonic reaction clindamycin - pseudomembranous colitis brufen - vomiting.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 35 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 75462 Seq: 1 Gender: M
Reported: 06/02/1992 Weight:
Hospitalisation: Age: 21Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Dotails.			
	Preferred Term	Severity	Report Description	Treatment
	Abdominal pain			
	Renal tubular necrosis			

Medicine Details:

NITROUS OXIDE (Suspected)		Reason:	Other disturbance of sensation	
	0.0			
Batch:	Started:	Stopped:		
ISOFLURANE (Suspected)		Reason:	Other disturbance of sensation	
	0.0			
Batch:	Started:		Stopped:	
DROPERIDOL (Suspected)		Reason:	Other disturbance of sensation	
	0.0			
Batch:	Started:		Stopped:	
FENTANYL CITRATE (Suspected)		Reason:	Other disturbance of sensation	
	0.0			
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine		03/12/1991	0.22	
	Creatinine		05/12/1991	0.29	
	Creatinine		07/12/1991	0.24	
	Renal biopsy =				Acute tubular necrosis.

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 36 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:			
Case Number: 754 Reported: 06/0 Hospitalisation: Onset Date: Outcome: Rec Reaction Details:)2/1992	Gender: Weight: Age: DOB: Causality:	21Y
Medicine Details PROPOFOL (Suspected		Reason: Other disturbance of sens.	ation
Batch:	0.0 Started:	Stopped:	
Laboratory Inves	etigations:		
Additional Inform	nation:		

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 37 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reported: 27/02 pspitalisation: Onset Date: 26/02 Outcome: Reco	2/1992	: 1			Gender: F Weight: Age: 33 DOB: Causality: Ca	Y nusality probable
action Details: Preferred Tel	rm Se	everity	Rei	oort Description		Treatment
ystonia	-		- 1			
ledicine Details:	Awara)		Pa	ason:		
MORPHINE NOS (Other of Injection	arug)	5.0	Milligram	As necessary	Subcutaneous	
Batch:	s	tarted:	Willing Carri	Stopped		
MANSERIN HYDROCHLO			Re	ason:	-	
	,	20.0	Milligram	Daily		
Batch:	s	tarted:		Stopped	l:	
		tarted:	Re	Stopped ason: Nausea and		
			R e Milligram			
DROPERIDOL (Suspecte	d)		Milligram	ason: Nausea and As necessary	vomiting	
DROPERIDOL (Suspecte Injection Batch:	d) S	2.5	Milligram 02/1992	ason: Nausea and As necessary	vomiting Intravenous	
Injection Batch: Batch:	s igations:	2.5 tarted: 25/0	Milligram 02/1992	ason: Nausea and As necessary	vomiting Intravenous 1: 26/02/1992	

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 38 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number: 76088 Seq: 1 Gender: M

Reported: 20/03/1992 Weight: 80.00 Hospitalisation: Age: 42Y

Onset Date: 20/03/1992 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Tonic clonic reaction	

Medicine Details:

PROPOPOL (Suspected)		Reason:		
	0.0			
Batch:	Started:		Stopped:	

TEMAZEPAM (Suspected)

Reason: Premedication

20.0 Milligram Daily

Batch: Started: 20/03/1992 Stopped:

MAXOLON (Suspected) Reason: Premedication

10.0 Milligram Daily

Batch: Started: 20/03/1992

Batch: Started: 20/03/1992 Stopped:

FENTANYL CITRATE (Suspected) Reason: Premedication

50.0 Microgram Daily

Batch: Started: 20/03/1992 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 39 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:				
Case Number: 76088 Reported: 20/03/1992 Hospitalisation: Onset Date: 20/03/1992 Outcome: Recovered	Seq: 1		Gender: Weight: Age: DOB:	80.00 42Y
Reaction Details:			odusanty.	Caddanty possible
Medicine Details:				
DROPERIDOL (Suspected)		Reason: Premedica	ation	
Batch:	1.2 Milligram Started: 20/03/1992	Daily Stopp	od:	
Laboratory Investigations:				
Additional Information:				

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 40 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 77057 Seq: 1 Gender: F
Reported: 18/05/1992 Weight:

Hospitalisation: Age: 36Y
Onset Date: 04/05/1992
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Post operative convulsions	

Medicine Details:

DROPERIDOL (Suspected)		Reason: Other disturbance of sensation
Injection	2.5 Millig	gram Intravenous
Batch:	Started:	Stopped:
NITROUS OXIDE (Suspected)		Reason: Other disturbance of sensation
	0.0	
Batch:	Started:	Stopped:
PROPOFOL (Suspected)		Reason: Other disturbance of sensation
Injection	150.0 Millig	gram Daily Intravenous
Batch:	Started:	Stopped:
MIDAZOLAM (Suspected)		Reason: Other disturbance of sensation
Injection	5.0 Millig	gram Daily Intravenous
Batch:	Started:	Stopped:

Laboratory Investigations:

Luboratory investigations.								
Date	Туре	Range	Date Tested	Result	Details			

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 41 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	77459	Seq: ²	1				Gender	: F	
Reported:		_					Weight		
spitalisation:							Age	: 28Y	
Onset Date:	07/03/1992	2					DOB	:	
Outcome:	Recovered					C	ausality	: Causality poss	ible
action Detai									
Preferre	ed Term	Sev	erity	Rep	ort Desc	ription		Treatme	
ystonia							C di	ogentin 2mg imi to operidol.	reverse
edicine Deta					ison:				
Injection Batch:		_	5.0 Milli rted: 04/03/19	_	5 times	Stopped:	Intramus		
aboratory In	vestigati Type		Date Tested	Result			Deta	nile	
Date	Туре	range L	Jale Tested	rtesuit			Deta	2113	
Additional Inf	ormation	:							
ort Run: 01/06/200									



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 77471 Seq: 1 Gender: M

Reported: 05/06/1992 Weight:
Hospitalisation: Age: 32Y

Onset Date: 05/06/1992 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Red blotchy rash on trunk and arms	

Medicine Details:

MORPHINE NOS (Suspected)		Reason: Pain	
Injection, intravenous infusion	50.0 Milligram	Daily	Intravenous
Batch:	Started: 05/06/1992	Stoppe	d: 05/06/1992
DROPERIDOL (Suspected)		Reason: Nausea and	l vomiting
Injection, intravenous infusion	5.0 Milligram	Daily	Intravenous
Batch:	Started: 05/06/1992	Stoppe	d: 05/06/1992

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 78254 Seq: 1 Gender: F

 Reported:
 03/10/1991
 Weight:
 75.00

 Hospitalisation:
 Age:
 45Y

Onset Date: 30/08/1991 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia			

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	Other&unspecified epilepsy	
Oral application	600.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	CONTIN
THYROXINE SODIUM (Other drug)		Reason:	Myxedema	
Tablet	150.0 Microgram	Daily	Oral	
Batch:	Started:		Stopped:	CONTIN
OXAZEPAM (Other drug)		Reason:		
Tablet	90.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	CONTIN
DROPERIDOL (Suspected)		Reason:	Nausea and vomiting	
Injection	10.0 Milligram	1 time	e Intramuscular	
Batch:	Started: 29/08/1991		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Oculogyric crisis previously experienced with maxolon and stemetil (phenothiazines) 29/10/82.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 44 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

R	Δ	n	<u></u>	rt	D	eta	۱i	le	•
	G	u	u	IL	$\boldsymbol{\omega}$	CLC			

Case Number: 78661 Seq: 1 Gender: F

Reported: 10/08/1992 Weight: 55.00 Hospitalisation: Age: 22Y

Onset Date: 06/08/1992 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin

Medicine Details:

DROPERIDOL (Suspected) Reason: Nausea and vomiting

Injection 2.5 Milligram Daily Intramuscular

Batch: Started: 05/08/1992 Stopped: 06/08/1992

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

 Case Number:
 79494
 Seq: 1
 Gender: M

 Reported:
 16/09/1992
 Weight:

Hospitalisation: Admitted to hospital Age: 15Y
Onset Date: 11/09/1992
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Betails.				
Preferred Term	Severity	Report Description	Treatment	ĺ
Tremor		Tremor in lower, then upper limbs.		l
Dystonia				l
Extrapyramidal disorder			Congentin 1mg im.	l

Medicine Details:

Medicine Details.				
MAXOLON (Suspected)		Reason: Surgery		
Injection	10.0 Milligram	1 time	Intravenous	
Batch:	Started: 11/09/1992	Stopp	ed:	
DROPERIDOL (Suspected)		Reason:		
Injection	2.5 Milligram	1 time	Intravenous	
Batch:	Started: 11/09/1992	Stopp	ed:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 46 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 80557 Seq: 1 Gender: F

Reported: 16/10/1992 Weight: 57.00 Hospitalisation: Age: 32Y

Onset Date: 14/10/1992 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Benztropine 2mg iv

Medicine Details:

RANITIDINE (Other drug)		Reason:			
Oral application	300.0 Milligram	Daily		Oral	
Batch:	Started: L	TERM	Stopped:		CONTIN
OMNOPON (Suspected)		Reason:	Other disturba	nce of sensation	
Injection	20.0 Milligram	1 time)	Intravenous	
Batch:	Started: 14/10/1992		Stopped:	14/10/1992	
STEMETIL (Suspected)		Reason:			
Injection	12.5 Milligram	1 time)	Intravenous	
Batch:	Started: 14/10/1992		Stopped:	14/10/1992	
DROLEPTAN (Suspected)		Reason:			
Injection	2.5 Milligram	1 time)	Intravenous	
Batch:	Started: 14/10/1992		Stopped:	14/10/1992	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 47 of 254



Report Details:

Case Number: 80557

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

Reported: 16/ italisation: Onset Date: 14/ Outcome: Re tion Details:	/10/1992 covered					Weight: 57 Age: 32 DOB:	
Outcome: Re	covered					DOB:	
Outcome: Re							
tion Details:					С	ausality: C	ausality possible
cine Details	. .						
	LORIDE (Suspected)		Re	ason:			
Injection			Milligram	1 time		Intramuscular	
Batch:		Started: 13/1	0/1992		Stopped:	13/10/1992	
LON (Suspected	i)		Re	ason:			
Injection		10.0	Milligram	1 time		Intramuscular	
Batch:		Started: 13/1	0/1992		Stopped:	13/10/1992	
RIN SODIUM (Su	spected)		Re	ason:			
Injection, intrave	enous infusion	1.0	Thousand Interna	at Per hour		Intravenous	
Batch:		Started: 14/1	0/1992		Stopped:		CONTIN

ADRS004 Page 48 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 80923 Seq: 1 Gender: F

Reported: 12/11/1992 Weight: 70.00 Hospitalisation: Age: 33

Onset Date: 11/11/1992 **DOB**: 27/01/1959

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor			Cogentin iv 2mg.

Medicine Details:

MAXOLON (Suspected)		Reason: Hyperemes gravidar w/o neurits
Injection	20.0 Milligram	2 times Intravenous
Batch:	Started: 11/11/1992	Stopped : 11/11/1992
STEMETIL (Suspected)		Reason: Hyperemes gravidar w/o neurits
Suppository	25.0 Milligram	As necessary Rectal
Batch:	Started: 03/11/1992	Stopped : 10/11/1992
PYRIDOXINE HYDROCHLORIDE (S	uspected)	Reason: Hyperemes gravidar w/o neurits
Injection	50.0 Milligram	Daily Intramuscular
Batch:	Started: 11/11/1992	Stopped:
DROPERIDOL (Suspected)		Reason: Hyperemes gravidar w/o neurits
Injection	7.5 Milligram	Daily Intramuscular
Batch:	Started: 10/11/1992	Stopped: 11/11/1992

Laboratory Investigations:

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

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 49 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

Case Number: 81751 Seq: 1 Gender: M

Reported: 24/12/1992 Weight:
Hospitalisation: Age: 12

Onset Date: 19/12/1992 DOB: 10/09/1980

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			8mg cogentin iv.

Medicine Details:

DROPERIDOL (Suspected) Reason:

Injection 3.0 Milligram 4 times Intramuscular

Batch: Started: 18/12/1992 Stopped: 19/12/1992

PANADOL (Suspected) Reason: Pain

750.0 Milligram As necessary

Batch: Started: 19/12/1992 Stopped: 21/12/1992

CODEINE (Suspected) Reason: Pain

20.0 Milligram As necessary

Batch: Started: 19/12/1992 **Stopped:** 19/12/1992

BRICANYL (Suspected) Reason: Bronchitis,unqualified

Inhalation 2.0 Dose Unspecified As necessary Inhalation

Batch: Started: 16/12/1992 Stopped: 21/12/1992

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient appears to be sensitive to narcotics.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 50 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	81751	Seq: 1		Gender:	M
Reported:	24/12/1992	•		Weight:	
ospitalisation:				Age:	12
Onset Date:	19/12/1992				10/09/1980
Outcome:	Recovered		С	ausality:	Causality possible
action Detail	ls:				
<u>ledicine Deta</u>					
	OCHLORIDE (Suspect		Reason: Pain		
	travenous infusion	6.5 Milligram	Per hour	Intravenous	
Batch:		Started: 16/12/1992	Stopped:	19/12/1992	
			,		
aboratory In	vestigations:				
aboratory In	vestigations:				
aboratory In	vestigations:				
aboratory In	vestigations:				
aboratory In	vestigations:				
aboratory In	vestigations:				
aboratory In	vestigations:				
aboratory In	vestigations:				
dditional Info	ormation:				
Additional Info					
dditional Info	ormation:				
dditional Info	ormation:				

Page 51 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 82184 Seq: 1 Gender: F

 Reported: 28/01/1993
 Weight: 60.00

 Hospitalisation:
 Age: 30Y

 Onset Date: 27/01/1993
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bronchospasm		Bronchoconstriction	Salbutamol.

Medicine Details:

ATRACURIUM BESYLATE (Suspected)			Reason:		
Injection	50.0	Milligram	Daily		Intravenous
Batch:	Started:			Stopped:	
SUXAMETHONIUM BROMIDE (Suspected)			Reason:		
Injection	100.0	Milligram	Daily		Intravenous
Batch:	Started:			Stopped:	
PROPOFOL (Suspected)			Reason:		
Injection	200.0	Milligram	Daily		Intravenous
Batch:	Started:			Stopped:	
TORADOL (Suspected)			Reason:		
Injection	30.0	Milligram	Daily		Intramuscular
Batch:	Started: 27/	/01/1993		Stopped:	27/01/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 52 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 82184 Seq: 1 Gender: F

Reported: 28/01/1993 Weight: 60.00 Hospitalisation: Age: 30Y

Onset Date: 27/01/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

DROLEPTAN (Suspected)	Reason:				
Injection	5.0 Milligram	Daily	Intravenous		
Batch:	Started: 27/01/1993	Stopped:	27/01/1993		
MAXOLON (Suspected)	R	Reason:			
Injection	10.0 Milligram	Daily	Intramuscular		
Batch:	Started: 27/01/1993	Stopped:	27/01/1993		
MEFOXIN (Suspected)	R	Reason:			
Injection	1.0 Gram	Daily	Intravenous		
Batch:	Started: 27/01/1993	Stopped:	27/01/1993		
FENTANYL CITRATE (Suspected)	R	Reason:			
Injection	100.0 Microgram	Daily	Intravenous		
Batch:	Started: 27/01/1993	Stopped:	27/01/1993		

Laboratory Investigations:

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 53 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:				
Case Number: 82184	Seq: 1		Gender:	F
Reported: 28/01/1993	•		Weight:	60.00
Hospitalisation:			Age:	
Onset Date: 27/01/1993			DOB:	
Outcome: Recovered				Causality possible
Reaction Details:				cadeamy possible
Medicine Details:				
ATROPINE (Suspected)		Reason:		
Injection	600.0 Microgram	Daily	Intravenou	s
Batch:	Started: 27/01/1993	·	Stopped: 27/01/1993	
Laboratory Investigations:				
g				
Additional Information:				

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 54 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

R	er	n	rt	D	eta	il	S	•

Gender: F Case Number: 83315 Seq: 1

Weight: 55.00 Reported: 19/03/1993 **Hospitalisation:** Age: 41Y

Onset Date: 23/02/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

eaction Details.							
Preferred Term	Severity	Report Description	Treatment				
Agitation			Cogentin				
Hyperkinesia							
Paraesthesia							
Thinking abnormal							

Medicine Details:

DROPERIDOL (Suspected)		Reason: Other disturbance of sensation	
	5.0 Microgram	1 time	
Batch:	Started: 23/02/1993	Stopped:	
MAXOLON (Suspected)		Reason: Other disturbance of sensation	
	10.0 Milligram	1 time	
Batch:	Started: 23/02/1993	Stopped:	
FENTANYL CITRATE (Suspected)		Reason: Other disturbance of sensation	
	80.0 Milligram	1 time	
Batch:	Started: 23/02/1993	Stopped:	
DIPRIVAN (Suspected)		Reason: Other disturbance of sensation	
	50.0 Milligram	1 time	
Batch:	Started: 23/02/1993	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 55 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:			
Case Number: 83315	Seq: 1	Gender:	F
Reported: 19/03/1993	•	Weight:	
Hospitalisation:		Age:	
-		DOB:	
Onset Date: 23/02/1993			
Outcome: Recovered		Causality:	Causality possible
Reaction Details:			
Medicine Details:			
MIDAZOLAM (Suspected)		Reason: Other disturbance of sens	ation
	3.5 Milligram	1 time	
Batch:	Started: 23/02/1993	Stopped:	
Laboratory Investigations			
Laboratory Investigations:			
Additional Information:			
Additional Information:			

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 56 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

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

Case Number: 84248 Seq: 1 Gender: F

Reported: 27/04/1993 Weight: 72.00 Hospitalisation: Age: 38

Onset Date: 19/03/1993 **DOB**: 31/10/1954

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ficiented Tellii	Seventy	Mehour Describition	Heatinent
Oculogyration			Valium 10mg, cogentin 2mg im, observation for 3 hours.

Medicine Details:

PANADEINE (Other drug) Reason: Pain

Oral application 2.0 Dose Unspecified Daily Oral

Batch: **Started**: 17/03/1993 **Stopped**: 20/03/1993

DROPERIDOL (Suspected) Reason: Nausea and vomiting

Injection 1.2 Milligram Daily Intravenous

Batch: Started: 18/03/1993 Stopped: 19/03/1993

Laboratory Investigations:

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

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 57 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 84781 Seq: 1 Gender: F

Reported: 31/05/1993 Weight:
Hospitalisation: Age: 18Y

Onset Date: 09/04/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			

Medicine Details:

TEMAZEPAM (Other drug)	Reas	on:	Specific disord	ders of sleep
Capsule	20.0 Milligram	Daily		Oral
Batch:	Started: 06/04/1993		Stopped:	12/04/1993
PANADEINE (Other drug)	Reas	on:	Pain	
Oral application	12.0 Dose Unspecified	Daily		Oral
Batch:	Started: 06/04/1993		Stopped:	13/04/1993
VALIUM (Suspected)	Reas	on:	Abnormal invo	luntary movement
	5.0 Milligram	1 time	e	
Batch:	Started: 09/04/1993		Stopped:	
MAXOLON (Suspected)	Reas	on:	Nausea and v	omiting
Injection	40.0 Milligram	Daily		Intramuscular
Batch:	Started: 06/04/1993			08/04/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 58 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:				
Case Number: 84781 Reported: 31/05/1993 Hospitalisation: Onset Date: 09/04/1993 Outcome: Recovered	Seq: 1		Gender: Weight: Age: DOB: Causality:	18Y
Reaction Details:				Table 1
Medicine Details: DROPERIDOL (Suspected)		Reason:	Nausea and vomiting	
Batch:	20.0 Milligram Started: 08/04/1993	Daily	Stopped: 09/04/1993	
Laboratory Investigations:				
Additional Information:				

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 59 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 87046 Seq: 1 Gender: F

 Reported: 25/08/1993
 Weight: 57.00

 Hospitalisation:
 Age: 45Y

Onset Date: 12/08/1993 **DOB:**

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

- 10 to 0 to 11 = 0 to 110 to 1			
Preferred Term	Severity	Report Description	Treatment
Dermatitis bullous		Blue/black blisters on r thumb & finger.	
Pruritus		Itchy at nape, breasts & extremities.	
Rash			

Medicine Details:

PETHIDINE HYDROCHLORIDE (Suspected)		Reas	on:	Other disturba	nce of sensation
Injection	75.0 M	lilligram	As neo	cessary	Intramuscular
Batch:	Started: 11/08/	/1993		Stopped:	13/08/1993
PANADEINE (Suspected)		Reas	on:		
Oral application	2.0 Do	ose Unspecified	Daily		Oral
Batch:	Started: 10/08/	/1993		Stopped:	14/08/1993
MONOPRIL (Suspected)		Reas	on:	Essential beniq	gn hypertension
Tablet	10.0 M	lilligram	Daily		Oral
Batch:	Started: 10/08/	/1993		Stopped:	14/08/1993
ADALAT (Suspected)		Reas	on:	Essential beniq	gn hypertension
Tablet	10.0 M	lilligram	Daily		Oral
Batch:	Started: 10/08/	/1993		Stopped:	13/08/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has had a previous reaction in penicillin.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 60 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 87046 Seq: 1 Gender: F

 Reported: 25/08/1993
 Weight: 57.00

 Hospitalisation:
 Age: 45Y

Onset Date: 12/08/1993 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

DROPERIDOL (Suspected)		Reason:	Nausea and v	omiting
Injection	2.0 Milligram	Daily		Intramuscular
Batch:	Started: 11/08/1993		Stopped:	13/08/1993
HEPARIN SODIUM (Suspected)		Reason:		
Injection	10.0 Thousand Inte	rnat Daily		Subcutaneous
Batch:	Started: 11/08/1993		Stopped:	13/08/1993
MAXOLON (Suspected)		Reason:	Nausea and ve	omiting
Injection	40.0 Milligram	Daily		Intramuscular
Batch:	Started: 11/08/1993		Stopped:	14/08/1993

Laboratory Investigations:

Additional Information:

Patient has had a previous reaction in penicillin.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 61 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:	Rei	port	Deta	ils:
-----------------	-----	------	------	------

Case Number: 87490 Seq: 1 Gender: F

Reported: 06/09/1993 Weight: 59.00 Hospitalisation: Age: 36Y

Onset Date: 11/06/1993 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	cuotion Details.										
	Preferred Term	Severity	Report Description	Treatment							
	Injection site reaction										
	Urticaria										

Medicine Details:

ISOFLURANE (Other drug) Reason	on: Ot	her disturbance of sensation
--------------------------------	--------	------------------------------

0.0

Batch: Started: Stopped:

ATROPINE (Suspected) Reason:

0.0

Batch: Started: Stopped:

NEOSTIGMINE NOS (Suspected) Reason:

0.0

Batch: Started: Stopped:

MORPHINE NOS (Suspected)Reason:Other disturbance of sensationInjection15.0MilligramDailyIntravenous

Batch: Started: 11/06/1993 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has had no known previous allergies.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 62 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 87490 Seq: 1 Gender: F

Reported: 06/09/1993 Weight: 59.00 Hospitalisation: Age: 36Y

Onset Date: 11/06/1993 **DOB:**

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

DROPERIDOL (Suspected)		Reason:		
Injection	15.0 Milligram	Daily	Intravenous	
Batch:	Started: 11/06/1993		Stopped:	
GLYCOPYRROLATE (Suspected)		Reason:		
Injection	200.0 Microgram	Daily	Intravenous	
Batch:	Started: 11/06/1993		Stopped:	
PROPOFOL (Suspected)		Reason:	Other disturbance of sensation	
Injection	150.0 Milligram	Daily	Intravenous	
Batch:	Started: 11/06/1993		Stopped:	
ATRACURIUM BESYLATE (Suspected)		Reason:		
Injection	35.0 Milligram	Daily	Intravenous	
Batch:	Started: 11/06/1993		Stopped:	

Laboratory Investigations:

Additional Information:

Patient has had no known previous allergies.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 63 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	87490	Seq: 1		Gender:	F
Reported:	06/09/1993			Weight:	59.00
Hospitalisation:				Age:	36Y
Onset Date:	11/06/1993			DOB:	
Outcome:	Recovered			Causality:	Causality possible
Reaction Detai	ls:				
Medicine Deta	aile:				
Keflin Neutral (Sus			Reason: Prop	hylaxis	
Injection	. ,	1.0 Gram	Daily	Intravenous	3
Batch:		Started: 11/06/1993		Stopped:	
l abaratanı in	vootigationa				
Laboratory In	vestigations.				
Additional Inf					
Patient has had no	known previous all	ergies.			

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 64 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

 Case Number:
 87961
 Seq: 1
 Gender:
 F

 Reported:
 28/09/1993
 Weight:
 68.00

Hospitalisation: Age: 39Y
Onset Date: 01/06/1993
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	toaction Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Nausea			
	Vomiting			

Medicine Details:

MORPHINE NOS (Suspected)		Reason:	Pain	
Injection, intravenous infusion	0.0			Intravenous
Batch:	Started: 31/05/1993		Stopped:	01/06/1993
MAXOLON (Suspected)		Reason:	Nausea and ve	omiting
Injection, intravenous infusion	0.0			Intravenous
Batch:	Started: 31/05/1993		Stopped:	01/06/1993
OMNOPON-SCOPOLAMINE (Suspected)		Reason:		
Injection	0.0			Intramuscular
	0.0			Intramuscular
Batch:	Started: 31/05/1993		Stopped:	ini amusculai
Batch: DROPERIDOL (Suspected)		Reason:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Infusion ceased and patient commenced on toradol im.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 65 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	87961	Seq: 1		Gender: F	=
	28/09/1993	•		Weight: 6	
lospitalisation:				Age: 3	
Onset Date:	01/06/1993			DOB:	
Outcome:	Not yet recovered	j	C		Causality possible
eaction Detai				-	• •
Medicine Det					
HEPARIN CALCIU	M (Suspected)	Rea	ason:		
Injection		15.0 Thousand Internat	Daily	Subcutaneou	us
Batch:		Started: 31/05/1993	Stopped:	01/06/1993	
Laboratory In	vestigations:				
Additional Infusion ceased ar	formation: nd patient commence	ed on toradol im.			
	07 04.40014 5 ' '		A D.D.0004		

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 66 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 88398 Seq: 1 Gender: U

Reported: 11/10/1993 **Weight:** 83.00

Hospitalisation: Age:
Onset Date: 30/09/1993
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Neck stiff.	Cogentin 1gm iv.

Medicine Details:

MORPHINE HYDROCHLORIDE (Suspected)			Reason:	Premedication	
Injection	15.0	Milligram	1 time	е	Intramuscular
Batch:	Started:			Stopped:	
DROPERIDOL (Suspected)			Reason:	Premedication	
Injection	1.0	Milligram	1 time	e	Intramuscular
Batch:	Started:			Stopped:	
Keflin Neutral (Suspected)			Reason:		
Injection	4.0	Gram	Daily		Intravenous
Batch:	Started:			Stopped:	
FLAGYL (Suspected)			Reason:		
Injection	1.0	Gram	Daily		Intravenous
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 67 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 88502 Seq: 1 Gender: M

Reported: 15/10/1993 Weight: 68.00 Hospitalisation: Age: 16Y

Onset Date: 30/09/1993 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Iv cogentin 2mg.

Medicine Details:

DROPERIDOL (Suspected) Reason:

Injection, intravenous infusion 4.0 Milligram Total Intravenous

Batch: Started: 29/09/1993 Stopped: 30/09/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has had no known previous allergies.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 68 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:		
Case Number: 89459	Sea: 1	Gender: F

Reported: 30/11/1993 Weight: 44.00
Hospitalisation: Age: 38Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Hypertonia			Benztropine 2mg im stat.

Medicine Details:

DROPERIDOL (Suspected)			Reason:	
Injection	10.0	Milligram	1 time	Intramuscular
Batch:	Started: 24	/11/1993	Stopped	:
PETHIDINE HYDROCHLORIDE (Suspected)			Reason:	
Injection	20.0	Milligram	1 time	Intramuscular
Batch:	Started:		Stopped	:
PROMETHAZINE HYDROCHLORIDE (Suspe	ected)		Reason:	
Injection	50.0	Milligram	As necessary	Intramuscular
Batch:	Started:		Stopped	:
DIAZEPAM (Suspected)			Reason:	
Injection	10.0	Milligram	As necessary	Intramuscular
Batch:	Started:		Stopped	:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 69 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Hospitalisation: Onset Date: Outcome: Reaction Detai	30/11/1993 Recovered Is:	Seq: 1			Gender: Weight: Age: DOB: Causality:	44.00 38Y
Medicine Deta						
PROTHIADEN (Sus	spected)			leason:		
			Milligram	Daily		
Batch:		Started:			Stopped:	
ROHYPNOL (Susp	ected)	4.0		leason:		
Batch:		Started:	Dose Unspecifie	ed Dally	Stopped:	
Laboratory In	vestigations:					
Additional Inf	ormation:					

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 70 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 90557 Seq: 1 Gender: F

Reported: 19/01/1994 Weight:
Hospitalisation: Age: 35Y

Onset Date: 12/01/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Cogentin 5mg iv.

Medicine Details:

DROPERIDOL (Suspected) Reason: Premedication

5.0 Milligram 1 time

Batch: Started: 12/01/1994 Stopped: 12/01/1994

MORPHINE NOS (Suspected) Reason: Premedication

10.0 Milligram 1 time

Batch: Started: 12/01/1994 Stopped: 12/01/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 71 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 90876 Seq: 1 Gender: F

Reported: 03/02/1994 Weight: 60.00 Hospitalisation: Age: 18Y

Onset Date: 21/01/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Benztropine 2mg

Medicine Details:

AMPICILLIN (Other drug)		Reason:			
	0.0				
Batch:	Started:			Stopped:	
FLAGYL (Other drug)			Reason:		
Injection	1.5	Gram	Daily		Intravenous
Batch:	Started:			Stopped:	
FENTANYL CITRATE (Suspected)			Reason:	Other disturba	nce of sensation
Injection	3.0	Millilitre	1 time)	Intravenous
Batch:	Started: 21/	01/1994		Stopped:	21/01/1994
DROPERIDOL (Suspected)			Reason:		
Injection	2.5	Milligram	1 time)	Intravenous
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Allergic to morphine, maxalon, stemetil

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 72 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 91229 Seq: 1 Gender: F

Reported: 23/02/1994 Weight: 68.00 Hospitalisation: Age: 34

Onset Date: 14/06/1993 **DOB**: 12/08/1958

Outcome: Recovered Causality: Causality possible

Reaction Details:

٠,	odotion botano								
	Preferred Term	Severity	Report Description	Treatment					
	Dystonia			Cogentin imi 1mg stat than repeat in 30 mins.					
	Oculogyration								

Medicine Details:

CALCIPARINE (Other drug)	R	eason:	
Injection	10.0 Thousand Intern	at Daily	Subcutaneous
Batch:	Started: 11/06/1993	Stopped:	14/06/1993
TORADOL (Other drug)	R	eason: Other disturba	nce of sensation
Injection	30.0 Milligram	Daily	Intramuscular
Batch:	Started: 11/06/1993	Stopped:	16/06/1993
PETHIDINE HYDROCHLORIDE (Other drug)	R	eason: Pain	
Injection	800.0 Milligram	Daily	Intramuscular
Batch:	Started: 11/06/1993	Stopped:	14/06/1993
VALIUM (Other drug)	R	eason:	
Injection	20.0 Milligram	Daily	Intravenous
Batch:	Started: 11/06/1993	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient allergic to voltaren, adhesive plaster, pethidine.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 73 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 91229 Seq: 1 Gender: F

Reported: 23/02/1994 Weight: 68.00 Hospitalisation: Age: 34

Onset Date: 14/06/1993 **DOB**: 12/08/1958

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

DROPERIDOL (Suspected)		Reason:	Nausea and vo	omiting
Injection	30.0 Milligram	Daily		Intramuscular
Batch:	Started: 10/06/1993		Stopped:	14/06/1993
STEMETIL (Suspected)		Reason:	Nausea and vo	omiting
Injection	75.0 Milligram	Daily		Intramuscular
Batch:	Started: 10/06/1993		Stopped:	14/06/1993
TEMAZEPAM (Suspected)		Reason:	Pain	
Capsule	1.0 Dose Unspeci	fied Daily		Oral
Batch:	Started: 10/06/1993		Stopped:	14/06/1993

Laboratory Investigations:

Additional Information:

Patient allergic to voltaren, adhesive plaster, pethidine.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 74 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 91605 Seq: 1 Gender: F

Reported: 14/03/1994 Weight: 56.00 Hospitalisation: Age: 16Y

Onset Date: 02/02/1994 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

100011011 D 0101101								
Preferred Term	Severity	Report Description	Treatment					
Opisthotonus		Arching back.						
Dystonia			Iv cogentin 2mg.					

Medicine Details:

MAXOLON (Suspected)	Reason:				
Injection	10.0	Milligram	1 time	Intravenou	ıs
Batch:	Started: 02/	02/1994		Stopped:	
PETHIDINE HYDROCHLORIDE (Suspected)			Reason:		
Injection	50.0	Milligram	1 time	Intravenou	ıs
Batch:	Started: 02/	02/1994		Stopped:	
ATROPINE (Suspected)			Reason:		
Injection	300.0	Microgram	1 time	Intravenou	JS
Batch:	Started: 02/	02/1994		Stopped:	
PROPOFOL (Suspected)			Reason:		
Injection	160.0	Milligram	1 time	Intravenou	us
Batch:	Started: 02/	00/4004		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 75 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 91605 Seq: 1 Gender: F

Reported: 14/03/1994 Weight: 56.00 Hospitalisation: Age: 16Y

Onset Date: 02/02/1994 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

LIGNOCAINE (Suspected)	ı	Reason:		
Injection	100.0 Milligram	1 time	Intravenous	
Batch:	Started: 02/02/1994	Stop	pped:	
DROPERIDOL (Suspected)	ı	Reason:		
Injection	4.0 Milligram	1 time	Intravenous	
Batch:	Started: 02/02/1994	Stop	pped:	
NARCAN (Suspected)	ı	Reason:		
Injection	400.0 Microgram	1 time	Intravenous	
Batch:	Started: 02/02/1994	Stop	pped:	
TORADOL (Suspected)	ı	Reason:		
Injection	30.0 Milligram	1 time	Intravenous	
Batch:	Started: 02/02/1994	Stor	pped:	

Laboratory Investigations:

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 76 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number: 91605 Reported: 14/03/1994 Hospitalisation: Onset Date: 02/02/1994 Outcome: Recovered Reaction Details: Medicine Details:	Seq: 1		Gender: Weight: Age: DOB: Causality:	56.00
TACRINE HYDROCHLORIDE (Suspec	ted)	Reason:		
Injection	30.0 Milligram	1 time	Intravenous	
Batch:	Started: 02/02/1994	Stop		
Laboratory Investigations	:			
Additional Information:				

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 77 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

 Case Number:
 91626
 Seq: 1
 Gender: M

 Reported:
 15/03/1994
 Weight:

Hospitalisation: Age: 20Y
Onset Date: 03/02/1994
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Dyspnoea			Cogentin 2mg, admission to icu.
	Dysphagia			

Medicine Details:

Keflin Neutral (Other drug)		Reason:	Prophylaxis	
Injection	4.0 Gram	Daily		Intravenous
Batch:	Started: 02/02/1994		Stopped:	04/02/1994
FLAGYL (Other drug)		Reason:	Prophylaxis	
Injection	1.0 Gram	Daily		Intravenous
Batch:	Started: 02/02/1994		Stopped:	04/02/1994
DROPERIDOL (Suspected)		Reason:	Nausea and v	omiting
Injection	1.0 Milligram	As ne	cessary	Intramuscular
Batch:	Started: 02/02/1994		Stopped:	03/02/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 78 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 91630 Seq: 1 Gender: M

Reported: 15/03/1994 Weight: 97.00 Hospitalisation: Age: 32Y

Onset Date: 07/07/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Dystonia		Lock-jaw.	
Dyspnoea			
Laryngospasm			Diazepam iv 2mg, cogentin 2mg imi.

Medicine Details:

PROPOFOL (Suspected)		Reason: Other disturbance of sensation
Injection	300.0 Milligram	1 time Intravenous
Batch:	Started: 07/07/1993	Stopped:
LIGNOCAINE (Suspected)		Reason: Other disturbance of sensation
Injection	60.0 Milligram	1 time Intravenous
Batch:	Started: 07/07/1993	Stopped:
ATROPINE (Suspected)		Reason: Other disturbance of sensation
Injection	400.0 Microgram	1 time Intravenous
Batch:	Started: 07/07/1993	Stopped:
DROPERIDOL (Suspected)		Reason: Other disturbance of sensation
Injection	4.0 Milligram	1 time Intravenous
Batch:	Started: 07/07/1993	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No previous problems with anaesthetics.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 79 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 91630 Seq: 1 Gender: M

Reported: 15/03/1994 Weight: 97.00 Hospitalisation: Age: 32Y

Onset Date: 07/07/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

MAXOLON (Suspected)		Reason: Other disturbance of sensation	n
Injection	10.0 Milligram	1 time Intravenous	
Batch:	Started: 07/07/1993	Stopped:	
THA (Suspected)		Reason: Other disturbance of sensation	n
Injection	30.0 Milligram	1 time Intravenous	
Batch:	Started: 07/07/1993	Stopped:	
NARCAN (Suspected)		Reason: Other disturbance of sensation	n
Injection	600.0 Microgram	1 time Intravenous	
Batch:	Started: 07/07/1993	Stopped:	

Laboratory Investigations:

Additional Information:

No previous problems with anaesthetics.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 80 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

 Case Number:
 93067
 Seq: 1
 Gender:
 F

 Reported:
 17/05/1994
 Weight:

Hospitalisation: Age: 30

Onset Date: 11/08/1993 **DOB**: 03/07/1963

Outcome: Recovered Causality: Causality possible

Reaction Details:

١,	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	l
	Hypoaesthesia		Numbness in fingers and toes.		ĺ
	Malaise				l
	Nausea			Stemetil iv.	ı

Medicine Details:

DROPERIDOL (Suspected)		Reason:		
Injection	1.2 Milligram	1 time	Intravenous	
Batch:	Started: 11/08/1993	Sto	opped:	
VALIUM (Suspected)		Reason:		
Injection	2.5 Milligram	1 time	Intravenous	
Batch:	Started: 11/08/1993	Sto	opped:	
FENTANYL CITRATE (Suspected)	!	Reason:		
Injection	15.0 Microgram	1 time	Intravenous	
Batch:	Started: 11/08/1993	Sto	opped:	
DIAZEPAM (Suspected)	!	Reason:		
Tablet	10.0 Milligram	1 time	Oral	
Batch:	Started: 11/08/1993	044	opped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Previous reactions to pethidine=vomiting, panadeine forte=vomiting.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 81 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 93487 Seq: 1 Gender: F

 Reported:
 06/06/1994
 Weight:
 57.00

 Hospitalisation:
 Age:
 85Y

Onset Date: 30/03/1994 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation			Nulax given

Medicine Details:

ZOFRAN (Suspected)		Rea	son: Nausea and v	omiting
Injection	4.0	Milligram	1 time	Intravenous
Batch:	Started: 28	/03/1994	Stopped:	28/03/1994
PANADEINE FORTE (Suspected)				
Capsule	1.0	Dose Unspecified	As necessary	Oral
Batch:	Started:		Stopped:	
DROPERIDOL (Suspected)		Rea	son:	
Injection	1.2	Milligram	As necessary	Intramuscular
Batch:	Started:		Stopped:	
STEMETIL (Suspected)		Rea	son:	
Injection	12.0	Milligram	Daily	Intramuscular
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 82 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

 Case Number:
 93490
 Seq: 1
 Gender: M

 Reported:
 06/06/1994
 Weight:
 73.00

 Hospitalisation:
 Age: 72

Onset Date: 26/05/1994 **DOB**: 12/06/1921

Outcome: Recovered Causality: Causality possible

Reaction Details:

iteaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Arrhythmia			
Dizziness			
Nausea			
Pallor			

Medicine Details:

CLEXANE (Other drug)		Reason:	Other prophyla	actic procedures
Injection	40.0 Milligram	Daily		Subcutaneous
Batch:	Started: 25/05/1994		Stopped:	CONTIN
PETHIDINE HYDROCHLORIDE (Other drug)		Reason:	Pain	
Injection	800.0 Milligram	Daily		Intramuscular
Batch:	Started: 26/05/1994		Stopped:	
DROPERIDOL (Suspected)		Reason:		
Injection	2.5 Milligram	Daily		Intramuscular
Batch:	Started: 26/05/1994		Stopped:	26/05/1994
Keflin Neutral (Suspected)		Reason:		
Injection	4.0 Gram	Daily		Intravenous
Batch:	Started: 25/05/1994		Stopped:	27/05/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Allergies to penicillin and garlic.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 83 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 93663 Seq: 1 Gender: F

Reported: 10/06/1994 Weight: 72.00 Hospitalisation: Age: 71

Onset Date: 26/04/1994 **DOB**: 26/01/1923

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	toaction Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Coma			
	Dystonia			

Medicine Details:

FLUCLOXACILLIN SODIUM (Other drug)		Reason:	
	1.5 Gram	Daily	
Batch:	Started: 25/04/1994	Stopped : 26/04/1994	
LASIX (Other drug)		Reason: Essential benign hypertension	1
	40.0 Milligram	Daily	
Batch:	Started: 26/04/1994	Stopped:	
OROXINE (Other drug)		Reason:	
Tablet	50.0 Microgram	Daily Oral	
Batch:	Started:	Stopped:	CONTIN
ISOPTIN (Other drug)		Reason: Essential benign hypertension	1
Tablet, modified release	240.0 Milligram	Daily Oral	
Batch:	Started:	Stopped: 03/05/1994	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 84 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details	:						
Case Number: 9 Reported: 7 Iospitalisation: Onset Date: 2 Outcome: F eaction Details	10/06/1994 26/04/1994 Recovered	Seq: 1			1		72.00
Medicine Deta	ils:						
ZANTAC (Other drug	g)			Reason:	Diaph hern of a	bd cav w/o	obst
Tablet			Milligram	Daily		Oral	
Batch:		Started:			Stopped:		
FRAGMIN (Other dr	ug)	40.0	Thomas	Reason:	Pulmonary emb	olism&infa	rction
Batch:		10.0 Started:	Thousand Inte	ernai Daily	Stannad:		
NORDIOL NOS (Oth	er drua)	Starteu:		Reason:	Stopped:		
		15.0	Milligram	Daily			
Batch:		Started:	5 - ···		Stopped:		
SPAN-K (Other drug	j)			Reason:	• • •		
		6.0	Dose Unspec	ified Daily			
Batch:		Started:			Stopped:		
_aboratory Inv	estigations:						
Additional Info	ormation:						

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 85 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number: 93663 Seq: 1 Gender: F

Reported: 10/06/1994 Weight: 72.00 Hospitalisation: Age: 71

Onset Date: 26/04/1994 **DOB**: 26/01/1923

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

DROPERIDOL (Suspected)	1	Reason:	
Injection	2.5 Milligram	1 time Intramuscular	
Batch:	Started: 26/04/1994	Stopped: 26/04/1994	
KEFLEX (Suspected)	ı	Reason:	
	1.5 Gram	Daily	
Batch:	Started: 25/04/1994	Stopped: 26/04/1994	
LOSEC (Suspected)	ı	Reason: Diaph hern of abd cav w/o ob	ost
	40.0 Milligram	Daily	
Batch:	Started: 26/04/1994	Stopped:	
ROHYPNOL (Suspected)	ı	Reason:	
	1.0 Dose Unspecifi	ed Daily	
Batch:	Started: 26/04/1994	Stopped:	

Laboratory Investigations:

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 86 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

Case Number: 95095 Seq: 1 Gender: U

Reported: 16/08/1994 Weight:
Hospitalisation: Age:
Onset Date: 28/07/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

reaction betails.								
Preferred Term Severity		Report Description	Treatment					
Opisthotonus		Tightness in neck and jaw						
Dystonia	Required Specialist Consultation		Cogentin 1mg iv					

Medicine Details:

PANADOL (Other drug)		Reason:	Pain	
Oral application	500.0 Milligram	Total		Oral
Batch:	Started: 28/07/1994		Stopped:	
PANADEINE FORTE (Suspected)		Reason:	Pain	
Tablet	0.0			Oral
Batch:	Started: 28/07/1994		Stopped:	
PETHIDINE HYDROCHLORIDE (Suspecte	d)	Reason:	Pain	
	300.0 Milligram	Total		
Batch:	Started: 27/07/1994		Stopped:	28/07/1994
MAXOLON (Suspected)		Reason:	Nausea and v	omiting
Injection	10.0 Milligram	Total		Intravenous
Batch:	Started: 27/07/1994		Stopped:	

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 87 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reported: pitalisation: Onset Date: Outcome: ction Detai	16/08/1994 28/07/1994 Recovered	Seq. 1		С	Weight: Age: DOB: ausality: Cau	usality possi	ble
adiaina Date	alla.						
edicine Deta			Reason:				
Injection		2.5 Milligram	Total		Intramuscular		
Batch:		Started: 27/07/1994		Stopped:			
eflin Neutral (Sus	pected)		Reason:	Prophylaxis			
Injection		1.0 Gram	Daily		Intravenous		
Batch:		Started: 27/07/1994		Stopped:	28/07/1994		
aboratory In	vestigations	:					
dditional Inf	ormation:						
ort Pun : 01/06/200)7 04·49PM Data	ahase: nusime02	ADRS00	14		Page 88	of 2

ADRS004 Page 88 of 254



Report Details:

Case Number: 96405

Reported: 10/10/1994

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight:

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

spitalisati		Age : 66							
Onset Date:					DOB : 08/10/1928				
Outcome: Not yet recovered				Causality: Caus			ausality poss	usality possible	
action D									
Pre	eferred Term	Se	everity	Repo	ort Des	cription		Treatmer	nt
nxiety		Seve	re				Xana	x	
allucination	า	Seve	re						
edicine				Pag					
KULEPIAN	I (Suspected)		2 በ	Milligram Rea	son: 1 time				
Bato	h:	S	tarted:	gram	i dillic	Stopped:			
IPRIVAN (S				Rea	son:	Other disturba	nce of sensation	on	
Inject			1.0	Dose Unspecified			Intravenous		
Batc		s	tarted:			Stopped:			
aborator	ry Investigat	ions:							
Date	Туре	Range	Date Tes	ted Result			Details		
.dditiona	l Informatio	ղ:							
ort Run: 01/0	06/2007 04:49PN	Database: p	usime02	A	ADRS004	4		Page 89	of 25



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Repor	t De	tail	s:
-------	------	------	----

Gender: F Case Number: 96932 Seq: 1

Reported: 07/11/1994 Weight: 56.00 **Hospitalisation:** Age: 20Y

Onset Date: 22/10/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Benztropine iv 2mg.
Mydriasis			
Opisthotonus			

Medicine Details:

METRONIDAZOLE (Other drug)		Reason: Prophylaxis	
Injection	1.5 Gram	Total	Intravenous
Batch:	Started: 21/10/1994	Stopped:	
AMOXYCILLIN SODIUM (Other drug)		Reason: Prophylaxis	
Injection	3.0 Gram	Total	Intravenous
Batch:	Started: 21/10/1994	Stopped:	
PETHIDINE HYDROCHLORIDE (Other drug	g)	Reason: Pain	
Injection	25.0 Milligram	As necessary	Intravenous
Batch:	Started: 20/10/1994	Stopped:	21/10/1994
PANADEINE (Other drug)		Reason: Pain	
Oral application	1.0 Dose Unspec	ified As necessary	Oral
Batch:	Started: 20/10/1994	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 90 of 254



Report Details:

Case Number: 96932

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

ospitalisation: Onset Date: 22/ Outcome: Red action Details:					C	Age: DOB:	
Outcome: Re					•	DOB:	
	covered				C		_
action Details:					C	ausality:	Causality possible
<u>edicine Details</u>							
BECOTIDE (Other drug)			eason:	Asthma		
Inhalation	_		Dose Unspecifie	d Daily		Inhalation	
Batch:		arted:			Stopped:		CONTIN
	/DROCHLORIDE (Suspe			eason:	Nausea and vo		
Injection	•		Milligram	2 time		Intravenous	
Batch:		arted: 21/1				22/10/1994	
ROLEPTAN (Suspect	εα)	20.1		eason:	Nausea and vo	-	
Injection	04		Milligram	1 time		Intravenous	5
Batch:	Sta	arted: 22/1	0/1994		Stopped:		

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 91 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

	tails:				
Hospitalisation	ed: 08/11/199	4		Gender: Weight: Age: DOB: Causality:	14Y
Reaction De		-			
	ferred Term	Severity	Report De	escription	Treatment
Dystonia Meningism				Co	gentin
Medicine I		1.0	Reason: Dose Unspecified 1 time	Nausea and vomiting	
Batch	n:	Started: 17/		Stopped: 17/08/1994	4
	y Investigat				
Laborator Date	y Investigat Type	ions: Range Date Test	ed Result	Detai	ls

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 92 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

Case Number: 98098 Seq: 1 Gender: F

Reported: 03/01/1995 Weight:
Hospitalisation: Age: 29Y

Onset Date: 21/07/1993 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	todotion Details.			
	Preferred Term	Severity	Report Description	Treatment
	Extrapyramidal disorder			
	Opisthotonus			

Medicine Details:

TEMAZE (Other drug) Reason: Specific disorders of sleep

Capsule 10.0 Milligram As necessary Oral

Batch: Started: 18/07/1993 Stopped:

PANADOL (Other drug) Reason:

0.0 As necessary

Batch: Started: 18/07/1993 Stopped:

PETHIDINE HYDROCHLORIDE (Other drug) Reason:

75.0 Milligram As necessary

Batch: Started: 19/07/1993 Stopped:

DRIXINE (Other drug) Reason:

3.0 Dose Unspecified Daily

Batch: Started: 20/07/1993 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Allergic to metoclopramide - extrapyramidal reaction.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 93 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reported: 03/01/1995 Hospitalisation: Onset Date: 21/07/1993 Outcome: Recovered Reaction Details: Weight: Age: 29Y Causality: Causality probable	
Onset Date: 21/07/1993 Outcome: Recovered DOB: Causality: Causality probable	
Outcome: Recovered Causality: Causality probable	
Reaction Details:	
Medicine Details:	
DROPERIDOL (Suspected) Reason: Nausea and vomiting	7
10.0 Milligram As necessary	
Batch: Started: 20/07/1993 Stopped: 21/07/1993	
	_
Laboratory Investigations:	
Laboratory investigations.	
Additional Information:	
Allergic to metoclopramide - extrapyramidal reaction.	

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 94 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

	s:							
Case Number:	98105	Seq:	1				Gender:	F
Reported:	03/01/1995						Weight:	
ospitalisation:							Age:	
Onset Date:							DOB:	
	Recovered					(Causality:	Causality possible
eaction Detai		1 0		D	-1 D		<u> </u>	Tarataran
	ed Term	Sev	erity	Керс	ort Des	scription	0-	Treatment
Extrapyramidal d	iisoruei						CO	gentin
Medicine Det	aile:							
ROHYPNOL (Othe				Rea	son:			
			1.0 Dos	se Unspecified	As nec	cessary		
Batch:		Sta	arted:			Stopped:		
DIHYDERGOT (Otl	her drug)			Reas	con.	Migraine		
Injection			4.0 Mill		Daily		Intravenous	s
Injection Batch:		Sta	4.0 Mill	ligram	Daily	Stopped:		s
Injection		Sta	arted:	ligram Rea	Daily son:			s
Injection Batch: DROPERIDOL (Su			arted: 15.0 Mill	ligram Rea s ligram	Daily	Stopped:	vomiting	
Injection Batch:			arted:	ligram Rea s ligram	Daily son:	Stopped:		
Injection Batch: DROPERIDOL (Sur	spected)	Sta	arted: 15.0 Mill	ligram Rea s ligram	Daily son:	Stopped:	vomiting	ı

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 95 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 99245 Seq: 1 Gender: F

Reported: 28/02/1995 Weight:
Hospitalisation: Age: 93

Onset Date: 03/01/1995 **DOB**: 10/01/1901

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoglycaemia			Actrapid insulin

Medicine Details:

ISOTARD MC (Other drug)			Reason:	Diabetes melli	tus
Injection	4.0	Unit	Daily		Subcutaneous
Batch:	Started:	L	TERM	Stopped:	
ASPIRIN (Other drug)			Reason:		
Oral application	150.0	Milligram	Daily		Oral
Batch:	Started:	L	TERM	Stopped:	
NICOTINIC ACID (Other drug)			Reason:		
Tablet	187.0	Milligram	Daily		Oral
Batch:	Started:	L	TERM	Stopped:	
ATENOLOL (Other drug)			Reason:	Essential beni	gn hypertension
Tablet	50.0	Milligram	Daily		Oral
Batch:	Started:	1	TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 96 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Medicine Details: DROPERIDOL (Suspected)	DROPERIDOL (Suspected) Reason: Premedication Injection 2.5 Milligram 1 time Intravenous Batch: Started: 03/01/1995 Stopped: DIAZEPAM (Suspected) Reason: Premedication Injection 10.0 Milligram 1 time Intravenous Batch: Started: 03/01/1995 Stopped:	ospitalisation: Onset Date:	28/02/1995 03/01/1995 Recovered	Seq: 1		Weig A <u>(</u> DC	ht: ge: 93 OB: 10/01/1901 ity: Causality possible
Injection 10.0 Milligram 1 time Intravenous Batch: Started: 03/01/1995 Stopped:	Injection 10.0 Milligram 1 time Intravenous Batch: Started: 03/01/1995 Stopped: -aboratory Investigations:	DROPERIDOL (Sur				e Intrave	enous
Injection 10.0 Milligram 1 time Intravenous Batch: Started: 03/01/1995 Stopped:	Injection 10.0 Milligram 1 time Intravenous Batch: Started: 03/01/1995 Stopped: -aboratory Investigations:		ected)	Starteu. 03/01/1993	Reason:		
Batch: Started: 03/01/1995 Stopped:	Batch: Started: 03/01/1995 Stopped: aboratory Investigations:			10.0 Milligram			enous
	aboratory Investigations:						
	Additional Information:	aboratory In	vestigations:				

Rep



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

Report Details:

 Case Number:
 99895
 Seq: 1
 Gender: M

 Reported:
 31/03/1995
 Weight:

Hospitalisation: Age: 27Y
Onset Date: 09/03/1995
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Haematuria		Gross haemoaturia	lv fluids and panadol prn
Renal pain		Loin pain both sides.	
Renal impairment		Renal impairment	
Myoglobinuria			
Myopathy	Severe		

Medicine Details:

NITROUS OXIDE (Suspected) Reason: Other disturbance of sensation

0.0

Batch: Started: 09/03/1995 Stopped:

ISOFLURANE (Suspected) Reason: Other disturbance of sensation

0.0

Batch: Started: 09/03/1995 Stopped:

SUXAMETHONIUM BROMIDE (Suspected) Reason: Other disturbance of sensation

Injection 100.0 Milligram 1 time Intravenous

Batch: Started: 09/03/1995 Stopped:

FENTANYL CITRATE (Suspected) Reason: Other disturbance of sensation

Injection 125.0 Microgram 1 time Intravenous

Batch: Started: 09/03/1995 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry	<10			Urine myoglobin 10/3/95 42500 ug/l
	Creatine	30 - 210	09/03/1995	74	
	Creatine	30 - 210	10/03/1995	160	
	Creatine	30 - 210	12/03/1995	281	
	Creatine	30 - 210	11/03/1995	102	
	Creatine	30 - 210	13/03/1995	-	
	Creatinine	0.06 - 0.12	09/03/1995	0.13	

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 98 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

 Case Number:
 99895
 Seq: 1
 Gender: M

 Reported:
 31/03/1995
 Weight:

Hospitalisation: Age: 27Y

Onset Date: 09/03/1995 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

TORADOL (Suspected)		Reason:	Pain
Injection	30.0 Milligram	1 time	Intramuscular
Batch:	Started: 09/03/1995		Stopped:
PROPOFOL (Suspected)		Reason:	Other disturbance of sensation
Injection	40.0 Milligram	1 time	Intravenous
Batch:	Started: 09/03/1995		Stopped:
DROPERIDOL (Suspected)		Reason:	Other disturbance of sensation
Injection	1.0 Milligram	1 time	Intravenous
Batch:	Started: 09/03/1995		Stopped:
HYPNOVEL (Suspected)		Reason:	Other disturbance of sensation
Injection	1.0 Milligram	1 time	Intravenous
Batch:	Started: 09/03/1995		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatinine	0.06 - 0.12	10/03/1995	0.13	
	Creatinine	0.06 - 0.12	11/03/1995	0.13	
	Creatinine	0.06 - 0.12	13/03/1995	0.12	
	Creatinine	0.06 - 0.12	12/03/1995	0.14	
	Urea	3 - 7.5	09/03/1995	8.0	
	Urea	3 - 7.5	10/03/1995	8.4	
	Urea	3 - 7.5	11/03/1995	9.2	

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 99 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1			Gender: M	
			Weight:	
			Age: 27Y	
			DOB:	
		С	ausality: Causality po	ssible
10.0			Introvonous	
			Intravenous	
s:				
Range Date Tested			Details	
	8.3		Details	
-			1.0 Gram 1 time	1.0 Gram 1 time Intravenous

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 100 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

 Case Number:
 102085
 Seq: 1
 Gender:
 F

 Reported:
 10/07/1995
 Weight:
 74.00

 Hospitalisation:
 Age: 27

Onset Date: DOB: 14/03/1968

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

caction Betails.			
Preferred Term	Severity	Report Description	Treatment
Brain oedema			
Hyponatraemia			
Nausea			
Vomiting			

Medicine Details:

LARGACTIL (Suspected)		Reason: Nausea and vomiting		
Injection	25.0 Milligram	As necessary Intravenous		
Batch:	Started:	Stopped:		
DROPERIDOL (Suspected)		Reason: Nausea and vomiting		
Injection	2.0 Milligram	As necessary Intravenous		
Batch:	Started:	Stopped:	topped:	
STEMETIL (Suspected)		Reason:		
Injection	12.5 Milligram	As necessary Intramuscular		
Batch:	Started:	Stopped:	Stopped:	
ZOFRAN (Suspected)		Reason:		
Injection	4.0 Milligram	Daily Intravenous		
Batch:	Started:	Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was not well controlled epileptic, who after surgery was hyponatraemic and vomiting, died of cerebral oedema.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 101 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Rei	port	Detail	ls:

 Case Number:
 102085
 Seq: 1
 Gender:
 F

 Reported:
 10/07/1995
 Weight:
 74.00

 Hospitalisation:
 Age: 27

Onset Date: DOB: 14/03/1968

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Medicine Details:

DILANTIN (Suspected)		Re	eason:	Other&unspec	ified epilepsy
Tablet	300.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
PETHIDINE HYDROCHLORIDE (Suspected)		Re	eason:		
Injection	400.0	Milligram	Daily		Intramuscular
Batch:	Started:			Stopped:	
PANADEINE FORTE (Suspected)		Re	eason:		
Tablet	12.0	Dose Unspecifie	d Daily		Oral
Batch:	Started:			Stopped:	

Laboratory Investigations:

Additional Information:

Patient was not well controlled epileptic, who after surgery was hyponatraemic and vomiting, died of cerebral oedema.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 102 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

lospitalisatio Onset Da Outcom	ed: 28/08/1995 on: te: 17/07/1995 ne: Recovered	5	1		V	ender: /eight: Age: DOB: usality:	
eaction De	etalis: erred Term	Se	verity	Report	Description		Treatment
Tremor						Cog	gentin
Medicine D							
PETHIDINE HY	DROCHLORIDE (Suspected)		Reaso			
Datak	_	0.4		e Unspecified 1			
Batch DROPERIDOL		St	arted:	Reaso	Stopped: n: Nausea and vom	itina	
DROPERIDOL	(Suspected)		2.5 Millig		n. Nausea and voin Daily	iurig	
Batch	•	St	arted: 17/07/19		Stopped: 1	7/07/1995	
	v Investigatio		Date Tested	Result		Detail	
Laboratory Date	Investigatio	ons: Range	Date Tested	Result		Detail	S

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 103 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:	Re	port	Detai	ls:
-----------------	----	------	-------	-----

Case Number: 105062 Seq: 1 Gender: F

Reported: 04/12/1995

Hospitalisation:
Onset Date:

Weight: 69.00
Age: 61Y
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin 2mg iv, midazolam 10mg

Medicine Details:

DROPERIDOL (Suspected) Reason:

0.0

Batch: **Started**: 28/11/1995 **Stopped**: 29/11/1995

MAXOLON (Suspected) Reason: Nausea and vomiting

Injection 10.0 Milligram Daily Intramuscular

Batch: Started: 29/11/1995 Stopped: 29/11/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 104 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 105289 Seq: 1 Gender: U

Reported: 11/12/1995 **Weight:** 63.00

Hospitalisation: Age:
Onset Date: 16/11/1995
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Over trunk and arms	Phenergan 25mg imi once

Medicine Details:

DIPRIVAN (Suspected)		Reason:	Surgery	
Injection	0.0			Intravenous
Batch:	Started: 15/11/1995		Stopped:	15/11/1995
MAXOLON (Suspected)		Reason:	Surgery	
Injection	0.0			Intravenous
Batch:	Started: 15/11/1995		Stopped:	15/11/1995
DROPERIDOL (Suspected)		Reason:	Surgery	
Injection	0.0			Intravenous
Batch:	Started: 15/11/1995		Stopped:	
CLAFORAN (Suspected)		Reason:	Surgery	
	2.0 Gram	1 tim	е	
Batch:	Started: 15/11/1995		Stopped:	15/11/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 105 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

 Case Number:
 105289
 Seq: 1
 Gender: U

 Reported:
 11/12/1995
 Weight:
 63.00

Hospitalisation: Age:
Onset Date: 16/11/1995
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

PETHIDINE HYDROCHLORIDE (Suspec	ted)	Reason: Pa	ain	
Injection	15.0 Milligram	Daily		Intravenous
Batch:	Started: 15/11/1995		Stopped:	17/11/1995
TEMAZEPAM (Suspected)		Reason:		
Oral application	20.0 Milligram	Daily		Oral
Batch:	Started: 15/11/1995		Stopped:	15/11/1995
RANITIDINE (Suspected)		Reason:		
Oral application	150.0 Milligram	Daily		Oral
Batch:	Started: 15/11/1995		Stopped:	15/11/1995

Laboratory Investigations:

Additional Information:

See original report for other drugs

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 106 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

Report Details:

Case Number: 105628 Seq: 1 Gender: F

Reported: 02/01/1996 Weight: 55.00 Hospitalisation: Age: 22Y

Onset Date: 18/12/1995 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia	Severe	Mainly in back, neck, legs and abdomen	7mg diazepam orally

Medicine Details:

BECONASE (Other drug)

Inhalation

4.0 Dose Unspecified Daily

Inhalation

Batch: Started: 01/01/1980 Stopped:

DROPERIDOL (Suspected) Reason: Nausea and vomiting

10.0 Milligram As necessary

Batch: **Started**: 17/12/1995 **Stopped**: 18/12/1995

STEMETIL (Suspected) Reason: Nausea and vomiting

Injection 12.5 Milligram As necessary Intramuscular

Batch: Started: 17/12/1995 Stopped: 18/12/1995

Keflin Neutral (Suspected) Reason: Othr diseases of urinary tract

4.0 Gram Daily

Batch: Started: 17/12/1995 **Stopped:** 18/12/1995

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.

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 107 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

 Case Number:
 105693
 Seq: 1
 Gender:
 F

 Reported:
 04/01/1996
 Weight:

Hospitalisation: Age: 0

Onset Date: 03/12/1995 **DOB**: 11/08/1995

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Bentztropine.

Medicine Details:

PETHIDINE HYDROCHLORIDE (Other drug	3)	Reason:	Pain	
Injection	200.0 Milligram	Daily	y Intravenous	
Batch:	Started: 30/11/1995		Stopped: 06/12/1995	
DOXYCYCLINE HYDROCHLORIDE (Other	drug)	Reason:	Female pelvic inflammatory dis	
Oral application	200.0 Milligram	Daily	y Oral	
Batch:	Started: 30/11/1995		Stopped:	
METRONIDAZOLE (Other drug)		Reason:	Female pelvic inflammatory dis	
Injection	1.5 Gram	Daily	y Intravenous	
Batch:	Started: 30/11/1995		Stopped:	
DROPERIDOL (Suspected)		Reason:	Nausea and vomiting	
Injection	10.0 Milligram	Daily	y Intravenous	
Batch:	Started: 02/12/1995		Stopped: 03/12/1995	l.

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:49PM Database: pusime02 ADRS004 Page 108 of 254



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reason: Nausea and vomiting Nausea and v	Reported: 0 pspitalisation: Onset Date: 0 Outcome: Reaction Details	4/01/1996 3/12/1995 Recovered	Зец. Т			
Injection 50.0 Milligram Daily Intramuscular Batch: Started: 01/12/1995 Stopped: 02/12/1995 aboratory Investigations:	MAXOLON (Suspectors) Batch:	ed)		Daily	Stopped: 01/12/1995	5
Batch: Started: 01/12/1995 Stopped: 02/12/1995 aboratory Investigations:		id)	50.0 Milligram		_	ılar
aboratory Investigations:				Daily		
dditional Information:	aboratory Inv	estigations	::			
	dditional Info	rmation:				

ADRS004 Page 109 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

Case Number: 105768 Gender: M Seq: 1 Weight: Reported: 03/01/1996

Hospitalisation: **Age:** 36Y **Onset Date:** DOB:

Outcome: Recovered with sequelae Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Hypertonia			
Pyrexia			Treated with 8 unilateral ect sessions
Tachycardia			555515115

Medicine Details:

DIAZEPAM (Suspected) Reason: Injection 0.0 Intravenous Batch: Started: Stopped:

DROPERIDOL (Suspected) Reason:

0.0

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)

Started:

Reason: Unspecified schizophrenia

> 50.0 Milligram Total

Stopped:

Batch: Started: Stopped:

Laboratory Investigations:

Dat	te	Туре	Range	Date Tested	Result	Details
		Creatine	25-125			Ck level in plasma- 1180 on 2nd day of admission; peaked at 2574 on 3rd day

Additional Information:

Overdose with 50mg trifluoperazine

ADRS004 Report Run: 01/06/2007 04:50PM Database: pusime02 Page 110 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 105919 Seq: 1 Gender: F
Reported: 18/01/1996 Weight:

Hospitalisation: Age: 22

Onset Date: 30/10/1995 **DOB**: 25/01/1973

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Agitation			Midazolam iv 2mg
Anxiety			
Palpitations			

Medicine Details:

DROPERIDOL (Suspected)			Reason:		
Injection	2.5	Milligram	1 time	:	Intramuscular
Batch:	Started: 30/	10/1995		Stopped:	30/10/1995
PETHIDINE HYDROCHLORIDE (Suspected)	l		Reason:	Other disturba	nce of sensation
Injection	100.0	Milligram	1 time	:	Intramuscular
Batch:	Started: 30/	10/1995		Stopped:	30/10/1995
BETAMETHASONE (Suspected)			Reason:		
Injection	11.0	Milligram	1 time	:	Intramuscular
Batch:	Started: 30/	10/1995		Stopped:	30/10/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 111 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reported: 03/05/1996 Iospitalisation: Onset Date: 20/03/1996 Outcome: Recovered		q : 1			Gender: F Weight: Age: DOB: Causality: Causality possib			
eaction Details: Preferred Term		Severity		Report De	scription		Tre	atment
Dystonia Extrapyramidal disorder						Со	gent	
				Posson:	Acuto paperos	titie		
		20.0 M	lilligram	Reason:	Acute pancrea	titis		
		20.0 M Started:		Reason: Daily TERM	Acute pancrea	titis		
PANCREASE (Other drug) Batch:				Daily		ititis		
PANCREASE (Other drug) Batch: TEMAZE (Other drug)		Started:	L ·	Daily TERM	Stopped:	titis		
PANCREASE (Other drug) Batch: TEMAZE (Other drug) Batch:		Started:	L ·	Daily TERM Reason: Daily	Stopped:	titis		
PANCREASE (Other drug) Batch: TEMAZE (Other drug) Batch:		10.0 M Started: 19/03	L - lilligram /1996	Daily TERM Reason: Daily Reason:	Stopped:	titis		
PANCREASE (Other drug) Batch: TEMAZE (Other drug) Batch: PANADEINE FORTE (Other dr	rug)	10.0 M Started: 19/03 20.0 M	L dilligram //1996	Daily TERM Reason: Daily	Stopped: Stopped:	titis		
PANCREASE (Other drug) Batch: TEMAZE (Other drug) Batch: PANADEINE FORTE (Other dr	rug)	10.0 M Started: 19/03	L dilligram //1996	Daily TERM Reason: Daily Reason:	Stopped: Stopped: Pain Stopped:			
PANCREASE (Other drug) Batch: TEMAZE (Other drug) Batch: PANADEINE FORTE (Other dr Batch: GENTAMICIN SULPHATE (Other	rug)	10.0 M Started: 19/03 20.0 M Started: 19/03	L - lilligram /1996 lilligram /1996	Daily Reason: Daily Reason: Daily Reason:	Stopped: Stopped:			
PANCREASE (Other drug) Batch: TEMAZE (Other drug) Batch: PANADEINE FORTE (Other dr	rug) her drug)	10.0 M Started: 19/03 20.0 M	L - lilligram /1996 lilligram /1996	Daily Reason: Daily Reason: Daily	Stopped: Stopped: Pain Stopped: Unspecified se	epticemia	6	
PANCREASE (Other drug) Batch: TEMAZE (Other drug) Batch: PANADEINE FORTE (Other dr Batch: GENTAMICIN SULPHATE (Other drag)	rug) ner drug)	10.0 M Started: 19/03 20.0 M Started: 19/03 240.0 M	L - lilligram /1996 lilligram /1996	Daily Reason: Daily Reason: Daily Reason:	Stopped: Stopped: Pain Stopped: Unspecified se	epticemia Oral	6	
Batch: TEMAZE (Other drug) Batch: PANADEINE FORTE (Other dr Batch: GENTAMICIN SULPHATE (Other dr) Oral application	rug) ner drug)	10.0 M Started: 19/03 20.0 M Started: 19/03 240.0 M	L - // // // // // // // // // // // // /	Daily TERM Reason: Daily Reason: Daily Reason: Daily	Stopped: Stopped: Pain Stopped: Unspecified se	epticemia Oral		

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 112 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:		
Case Number: 108250	Seq: 1	Gender: F
Reported: 03/05/1996		Weight:

Hospitalisation: Age:
Onset Date: 20/03/1996 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

AMOXYCILLIN SODIUM (Other drug)		Reason:	Unspecified se	epticemia
Injection	3.0 Gram	Daily		Intravenous
Batch:	Started: 19/03/1996		Stopped:	25/03/1996
METRONIDAZOLE (Other drug)		Reason:	Unspecified se	epticemia
Injection	1.5 Gram	Daily		Intravenous
Batch:	Started: 19/03/1996		Stopped:	25/03/1996
MORPHINE NOS (Other drug)		Reason:	Pain	
Injection	60.0 Milligram	Daily		Intramuscular
Batch:	Started: 19/03/1996		Stopped:	27/03/1996
DROPERIDOL (Suspected)		Reason:	Nausea and ve	omiting
Injection	15.0 Milligram	Daily		Intravenous
Batch:	Started: 20/03/1996		Stopped:	21/03/1996

Laboratory Investigations:

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 113 of 254



Case Number: 108350

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

=	ed: 08/05/199	96					Weight:	
ospitalisatio	on:						Age: 48	3Y
Onset Da	ate: 12/04/199	96					DOB:	
Outcon	ne: Recovere	ed				C	ausality: C	ausality possible
action De	etails:							
Pre	ferred Term	Se	everity	Repo	ort Desc	ription		Treatment
onchospas	m							
ushing								
acrimal diso								
eriorbital oe	dema							
edicine [Details:							
EPARIN SOI	OIUM (Other drug	g)		Reas	son:			
Injection	on		0.0 Tho	usand Internat	5 times		Subcutaneous	3
Batch	n:	S	Started: 10/04/19	996		Stopped:		
ANTAC (Oth	er drug)			Reas	son:			
Tablet			150.0 Milli	gram	1 time		Oral	
Batch		S	Started: 08/04/19	996		Stopped:		
TROPINE (O	ther drug)			Reas	son: O	tr&nos disord	l of heart rhythi	m
			600.0 Mici	rogram	1 time			
Batch		S	Started: 09/04/19			Stopped:		
EFOXIN (Oth	•			Reas	son:			
Injection	on		4.0 Gra	m	Total		Intravenous	
	1:	S	Started: 09/04/1	996		Stopped:		
Batch								
	v Investiga	tions:						
	y Investigat Type	tions:	Date Tested	Result			Details	

Page 114 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reported: 08 ospitalisation: Onset Date: 12 Outcome: Re	2/04/1996						
Onset Date: 12 Outcome: Re						Weight:	
Outcome: Re						Age:	
						DOB:	
eaction Details:					С	ausality:	Causality possible
	i 1						
Andinina Datail							
ledicine Details EPHEDRINE (Other dr				Reason:	Hypotension		
Injection	ug)	12 0	Milligram	Total	туровеняюн	Intravenous	
Batch:		Started: 10/0		iolai	Stopped:	muavenous	•
MORPHINE NOS (Sus	nected)	Starteu: 10/	J + / 1330	Reason:	Stopped:		
MUNTHINE NUS (SUS	pecieu <i>j</i>	2.0	Milligram	1 time			
Batch:		2.0 Started: 12/0		i uiiie	Stopped:		
DROPERIDOL (Suspe	cted)	Giarteu. 12/	J-7/ 1 J J U	Reason:	otoppeu.		
z.to. z.tiboz (ouspe	,	83.0	Microgram	1 time			
Batch:		Started: 12/0		Tune	Stopped:		
- Batcii.		Otartea. 12/	J 4 /1000		Otoppeu.		

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 115 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Gender: F Case Number: 108934 Seq: 1 Reported: 03/06/1996 Weight: **Hospitalisation:** Age: 23Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration		Eyes rolling up	
Hypertonia		Rigidity and spasms in leg	
Abdominal pain			
Bronchospasm			
Dyspnoea			
Dystonia			
Extrapyramidal disorder			
Neuroleptic malignant syndrome			
Paraesthesia			
Tachycardia			

Medicine Details:

PETHIDINE HYDROCHLORIDE (Suspecte	ed)	Reason: Pain	
	200.0 Milligram	Total	
Batch:	Started: 29/11/1995	Stopped: 30/11/1995	
DROLEPTAN (Suspected)		Reason: Nausea and vomiting	
	10.0 Milligram	Daily	

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient known as 'vomiter'.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 116 of 254



Case Number: 109165

Reported: 17/06/1996

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 97.00

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

Onset Date: 28/05/1996 Outcome: Unknown eaction Details: Preferred Term rug ineffective lausea omiting		everity		Report Des		DOB: 15/03/1953 sality: Causality p Treati	ossible
Preferred Term rug ineffective ausea	S	everity		Report Des		Treati	
Preferred Term ug ineffective ausea	S	everity		Report Des	scription		ment
ug ineffective ausea	S	everity		Report Des	scription		ment
usea						Ondansetron	
						Ondansetron	
miting			<u> </u>				
edicine Details:							
OFLURANE (Suspected)				Reason:			
		0.0					
Batch:		Started:			Stopped:		
ENTANYL CITRATE (Suspecte	ed)			Reason:			
			Milligram	1 time			
Batch:	•	Started:			Stopped:		
ROPERIDOL (Suspected)				Reason:			
D-4-b-			Microgram	1 time			
Batch:		Started:		Danasas	Stopped:		
ETHIDINE HYDROCHLORIDE ((Suspected)	75.0	Milligram	Reason: 1 time			
Batch:		75.0 Started:	Milligram	i uiile			
Daten.	•	Starteu.			Stopped:		
boratory Investigati	ons:						
Date Type	Range	Date Test	ted Res	sult		Details	



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	109165	Seq: 1			Gender:	F
Reported:	17/06/1996	•			Weight:	97.00
Hospitalisation:					Age:	
Onset Date:	28/05/1996					15/03/1953
Outcome:	Unknown				Causality:	Causality possible
Reaction Detai	ls:				-	• •
Medicine Deta						
MAXOLON (Suspe	cted)			Reason:		
		10.0	Milligram	1 time		
Batch:		Started:			Stopped:	
DIPRIVAN (Suspec	cted)			Reason:		
		200.0	Milligram	1 time		
Batch:		Started:			Stopped:	
VECURONIUM BRO	OMIDE (Suspected)			Reason:		
		5.0	Milligram	1 time		
Batch:		Started:			Stopped:	
Laboratory In	vootigationa					
Laboratory III	vestigations.					
Additional Inf	ormation:					

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 118 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

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

Case Number: 109297 Seq: 1 Gender: F

Reported: 17/06/1996 Weight: 58.00 Hospitalisation: Age: 36

Onset Date: 23/05/1996 **DOB**: 28/10/1959

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea			Maxolon, stemetil

Medicine Details:

FENTANYL CITRATE (Suspected) Reason: Other disturbance of sensation

0.0

Batch: Started: 23/05/1996 **Stopped:** 23/05/1996

VECURONIUM BROMIDE (Suspected)Reason: Other disturbance of sensation

0.0

Batch: Started: 23/05/1996 **Stopped:** 23/05/1996

ISOFLURANE (Suspected) Reason: Other disturbance of sensation

0.0

Batch: Started: 23/05/1996 **Stopped:** 23/05/1996

DROPERIDOL (Suspected)Reason: Other disturbance of sensation

2.5 Milligram 1 time

Batch: **Started**: 23/05/1996 **Stopped**: 23/05/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 119 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:			
Case Number: 109297 Reported: 17/06/1996 Hospitalisation: Onset Date: 23/05/1996 Outcome: Recovered Reaction Details:	Seq: 1		58.00
Medicine Details:			
PETHIDINE HYDROCHLORIDE (Suspecte		Reason: Pain	
Batch:	50.0 Milligram Started: 23/05/1996	1 time Stopped: 23/05/1996	
Laboratory Investigations:			
Additional Information:			

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 120 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Gender: F Case Number: 109309 Seq: 1

Reported: 17/06/1996 Weight: 81.00 **Hospitalisation:** Age: 58

Onset Date: 20/05/1996 **DOB**: 02/04/1938

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	toaction Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Headache			
	Nausea			Maxolon

Medicine Details:

ISOFLURANE (Suspected)		Reason: Other disturbance of sensation
	0.0	
Batch:	Started: 20/05/1996	Stopped: 20/05/1996
FENTANYL CITRATE (Suspected)		Reason: Other disturbance of sensation
Injection	100.0 Milligram	1 time Intravenous
Batch:	Started: 20/05/1996	Stopped: 20/05/1996
OMNOPON (Suspected)		Reason: Other disturbance of sensation
Injection	20.0 Milligram	1 time Intramuscular
Batch:	Started: 20/05/1996	Stopped: 20/05/1996
DIPRIVAN (Suspected)		Reason: Other disturbance of sensation
Injection	200.0 Milligram	1 time Intravenous

Stopped: 20/05/1996

Laboratory Investigations:

Batch:

Date	Туре	Range	Date Tested	Result	Details

Started: 20/05/1996

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 121 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number: 109309 Seq: 1 Gender: F	
Reported: 17/06/1996 Weight: 81.00	
Hospitalisation: Age: 58	
Onset Date : 20/05/1996 DOB : 02/04/1938	
Outcome: Recovered Causality: Causality po	ssible
Reaction Details:	
Medicine Detailer	
Medicine Details: DROPERIDOL (Suspected) Reason: Other disturbance of sensation	
Injection 5.0 Milligram Daily Intravenous	
Batch: Started: 20/05/1996 Stopped: 20/05/1996	
Laboratory Investigations:	
Additional Information:	
Additional information.	
	l

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 122 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Gender: F Case Number: 109310 Seq: 1 Reported: 17/06/1996 **Weight:** 71.00

Hospitalisation: Age: 64

Onset Date: 20/05/1996 **DOB**: 14/10/1931

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea			Maxolon

Medicine Details:

ISOFLURANE (Suspected)		Reason: Other disturbance of sensation
	0.0	
Batch:	Started: 20/05/1996	Stopped: 20/05/1996
FENTANYL CITRATE (Suspected)		Reason: Other disturbance of sensation
Injection	100.0 Milligram	1 time Intravenous
Batch:	Started: 20/05/1996	Stopped:
DROPERIDOL (Suspected)		Reason: Other disturbance of sensation
Injection	2.5 Milligram	1 time Intravenous
Batch:	Started: 20/05/1996	Stopped: 20/05/1996
DIPRIVAN (Suspected)		Reason: Other disturbance of sensation
Injection	200.0 Milligram	1 time Intravenous

Batch: Started: 20/05/1996 Stopped: 20/05/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 123 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	109310	Seq: 1	Gende	er: F
Reported:	17/06/1996		Weigh	t : 71.00
Hospitalisation:			Ag	e : 64
Onset Date: 2	20/05/1996		DO	B : 14/10/1931
Outcome:	Not yet recovered		Causalit	y: Causality possible
Reaction Detail	s:			
Medicine Deta		ال.	Reason: Other disturbance of se	nantion
	BROMIDE (Suspecte			
Injection Batch:		50.0 Milligram Started: 20/05/1996		
Batch:		Started: 20/05/1996	Stopped: 20/05/1	996
Laboratory Inv	vestigations:			
Laboratory Inv	vestigations:			
Laboratory Inv	vestigations:			
Laboratory Inv	vestigations:			
Laboratory Inv	vestigations:			
Laboratory Inv	estigations:			
Laboratory Inv	estigations:			
Laboratory Inv	vestigations:			
Laboratory Inv				

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 124 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

 Case Number:
 109720
 Seq: 1
 Gender: M

 Reported:
 04/07/1996
 Weight:

Hospitalisation: Age: 12

Onset Date: 14/06/1996 **DOB**: 24/04/1984

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	touction Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Dystonia		Jaw tightness	Benztropine 0.7mg ivi stat only
	Hypertonia		Neck stiffness	

Medicine Details:

BISACODYL (Other drug)		Reason:	
Suppository	5.0 Milligram	1 time	Rectal
Batch:	Started: 11/06/1996	Stopped:	
IBUPROFEN (Other drug)		Reason: Pain	
	200.0 Milligram	As necessary	
Batch:	Started: 11/06/1996	Stopped:	CONTIN
CEFACLOR MONOHYDRATE (Other drug)		Reason:	
	750 0 Milliarom	Doily	
	750.0 Milligram	Daily	
Batch:	750.0 Willigram Started: 11/06/1996	Stopped:	14/06/1996
Batch: DROPERIDOL (Suspected)	ğ	•	14/06/1996
	ğ	Stopped:	14/06/1996 Intravenous

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Droperidol 5mg into pca with morphine 60mg 1mg/ml. see original report for other drugs.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 125 of 254



Gender: M

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:		
Case Number: 109720	Seq: 1	

Reported: 04/07/1996 Weight:
Hospitalisation: Age: 12

Onset Date: 14/06/1996 **DOB**: 24/04/1984

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Micalchic Details.				
MORPHINE NOS (Suspected)		Reason:		
Injection, intravenous infusion	0.0	As necessary	Intravenous	
Batch:	Started:	Stoppe	d:	
CEPHAZOLIN SODIUM (Suspected)		Reason:		
Injection	1.5 Gram	Daily	Intravenous	
Batch:	Started: 13/06/1996	Stoppe	d:	2D

Laboratory Investigations:

Additional Information:

Droperidol 5mg into pca with morphine 60mg 1mg/ml. see original report for other drugs.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 126 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

Report Details:

Case Number: 109798 Seq: 1 Gender: U

Reported: 05/07/1996 **Weight:** 72.00

Hospitalisation: Age:
Onset Date: 16/12/1995
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Nouville Botano:							
	Preferred Term	Severity	Report Description	Treatment			
	Dizziness						
	Visual disturbance						

Medicine Details:

PANADOL (Other drug) Reason: Other disturbance of sensation

Oral application 2.0 Dose Unspecified Daily Oral

Batch: Started: 14/12/1995 Stopped:

PANADEINE FORTE (Suspected) Reason: Other disturbance of sensation

Tablet 2.0 Dose Unspecified As necessary Oral

Batch: Started: 15/12/1995 Stopped: 16/12/1995

MAXOLON (Suspected) Reason:

Injection 10.0 Milligram As necessary Intramuscular

Batch: Started: Stopped:

PREMARIN (Suspected) Reason: Menopausal symptoms

Tablet 625.0 Microgram Daily Oral

Batch: Started: 16/12/1995 **Stopped:** 17/12/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Premarin recommenced on 18/12/95 without any further dizziness or blurred vision.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 127 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

 Case Number:
 109798
 Seq: 1
 Gender: U

 Reported:
 05/07/1996
 Weight:
 72.00

Hospitalisation: Age:
Onset Date: 16/12/1995
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.				
PETHIDINE HYDROCHLORIDE (Suspected)		Reason:		
	20.0 Milligram	Daily		
Batch:	Started: 13/12/1995		Stopped:	15/12/1995
DROPERIDOL (Suspected)		Reason:	Nausea and vo	omiting
Injection	3.0 Milligram	Daily		Intramuscular
Batch:	Started: 14/12/1995		Stopped:	15/12/1995

Laboratory Investigations:

Additional Information:

Premarin recommenced on 18/12/95 without any further dizziness or blurred vision.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 128 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

Case Number: 110509 Seq: 1 Gender: F

Reported: 06/08/1996 Weight: 100.00 Hospitalisation: Age: 38Y

Onset Date: 30/07/1996 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus			Promethazine 25mg imi six hourly prn.
Rash erythematous			

Medicine Details:

DROLEPTAN (Suspected) Reason: Nausea and vomiting

Injection 2.5 Milligram As necessary Intramuscular

Batch: Started: 30/07/1996 Stopped:

PANADEINE (Suspected) Reason: Pain

2.0 Dose Unspecified As necessary

Batch: Started: 30/07/1996 Stopped:

FORTRAL (Suspected) Reason: Pain

45.0 Milligram As necessary

Batch: Started: 30/07/1996 Stopped:

PAPAVERETUM (Suspected) Reason: Pain

Injection, intravenous infusion 4.0 Milligram Per hour Intravenous

Batch: Started: 30/07/1996 Stopped: 30/07/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has previous allergy to pethidine.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 129 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number: 110509 Reported: 06/08/199 Hospitalisation: Onset Date: 30/07/199 Outcome: Recovere	96		Gender: Weight: Age: DOB: Causality:	100.00 38Y
Medicine Details:		Reason:	Pain	
Suppository	1.0 Gram	Daily	Rectal	
Batch:	Started : 30/07/1996		Stopped:	
ESTIGYN (Suspected) Batch:	20.0 Microgram Started: 30/07/1996	Reason: Daily	Menopausal symptoms Stopped:	
Laboratory Investigat	ions:			

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 130 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 110815 Seq: 1 Gender: M

Reported: 13/08/1996 Weight: 80.00 Hospitalisation: Age: 57

Onset Date: 29/07/1996 **DOB**: 31/10/1938

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting		Post-op emesis	Maxolon 10mg im at 5:10pm

Medicine Details:

OMNOPON (Suspected)		Reason: Pain	
Injection	20.0 Milligram	1 time Intramuscular	
Batch:	Started: 29/07/1996	Stopped:	
DIPRIVAN (Suspected)		Reason: Other disturbance of sensation	
Injection	200.0 Milligram	1 time Intravenous	
Batch:	Started: 29/07/1996	Stopped:	
FENTANYL CITRATE (Suspected)		Reason: Other disturbance of sensation	
Injection	100.0 Microgram	1 time Intravenous	
Batch:	Started: 29/07/1996	Stopped:	
DROPERIDOL (Suspected)		Reason: Other disturbance of sensation	
Injection	5.0 Milligram	1 time Intravenous	
Batch:	Started: 29/07/1996	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 131 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 110818 Seq: 1 Gender: F

Reported: 13/08/1996 Weight: 90.00
Hospitalisation: Admitted to hospital Age: 53

Onset Date: 24/07/1996 **DOB**: 04/10/1942

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	teaction Betails.			
	Preferred Term	Severity	Report Description	Treatment
	Nausea		Post-op nausea	
	Pain			
	Vomiting			

Medicine Details:

PETHIDINE HYDROCHLORIDE (Suspected	d)	Reason:	
Injection	100.0 Milligram	2 times	Intramuscular
Batch:	Started: 24/07/1996	Stopped:	
MAXOLON (Suspected)		Reason:	
Injection	10.0 Milligram	2 times	Intramuscular
Batch:	Started: 24/07/1996	Stopped:	
THIOPENTONE SODIUM (Suspected)		Reason: Other disturb	ance of sensation
Injection	300.0 Milligram	1 time	Intravenous
Batch:	Started: 24/07/1996	Stopped:	
FENTANYL CITRATE (Suspected)		Reason: Other disturb	ance of sensation
Injection	100.0 Microgram	1 time	Intravenous
Batch:	Started: 24/07/1996	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 132 of 254



Causality: Causality possible

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

 Case Number:
 110818
 Seq: 1
 Gender:
 F

 Reported:
 13/08/1996
 Weight:
 90.00

Hospitalisation: Admitted to hospital Age: 53

Onset Date: 24/07/1996 **DOB**: 04/10/1942

Outcome: Not yet recovered

Reaction Details:

Medicine Details:

Medicine Details.			
DROPERIDOL (Suspected)		Reason: Other disturbance of sensation	
Injection	1.5 Milligram	1 time Intravenous	
Batch:	Started: 24/07/1996	Stopped:	
ATROPINE (Suspected)		Reason: Other disturbance of sensation	
Injection	1.2 Milligram	1 time Intravenous	
Batch:	Started: 24/07/1996	Stopped:	

Laboratory Investigations:

Additional Information:

See original report for other drugs

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 133 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

Case Number: 110827 Seq: 1 Gender: F

Reported: 13/07/1996 Weight: 63.00 Hospitalisation: Age: 36

Onset Date: 10/07/1996 **DOB**: 14/08/1959

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea		Post-op nausea	Maxolon 10mg imi 10:20am

Medicine Details:

NEOSTIGMINE NOS (Other drug)

Reason: Other disturbance of sensation

2.5 Milligram 1 time

Batch: Started: 10/07/1996 Stopped:

ATROPINE (Other drug) Reason: Other disturbance of sensation

1.0 Milligram 1 time

Batch: Started: 10/07/1996 Stopped:

NITROUS OXIDE (Other drug) Reason:

1.0 Dose Unspecified 1 time

Batch: Started: Stopped:

FENTANYL CITRATE (Suspected) Reason: Other disturbance of sensation

Injection 100.0 Microgram 1 time Intravenous

Batch: Started: 10/07/1996 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 134 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

Case Number: 110827 Seq: 1 Gender: F

Reported: 13/07/1996 Weight: 63.00 Hospitalisation: Age: 36

Onset Date: 10/07/1996 **DOB**: 14/08/1959

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

DROPERIDOL (Suspected)		Reason: Other disturbance of sensation
Injection	500.0 Microgram	1 time Intravenous
Batch:	Started: 10/07/1996	Stopped:
DIPRIVAN (Suspected)		Reason: Other disturbance of sensation
	150.0 Milligram	1 time
Batch:	Started: 10/07/1996	Stopped:
VECURONIUM BROMIDE (Suspected)		Reason: Other disturbance of sensation
	4.0 Milligram	1 time
Batch:	Started: 10/07/1996	Stopped:
ISOFLURANE (Suspected)		Reason: Other disturbance of sensation
	0.0	1 time
Batch:	Started: 10/07/1996	Stopped:

Laboratory Investigations:

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 135 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detail	13/07/1996 10/07/1996 Recovered	Seq: 1			63.00
Medicine Deta					
	OCHLORIDE (Suspect		Reason: Pain		
Injection		100.0 Milligram	Total	Intramuscu	
Batch:		Started: 10/07/1996	Sto	pped: 10/07/1996	
Laboratory In	vestigations:				
Additional Inf	ormation:				

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 136 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

Case Number: 110832 Seq: 1 Gender: F

Reported: 13/08/1996 Weight: 54.00
Hospitalisation: Age: 36Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment			
Dizziness						
Nausea						
Somnolence						

Medicine Details:

FENTANYL CITRATE (Suspected)		Reason: Other disturbance of sensation
	100.0 Microgram	1 time
Batch:	Started: 01/09/1995	Stopped:
PROPOFOL (Suspected)		Reason: Other disturbance of sensation
	200.0 Milligram	1 time
Batch:	Started: 01/09/1995	Stopped:
DROPERIDOL (Suspected)		Reason: Other disturbance of sensation
	2.0 Milligram	1 time
Batch:	Started: 01/09/1995	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Immunology				Skin tests done and show reactivity to droperidol.

Additional Information:

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

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 137 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

Report Details:

Case Number: 110914 Seq: 1 Gender: U

Reported: 16/08/1996 Weight: Age:

Onset Date: 13/08/1996 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

٠,	todotion Botanoi						
	Preferred Term	Severity	Report Description	Treatment			
	Dystonia			lv cogentin 1.5ml, iv midazolam 3mg,			
	Torticollis						

Medicine Details:

PETHIDINE HYDROCHLORIDE (Other d	rug)	Reason: Pain	
Injection	75.0 Milligram	As necessary	Intramuscular
Batch:	Started: 09/08/1996	Stopped:	CONTIN
PANADEINE FORTE (Other drug)		Reason: Pain	
	1.0 Dose Unspe	cified As necessary	
Batch:	Started: 11/08/1996	Stopped:	CONTIN
FLAGYL (Other drug)		Reason: Gastritis&duod	enitis
Suppository	2.0 Gram	Daily	Rectal

 Suppository
 2.0 Gram
 Daily
 Rectal

 Batch:
 Started: 12/08/1996
 Stopped: 13/08/1996

BUSCOPAN (Other drug) Reason: Pain

Injection 60.0 Milligram Daily Intramuscular

Batch: Started: 09/08/1996 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

One previous dose of droperidol 12/8/96 with no reaction observed.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 138 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:					
Case Number: 110914 Reported: 16/08/1996 ospitalisation: Onset Date: 13/08/1996 Outcome: Recovered eaction Details:	Seq: 1		С	Gender: U Weight: Age: DOB: ausality: C	Causality possible
Medicine Details:					
MAXOLON (Other drug)		Reason:	Nausea and vo		
		Daily	Stannad:	Intramusculai	
Daton.	Started: 09/00/1990	Reason:	Stoppeu.		CONTIN
DROPERIDOL (Suspected)					
	5.0 Milligram	1 time		Intravenous	
Injection Batch:	40.0 Milligram Started: 09/08/1996	Daily Reason:	Stopped:	Intramuscular	CONTIN
DROPERIDOL (Suspected) Injection Batch:	5.0 Milligram Started: 13/08/1996		Stopped:	Intravenous	
Injection	Started: 13/08/1996			Intravenous	

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 139 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

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

Case Number: 110992 Seq: 1 Gender: F

Reported: 20/08/1996 Weight: 65.00 Hospitalisation: Age: 26Y

Onset Date: 13/08/1996 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity Report Description		Treatment	
Dystonia		Locked jaw unable to open mouth + neck stiffness.	Cogentin, midazolam.	
Extrapyramidal disorder				

Medicine Details:

BUSCOPAN (Other drug) Reason: Abdominal pain

80.0 Milligram Total

Batch: Started: 09/08/1996 Stopped: 12/08/1996

STEMETIL (Suspected) Reason: Nausea and vomiting

1.0 Dose Unspecified 1 time

Batch: Started: Stopped:

DROPERIDOL (Suspected)Reason: Nausea and vomiting

10.0 Milligram Total

Batch: Started: 12/08/1996 Stopped: 13/08/1996

PETHIDINE HYDROCHLORIDE (Suspected) Reason: Pain

75.0 Milligram As necessary

Batch: Started: 09/08/1996 **Stopped:** 13/08/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 140 of 254



Case Number: 110992

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

ospitalisation: Onset Date: 13/08/1996 Outcome: Recovered eaction Details:			С	Age: DOB: ausality:	26Y Causality possible
Outcome: Recovered			С		Causality possible
			С	ausality:	Causality possible
eaction Details:					
Medicine Details:					
PANADEINE (Suspected)	Rea	son:	Pain		
, ,	1.0 Dose Unspecified		essary		
Batch:	Started: 11/08/1996			13/08/1996	
PANADEINE FORTE (Suspected)		son:	Pain		
,	2.0 Dose Unspecified				
Batch:	Started: 12/08/1996			15/08/1996	
MAXOLON (Suspected)		son:	Nausea and vo		
, , ,	40.0 Milligram	Daily		Ū	
Batch:	Started: 09/08/1996		Stopped:	12/08/1996	

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 141 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

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

 Case Number:
 112232
 Seq: 1
 Gender:
 F

 Reported:
 14/10/1996
 Weight:

Hospitalisation:
Onset Date: 01/10/1996
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Bentztropine.

Medicine Details:

TEMAZEPAM (Other drug) Reason:

Oral application 10.0 Milligram As necessary Oral

Batch: **Started**: 26/09/1996 **Stopped**: 02/10/1996

SEREVENT (Other drug) Reason: Asthma

Inhalation 2.0 Dose Unspecified As necessary Inhalation

Batch: Started: Stopped:

VENTOLIN (Other drug) Reason: Asthma

20.0 Milligram Daily

Batch: Started: 26/09/1996 **Stopped:** 02/10/1996

ONDANSETRON HYDROCHLORIDE DIHYDRATE (Other drug) Reason: Nausea and vomiting

Injection 16.0 Milligram Daily Intravenous

Batch: Started: 26/09/1996 Stopped: 02/10/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 142 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	112232	Seq: 1				Gender:	F
Reported:	14/10/1996					Weight:	
lospitalisation:						Age:	44Y
Onset Date:	01/10/1996					DOB:	
Outcome:	Recovered				С	ausality:	Causality possible
eaction Detai	ls:						
Medicine Deta				Reason:	Other prophyla		
Injection			Thousand Inf	ternat Daily		Subcutane	
Batch:		Started: 26	/09/1996			02/10/1996	3
THEO-DUR (Other	drug)			Reason:	Asthma		
Tablet			Milligram	Daily		Oral	
Batch:		Started:			Stopped:		
PREDNISONE (Oth				Reason:	Asthma		
Oral applica	ation		Milligram	Daily		Oral	
Batch:		Started:			Stopped:		
ROCALTROL (Oth	er drug)	050.0	N 4:	Reason:		01	
Capsule Batch:		Started:	Microgram	Daily	04	Oral	
	vestigations:	Started.			Stopped:		
Additional Inf	[;] ormation:						

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 143 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 144 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Gender: F Case Number: 112341 Seq: 1 Reported: 17/10/1996 Weight:

Hospitalisation: Age: 45Y Onset Date: 09/10/1995 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Tingles in hands and toes.	

Medicine Details:

MIDAZOLAM (Suspected)		Reason:	
	0.0		
Batch:	Started: 09/10/1995		Stopped:
FENTANYL CITRATE (Suspected)		Reason:	
	0.0		
Batch:	Started: 09/10/1995		Stopped:
DROPERIDOL (Suspected)		Reason:	
	0.0		
Batch:	Started: 09/10/1995		Stopped:
METOCLOPRAMIDE HYDROCHLORID	E (Suspected)	Reason:	

0.0

Batch: Started: 09/10/1995 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				All tests and mri scan normal

Additional Information:

Reaction started when patient woke from anaesthetic.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 145 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	112341	Seq: 1		Gender:	F
Reported:	17/10/1996			Weight:	
Hospitalisation:				Age:	45Y
Onset Date:	09/10/1995			DOB:	
Outcome:	Not yet recovered			Causality:	Causality possible
Reaction Detai	ls:				
Medicine Deta	oilor				
	alis. DCHLORIDE (Suspect	red)	Reason:		
		0.0			
Batch:		Started: 09/10/1995		Stopped:	
	TABLE (Suspected)		Reason:	•••	
	,	35.0 Milligram	Total		
Batch:		Started: 09/10/1995		Stopped:	
l abaratamı la	4! 4!				
Laboratory In	vestigations:				
Additional Inf					
Reaction started w	hen patient woke fro	m anaesthetic.			

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 146 of 254



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Weight:
Causality: Causality possible Report Description Treatment ing red areas chest/neck/face Cepahazolin ceased
Report Description Treatment ing red areas chest/neck/face Cepahazolin ceased
Report Description Treatment ing red areas chest/neck/face Cepahazolin ceased
ing red areas chest/neck/face Cepahazolin ceased
ing red areas chest/neck/face Cepahazolin ceased
Reason: Premedication
Reason: Premedication
Stopped:
Reason:
Stopped:
Reason:
Stopped:
Reason:
Stopped:
осоррец.
Result Details

Page 147 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	112803	Seq: 1		Gender:	M
Reported:	01/11/1996			Weight:	
Hospitalisation:				Age:	8
Onset Date:	05/10/1994			DOB:	06/11/1985
Outcome:	Unknown			Causality:	Causality possible
Reaction Detai	ls:				
Medicine Det	ails:				
DROPERIDOL (Su			Reason:		
		0.0			
Batch:		Started:		Stopped:	
CEPHAZOLIN SOL	OIUM (Suspected)		Reason:		
Injection		500.0 Milligram	2 times	Intravenou	S
Batch:		Started: 05/10/1994		Stopped: 06/10/1994	•
Laboratory In	vestigations:				
,					
Additional Inf	ormation:				
Additional ini	omation.				

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 148 of 254



Case Number: 113748

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

spitalisati						Weig	
	on:						ge : 62Y
Onset Da	ate:						OB:
	ne: Recovered					Causal	ity: Causality possible
action De				D	t D	olos II a sa	T to
	ferred Term	5	Severity	кер	ort Desc	ription	Treatment
ma and mal co	any ulaian						
aria mai oc	51144101011	<u> </u>	I				I
edicine [Doc			
AROPIN (Su	spected)		400.0 Mil		son: 1 time		
Batch	ı·	9	Started:	ligraili	i tillie	Stopped:	
	(Suspected)	•	otartea.	Rea	son:	оторрец.	
Injecti			1.0 Mil		1 time	Intrave	enous
Batch		:	Started:	3		Stopped:	
	ITRATE (Suspected	d)		Rea	son:		
ENTANYL C			50.0 Mic	rrogram	1 time	Intrave	enous
ENTANYL CI Injecti	on		30.0 WIIC	orogram	1 tillic		
		;	Started:	orogram	T time	Stopped:	
Injecti Batch		•			son:		
Injecti Batch	n: _ (Suspected)	!		Rea			enous
Injecti Batch ROPERIDOL	n: _ (Suspected) on		Started:	Rea	son:	Stopped:	enous
Injecti Batch ROPERIDOL Injecti Batch	n: _ (Suspected) on n:	:	Started: 5.0 Mill	Rea	son:	Stopped:	enous
Injecti Batch ROPERIDOL Injecti Batch	n: _ (Suspected) on	:	Started: 5.0 Mill	Rea	son:	Stopped: Intrave	enous Details



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reportalisat Onset E	Oate: ome: Unknown	Seq :	1		Wei	nder: M ight: Age: DOB: ality: Causality possible
eaction D	eferred Term	Se	verity	Reno	ort Description	Treatment
 Dystonia						7755011511
Medicine						
DROPERIDO	DL (Suspected)		0.0	Rea	son:	
Bate	ch:	Si	tarted:		Stopped:	5D
Laborato	ry Investigat	ions:				
Date	Туре	Range	Date Tested	Result		Details
Additiona	al Informatio	n:				
eport Run: 01/	/06/2007 04:50PM	l Database: pu	ısime02	A	DRS004	Page 150 of 254

Rep



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 113968 Seq: 1 Gender: F

Reported: 16/12/1996 Weight: 62.00 Hospitalisation: Age: 22Y

Onset Date: 04/09/1996 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoxia		Oxygen saturation dropped to about 60	
Shock		Peripheral circulatory failure	Ceased minomycin; resuscitation; iv fluids (haemaccel); iv ephedrine 10mg; iv adrenaline 1:1000 diluted to 10ml - 5ml given; iv dexamethasone 4mg; iv lignocaine 50mg
Extrasystoles			
Ventricular tachycardia			

Medicine Details:

INDOCID (Suspected)		Reason:	
Suppository	0.0	Rectal	
Batch:	Started:	Stopped:	
PROPOFOL (Suspected)		Reason: Surgery	
	130.0 Milligram	1 time	
Batch:	Started:	Stopped:	
FENTANYL CITRATE (Suspected)		Reason: Surgery	
	100.0 Microgram	1 time	
Batch:	Started: 04/09/1996	Stopped:	
DROPERIDOL (Suspected)		Reason: Surgery	
	2.5 Milligram	1 time	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Minomycin 100mg in 500mls of normal saline over 1/2 hour.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 151 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:				
Case Number: 113968	Seq: 1		Gender:	F
Reported: 16/12/1996	·		Weight:	62.00
ospitalisation:			Age:	22Y
Onset Date: 04/09/1996			DOB:	
Outcome: Recovered			Causality:	Causality possible
eaction Details:				
Andret on Betatle				
Medicine Details: ATRACURIUM BESYLATE (Suspected)		Reason: Surgery		
ATRACORION BESTEATE (Suspected)	30.0 Milligram	1 time		
Batch:	Started: 04/09/1996	Stopped	l:	
MINOMYCIN (Suspected)		Reason:		
Injection, intravenous infusion	100.0 Milligram	Total	Intravenou	3
	•			
Batch:	Started: 04/09/1996	Stopped	l:	
Batch:	Started: 04/09/1996	Stopped	l:	
Batch:	Started : 04/09/1996	Stopped	<u> :</u>	
Batch:	Started: 04/09/1996	Stopped	l: 	
Batch:	Started : 04/09/1996	Stopped	l:	
Batch:	Started : 04/09/1996	Stopped	l:	
Batch:	Started: 04/09/1996	Stopped	l:	
	Started : 04/09/1996	Stopped	l:	
	Started : 04/09/1996	Stopped	l:	
	Started : 04/09/1996	Stopped	l:	
	Started : 04/09/1996	Stopped	l:	
Batch: Laboratory Investigations:	Started : 04/09/1996	Stopped	l:	
	Started: 04/09/1996	Stopped	l:	
	Started: 04/09/1996	Stopped	l:	
	Started: 04/09/1996	Stopped	l:	
	Started: 04/09/1996	Stopped	l:	

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 152 of 254

Minomycin 100mg in 500mls of normal saline over 1/2 hour.



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

R۵	nai	rt D)eta	ile:
116	\mathbf{v}		GLO	11.3.

Case Number: 113992 Seq: 1 Gender: M

Reported: 18/12/1996 Weight: 71.00 Hospitalisation: Age: 16Y

Onset Date: 21/11/1996 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

'	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Oculogyration		Upper rotation of eyes	
	Diplopia			
	Tremor			

Medicine Details:

ZOFRAN (Suspected) Reason:

Injection 4.0 Milligram 1 time Intravenous

Batch: Started: 21/11/1996 Stopped:

DROLEPTAN (Suspected) Reason: Nausea and vomiting

Injection, intravenous infusion 5.0 Milligram Total Intravenous

Batch: Started: 20/11/1996 Stopped: 21/11/1996

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 153 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

ĸ	an	α rt	De	\ta	ıe.
	-	VI L		La	

Case Number: 114424 Seq: 1 Gender: F

Reported: 08/01/1997 Weight: 65.00 Hospitalisation: Age: 19Y

Onset Date: 25/08/1996 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Extrapyramidal disorder	Benztropine 2mg 9v 2230 25/8/96.
Rash maculo-papular		Maculo-papular rash on neck and back	

Medicine Details:

PANADOL (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ATIVAN (Other drug)		Reason:	
Tablet	1.0 Milligram	As necessary Sub	lingual
Batch:	Started:	Stopped:	
ZYCLIR (Other drug)		Reason:	
Injection	750.0 Milligram	Daily Intra	avenous
Batch:	Started: 16/08/1996	Stopped:	
DIFLUCAN (Other drug)		Reason: Prophylaxis	
Injection	400.0 Milligram	Daily Intra	avenous
Batch:	Started: 16/08/1996	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 154 of 254



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

edicine Details: ITEMETIL (Suspected) Injection 12.5 Milligram 2 times Intravenous Batch: Started: 24/08/1996 Stopped: 25/08/1996 ROLEPTAN (Suspected) Injection 2.5 Milligram 1 time Intravenous Batch: Started: 19/08/1996 Stopped: 25/08/1996 Reason: Injection 2.5 Milligram 1 time Intravenous Batch: Started: 19/08/1996 Stopped: 25/08/1996 Raboratory Investigations:	Reported: 08/01/1997 spitalisation: Onset Date: 25/08/1996 Outcome: Recovered action Details:	Зец. 1		С	Weight: 66 Age: 19 DOB: ausality: C	5.00	ible
Batch: Started: 19/08/1996 Stopped: 25/08/1996 aboratory Investigations:	TEMETIL (Suspected) Injection Batch:		2 times	Stopped:			
aboratory Investigations:		2.5 Milligram			Intravenous		
	Batch:	Started: 19/08/1996		Stopped:	25/08/1996		
dditional Information:	aboratory Investigations	3 :					
	dditional Information:						

ADRS004 Page 155 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

 Case Number:
 115265
 Seq: 1
 Gender:
 F

 Reported:
 14/02/1997
 Weight:

Hospitalisation: Age: 26

Onset Date: 25/07/1996 **DOB**: 07/02/1970

Outcome: Recovered Causality: Causality possible

Reaction Details:

٠,	todotion Botanoi			
Preferred Term Severity		Report Description	Treatment	
	Angioedema			Adrenaline, hydrocortisone, ventilated, intubated, paralysed & o/night icu.

Medicine Details:

viedicine Details:					
DROPERIDOL (Suspected)			Reason:	Nausea and v	omiting
Injection	2.5	Milligram	1 time	e	Intramuscular
Batch:	Started:			Stopped:	
PETHIDINE HYDROCHLORIDE (Suspected	d)		Reason:	Pain	
Injection	75.0	Milligram	1 time	e	Intramuscular
Batch:	Started:			Stopped:	
TRIMETHOPRIM (Suspected)			Reason:		
Oral application	300.0	Milligram	1 time	e	Oral
Batch:	Started: 25	/07/1996		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Previous history of dystonic reactions to metaclopramide, promethazine and prochlorperizine.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 156 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 115266 Seq: 1 Gender: F

Reported: 14/02/1997 Weight:
Hospitalisation: Age: 24

Onset Date: 07/03/1995 **DOB**: 24/10/1970

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration	-		Benztropine 2mg im, droperidol ceased.

Medicine Details:

DROPERIDOL (Suspected) Reason: Nausea and vomiting

Injection 2.0 Milligram Total Intravenous

Batch: Started: 07/03/1995 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred 165 minutes after receiving second dose. has had similar reactions to metoclopramide and prochlorperazine.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 157 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 116853 Seq: 1 Gender: F

Reported: 18/04/1997 Weight: 12.00 Hospitalisation: Age: 3Y

Onset Date: 10/04/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Benztropine 0.25mg im bd

Medicine Details:

DROPERIDOL (Suspected) Reason: Pain

Injection 3.6 Milligram Total Intramuscular

Batch: Started: 02/04/1997 Stopped: 10/04/1997

PETHIDINE HYDROCHLORIDE (Suspected) Reason: Other disturbance of sensation

Injection 12.5 Milligram Daily Intravenous

Batch: Started: 10/04/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 158 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 116915 Seq: 1 Gender: M

Reported: 18/04/1997 Weight: 31.00 Hospitalisation: Age: 8Y

Onset Date: 21/03/1997 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Diazepam

Medicine Details:

DROPERIDOL (Suspected) Reason:

3.0 Milligram Daily

Batch: Started: 21/03/1997 **Stopped:** 21/03/1997

PETHIDINE HYDROCHLORIDE (Suspected) Reason:

30.0 Milligram Daily

Batch: Started: 21/03/1997 **Stopped:** 21/03/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 159 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

•	ils:						
Hospitalisation	: 18/04/1997	Seq: 1				Gender: Weight: Age: DOB	16.00 3Y
	: Recovered				С	ausality:	Causality possible
Reaction Deta							
Prefer Oculogyration	red Term	Severity	Repo	ort Desc	ription		Treatment
Madiaina Da	t oile.						
Medicine De			Rea	son:			
	· · · · · · · · · · · · · · · · · · ·	1.5 N	1illigram	1 time			
Batch:		Started: 02/04			Stopped:	02/04/199	7
PETHIDINE HYDI	ROCHLORIDE (Suspec	ted)	Rea	son:			
			1illigram	1 time			
Batch:		Started: 02/04	1/1997		Stopped:	02/04/199	7
							ile.
Laboratory I	nvestigations: Type Ran	ge Date Tested	d Result			Deta	

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 160 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reporte ospitalisatio	er: 117716	Seq:	: 1				Gend	er: M
osnitalisatio	ed: 20/05/19	97					Weigh	nt:
-							_	e: 31Y
Onset Da	te: 15/05/19	97					DC	
Outcom	e: Recovere	ed				С	ausali	ty: Causality possible
eaction De								
	erred Term	Se	everity	Rep	ort Desci	ription		Treatment
nxiety								Benztropine
Dystonia Typertonia		Sever	re					
		•	·					
	. 4 11							
ledicine D				Doc	ason:			
LIGNOCAINE (Suspectea)		0.0	Rea	ason:			
Batch:		•	0.0 tarted: 15/05/19	007		Stopped:	15/05/1	007
ETHRANE (Sus			tarteu. 15/05/18		ason:	Stoppeu.	13/03/1	991
ETTINANE (Out	specieu _j		0.0	1100	13011.			
Batch:	<u>'</u>	S	o.o tarted: 15/05/19	997		Stopped:	15/05/1	997
DIPRIVAN (Sus					ason:			
`	. ,		200.0 Milli	gram	1 time			
Batch:	:	S	tarted: 15/05/19	997		Stopped:	15/05/1	997
DROLEPTAN (Suspected)			Rea	ason:			
			1.5 Milli	gram	1 time			
Batch:	:	S	tarted: 15/05/19	997		Stopped:	15/05/1	997
	lovostino	4:000:						
ah aratam				Desult	ı			
aboratory Date	Type	Range	Date Tested	Result			D	etails

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 161 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reported: Reported: lospitalisation: Onset Date: Outcome: eaction Detai	20/05/1997 15/05/1997 Recovered	Seq: 1			Gender: Weight: Age: DOB: ausality:	
ledicine Deta ATROPINE (Suspe			Reason:			
711101 III <u> </u>	,	600.0 Microgram	1 time			
Batch:		Started: 15/05/1997		Stopped:	15/05/1997	
TORADOL (Suspec	cted)		Reason:			
Batch:		30.0 Milligram Started: 15/05/1997	1 time		15/05/1997	
aboratory In	vestigations:					
Additional Inf	ormation:					

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 162 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

 Case Number:
 117857
 Seq: 1
 Gender: M

 Reported:
 26/05/1997
 Weight:

Hospitalisation: Age: 31

Onset Date: 19/02/1997 **DOB**: 23/04/1965

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botano			
Preferred Term	Severity	Report Description	Treatment
Hypertonia		Muscle spasm in neck and face.	
Anxiety			
Dyspnoea			
Tongue oedema			Oxygen, diazepam.

Medicine Details:

EPOETIN ALFA (Other drug)			Reas	son:	Chronic nephri	tis
Injection	8.0	Thousand	Internat	Week	ly	Subcutaneous
Batch:	Started:	l	TERM		Stopped:	
COLCHICINE (Other drug)			Reas	son:	Gout	
	500.0	Microgram		Daily		
Batch:	Started: 17	/02/1997			Stopped:	
ZANTAC (Other drug)			Reas	son:		
Tablet	1.0	Gram		Daily		Oral
Batch:	Started:	l	TERM		Stopped:	
NORVASC (Other drug)			Reas	son:	Essential beniq	gn hypertension
Tablet	40.0	Milligram		Daily		Oral
Batch:	Started:	l	TERM		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking tritace.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 163 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

 Case Number:
 117857
 Seq: 1
 Gender: M

 Reported:
 26/05/1997
 Weight:

Hospitalisation: Age: 31

Onset Date: 19/02/1997 **DOB**: 23/04/1965

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

TRITACE (Other drug)		Rea	son:	Essential beni	gn hypertension
Capsule	5.0	Milligram	Daily		Oral
Batch:	Started:	L TERM		Stopped:	
CALTRATE (Other drug)		Rea	son:	Other specified	d symptoms nec
Tablet	1.0	Dose Unspecified	Daily		Oral
Batch:	Started:	L TERM		Stopped:	
VITAMIN B COMPLEX (Other drug)		Rea	son:		
Oral application	2.0	Dose Unspecified	Daily		Oral
	2.0	Dose Orispecified	Daily		Olai
Batch:	Started:	L TERM	Dally	Stopped:	Olai
1		L TERM	son:	Stopped:	
Batch:		L TERM	,		

Laboratory Investigations:

Additional Information:

Patient also taking tritace.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 164 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Case Number: 118506 Seq: 1 Gender: F

Reported: 24/06/1997 Weight: 61.00 Hospitalisation: Age: 13Y

Onset Date: 07/06/1997 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

touction Dotains:			
Preferred Term	Severity	Report Description	Treatment
Dystonia			Benztropine 1mg im given orally
Oculogyration			
Opisthotonus			

Medicine Details:

DROPERIDOL (Suspected) Reason: Depression

Injection 0.0 As necessary Intramuscular

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 165 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

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

 Case Number:
 118725
 Seq: 1
 Gender:
 F

 Reported:
 01/07/1997
 Weight:

Hospitalisation: Age: 47Y
Onset Date: 03/06/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Benztropine.

Medicine Details:

DOMPERIDONE (Other drug) Reason: Vertigo

Tablet 10.0 Milligram As necessary Oral

Batch: Started: 01/06/1997 **Stopped:** 02/06/1997

PROMETHAZINE HYDROCHLORIDE (Other drug) Reason:

Oral application 20.0 Milligram As necessary Oral

Batch: Started: 31/05/1997 Stopped:

PETHIDINE HYDROCHLORIDE (Other drug) Reason: Pain

Injection 100.0 Milligram As necessary Intramuscular

Batch: Started: 31/05/1997 Stopped:

PANADEINE FORTE (Other drug) Reason: Pain

Tablet 1.0 Dose Unspecified As necessary Oral

Batch: Started: 31/05/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 166 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

F
47Y
Causality possible
-
S
S
_

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 167 of 254



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Reason: Other cellulitis and abscess Daily Intravenous	Reported: 01/07/1997 Hospitalisation: Onset Date: 03/06/1997 Outcome: Not yet recovere	Seq: 1	We	eight: Age: 47Y DOB: sality: Causality possible
Injection 2.5 Milligram As necessary Intramuscular	Injection Batch:	350.0 Milligram	Daily Into Stopped:	ravenous
Batch: Started: 01/06/1997 Stopped: 03/06/1997 Laboratory Investigations:		2.5 Milligram		-
Laboratory Investigations:			•	
Additional Information:	Laboratory Investigations:			
	Additional Information:			

Rep



Case Number: 119047

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

spitalisatio Onset Dat	d: 14/07/199	∂ 7			Weight:			
Onset Dat	n:				Age : 30			
-u	te: 07/07/199	97			DOB : 01/04/1967			
Outcom	e: Not yet re	covered			Caus	ality: Causality possible		
action De	tails:							
Prefe	erred Term	Se	everity	Rep	ort Description	Treatment		
ausea		Seve	re s	Severe nausea	postoperatively			
omiting		Severe S		Severe vomiting	postoperatively			
edicine D				Rea	son:			
•	. ,		0.0					
Batch:		S	started:		Stopped:			
TRACURIUM	BESYLATE (Su	spected)		Rea	son:			
			0.0					
Batch:		s	started:		Stopped:			
ROPERIDOL ((Suspected)			Rea	son:			
			0.0					
Batch:		S	started:		Stopped:			
EFZOL (Susp	ected)			Rea	son:			
			0.0					
Batch:		S	tarted:					
. h o roto m /	Investige	tionor						
Date	Investigat Type	Range	Date Teste	d Result		Details		
24.0	.) 0	. tange	Date recto	11000.1				

ADRS004 Page 169 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	119047	Seq: 1			Gender:	F
Reported:	14/07/1997				Weight:	
Hospitalisation:					Age:	30
Onset Date:	07/07/1997				DOB:	01/04/1967
	Not yet recovered			С	ausality:	Causality possible
Reaction Detai	ls:					
Medicine Deta	oilo					
FLAGYL (Suspect			Reason:			
l = 101 = (ouopool	- u,	0.0				
Batch:		Started:		Stopped:		
NITROUS OXIDE (Suspected)		Reason:			
,	,	0.0				
Batch:		Started:		Stopped:		
ISOFLURANE (Sus	spected)		Reason:			
		0.0				
Batch:		Started:		Stopped:		
MORPHINE NOS (Suspected)		Reason:	Prophylaxis		
Injection, ir	ntravenous infusion	48.0 Milligram	Daily		Intravenou	S
Batch:		Started: 07/07/1997		Stopped:	08/07/1997	,
1 ala aa4 a 1	4! 4!					<u>-</u>
Laboratory In	vestigations:					
Additional Inf	formation:					

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 170 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Gender: F Case Number: 119204 Seq: 1 Weight: 83.00 Reported: 17/07/1997

Hospitalisation: Hospitalisation prolonged **Age:** 32

Onset Date: 24/06/1997 **DOB**: 23/08/1964

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea			Sleep.

Medicine Details:

DROPERIDOL (Suspected)		Reason:	Other disturba	nce of sensation
Injection	0.0			Intravenous
Batch:	Started: 24/06/1997		Stopped:	24/06/1997
SEVORANE (Suspected)		Reason:	Other disturba	nce of sensation
Injection	0.0			Intravenous
Batch:	Started: 24/06/1997		Stopped:	24/06/1997
PANADEINE FORTE (Suspected)		Reason:	Pain	
Tablet	2.0 Dose Unspeci	fied 1 time		Oral
Batch:	Started: 24/06/1997		Stopped:	24/06/1997
FENTANYL CITRATE (Suspected)		Reason:	Other disturba	nce of sensation
Injection	100.0 Milligram	1 time		Intravenous
Batch:	Started: 24/06/1997		Stopped:	24/06/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Oral analgesia given on an empty stomach

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 171 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	119204	Seq: 1		Gender:	F
Reported:	17/07/1997			Weight:	83.00
spitalisation:	Hospitalisation pr	rolonged		Age:	32
Onset Date:	24/06/1997			DOB:	23/08/1964
Outcome:	Recovered			Causality:	Causality possible
action Detai	ls:				
<u>ledicine Deta</u>					
DIPRIVAN (Suspec	cted)			turbance of sensa	ation
Injection		180.0 Milligram	1 time	Intravenous	S
Batch:		Started : 24/06/1997		24 /06/1997	'
Batch:				24 /06/1997	
	vestigations:			24 /06/1997	
	vestigations:			24 /06/1997	
	vestigations:			24 /06/1997	
	vestigations:			ped: 24/06/1997	•
	vestigations:			ped: 24/06/1997	
	vestigations:			24 /06/1997	
	vestigations:			ped: 24/06/1997	•
	vestigations:			ped: 24/06/1997	
aboratory In		Started: 24/06/1997		24 /06/1997	
aboratory In	formation:	Started: 24/06/1997		ped: 24/06/1997	
aboratory In	formation:	Started: 24/06/1997		ped: 24/06/1997	

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 172 of 254



DOB: 25/11/1950

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

Report Details:

Gender: F Case Number: 119210 Seq: 1 Weight: 97.00 Reported: 17/07/1997

Hospitalisation: Hospitalisation prolonged Age: 46

Onset Date: 12/06/1997 Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Ì	Preferred Term	Severity	Report Description	Treatment
			- · ·	Maxolon, ondansetron

Medicine Details:

SEVOFLURANE (Suspected)

	0.0	
Batch:	Started: 12/06/1997	Stopped: 12/06/1997
NEOSTIGMINE NOS (Suspected)		Reason: Other disturbance of sensation
Injection	0.0	Intravenous
Batch:	Started: 12/06/1997	Stopped: 12/06/1997
FENTANYL CITRATE (Suspected)		Reason: Other disturbance of sensation
Injection	100.0 Milligram	1 time Intravenous
Batch:	Started: 12/06/1997	Stopped: 12/06/1997
DROPERIDOL (Suspected)		Reason: Other disturbance of sensation

Reason:

Other disturbance of sensation

1 time

500.0 Microgram Injection Intravenous Started: 12/06/1997 Batch: Stopped: 12/06/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 173 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:		Seq: 1				Gender:		
Reported:		lan mad				Weight:		
-	Hospitalisation pro	longed				Age:		
Onset Date:					C		25/11/1950	blo
eaction Detail	Not yet recovered				C	ausanty:	Causality possil	oie
action Detail	.s.							
<u>ledicine Deta</u>								
DIPRIVAN (Suspec	ted)				Other disturba			
Injection			Milligram	1 time		Intravenou		
Batch:		Started: 12/	06/1997			12/06/1997		
ATROPINE (Suspe	cted)				Other disturba			
Injection			Dose Unspec	ified 1 time		Intravenou		
Batch:		Started: 12/0	06/1997			12/06/1997	•	
	OCHLORIDE (Suspecte				Pain			
			_	Total				
Batch:		Started: 12/	06/1997		Stopped:	12/06/1997	,	
Injection Batch: Laboratory Inv			Milligram 06/1997	Total		Intravenou: 12/06/1997		
Additional Inf	ormation:							

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 174 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

Report Details:

 Case Number:
 119222
 Seq: 1
 Gender:
 F

 Reported:
 17/07/1997
 Weight:

Hospitalisation: Hospitalisation prolonged Age: 31

Onset Date: 16/06/1997 **DOB**: 02/06/1966

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea		Post op nausea	Maxolon

Medicine Details:

ISOFLURANE (Suspected) Reason: Other disturbance of sensation

0.0

Batch: Started: 16/06/1997 **Stopped:** 16/06/1997

PETHIDINE HYDROCHLORIDE (Suspected) Reason: Pain

 Injection
 75.0 Milligram
 1 time
 Intramuscular

 Batch:
 Started: 16/01/1997
 Stopped: 16/06/1997

ROCURONIUM BROMIDE (Suspected) Reason: Other disturbance of sensation

 Injection
 40.0
 Milligram
 1 time
 Intravenous

 Batch:
 Started: 16/06/1997
 Stopped: 16/06/1997

FENTANYL CITRATE (Suspected) Reason: Other disturbance of sensation

 Injection
 75.0 Milligram
 1 time
 Intravenous

 Batch:
 Started: 16/06/1997
 Stopped: 16/06/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 175 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Re	oa	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 119222
 Seq: 1
 Gender:
 F

 Reported:
 17/07/1997
 Weight:

Hospitalisation: Hospitalisation prolonged **Age**: 31

Onset Date: 16/06/1997 **DOB**: 02/06/1966

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

DROPERIDOL (Suspected)		Reason: Other distur	bance of sensation
Injection	1.5 Milligram	1 time	Intravenous
Batch:	Started: 16/06/1997	Stopped	1: 16/06/1997
ATROPINE (Suspected)		Reason: Other distur	bance of sensation
Injection	1.6 Milligram	1 time	Intravenous
Batch:	Started: 16/06/1997	Stopped	1: 16/06/1997
NEOSTIGMINE NOS (Suspected)		Reason: Other distur	bance of sensation
Injection	3.5 Milligram	1 time	Intravenous
Batch:	Started: 16/06/1997	Stopped	1 : 16/06/1997
THIOPENTONE SODIUM (Suspected)		Reason: Other distur	bance of sensation
Injection	425.0 Milligram	Daily	Intravenous
Batch:	Started: 16/06/1997	Stopped	i : 16/06/1997

Laboratory Investigations:

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 176 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 120877 Seq: 1 Gender: F

Reported: 16/09/1997 Weight: 68.00 Hospitalisation: Age: 24Y

Onset Date: 24/12/1996 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Couldnt breathe properly	

Medicine Details:

DROPERIDOL (Suspected) Reason: Nausea and vomiting

 Injection
 2.5 Milligram
 1 time
 Intramuscular

 Batch:
 Started: 24/12/1996
 Stopped: 24/12/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 177 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

 Case Number:
 121866
 Seq: 1
 Gender: M

 Reported:
 27/10/1997
 Weight:
 61.00

Hospitalisation: Age: 67Y
Onset Date: 22/10/1997
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u>teaction Details.</u>			
Preferred Term	Severity	Report Description	Treatment
Pyrexia		Temp 38 oc	
Confusional state			
Hypertonia			
Neuroleptic malignant syndrome			lv dantrolene and bromocryptine

Medicine Details:

ISOFLURANE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
DROPERIDOL (Suspected)		Reason: Other disturbance of sensation	
Injection	1.5 Milligram	1 time Intravenous	
Batch:	Started: 21/10/1997	Stopped:	
PROPOFOL (Suspected)		Reason: Other disturbance of sensation	
Injection	100.0 Milligram	1 time Intravenous	
Batch:	Started:	Stopped:	
DICLOXACILLIN SODIUM (Suspected)		Reason:	
Injection	2.0 Gram	1 time Intravenous	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of previous anaesthetics without problems, has history of hypertension

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 178 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 121866 Seq: 1 Gender: M

Reported: 27/10/1997 Weight: 61.00 Hospitalisation: Age: 67Y

Onset Date: 22/10/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

GENTAMICIN SULPHATE (Suspected)		Reason:	
Injection	180.0 Milligram	1 time Intravenous	
Batch:	Started:	Stopped:	
FENTANYL CITRATE (Suspected)		Reason: Other disturbance of sensation	
Injection	162.5 Milligram	Total Intravenous	
Batch:	Started:	Stopped:	
ATRACURIUM BESYLATE (Suspected)		Reason: Other disturbance of sensation	
Injection, intravenous infusion	10.0 Milligram	Per hour Intravenous	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

History of previous anaesthetics without problems, has history of hypertension

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 179 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:		
Case Number: 122742	Seq: 1	Gender: F

 Reported: 24/11/1997
 Weight:

 Hospitalisation:
 Age: 60Y

 Onset Date: 15/10/1997
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

MIDAZOLAM (Suspected)		Reason: Other disturbance of sensation	
	2.5 Milligram	2 times	
Batch:	Started:	Stopped:	
PROPOFOL (Suspected)		Reason: Other disturbance of sensation	
	100.0 Milligram	1 time	
Batch:	Started:	Stopped:	
DROPERIDOL (Suspected)		Reason: Other disturbance of sensation	
	15.0 Milligram	1 time	
Batch:	Started:	Stopped:	
BUPIVACAINE HYDROCHLORIDE (Suspected)	Reason: Other disturbance of sensation	
	75.0 Milligram	1 time	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 180 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	122742	Seq: 1			Gender:	: F	
Reported: 2	24/11/1997				Weight:		
Hospitalisation:					Age:	60Y	
Onset Date:	15/10/1997				DOB	:	
Outcome:	Recovered				Causality:	Causality possible	
Reaction Details	s:						
Medicine Deta	ils:						
	CHLORIDE (Suspecte	ed)		Reason:	Other disturbance of sens	sation	
			Milligram	1 time	:		
Datah.			J				
Batch:		Started:			Stopped:		
Batch:	pected)	Started:		Reason:	Stopped: Other disturbance of sens	sation	
ISOFLURANE (Susp	pected)		Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp	pected)	1.0	Percent	Reason: 1 time	Other disturbance of sens	sation	
	pected)		Percent		Other disturbance of sens	eation	
ISOFLURANE (Susp	pected)	1.0	Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp	pected)	1.0	Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp	pected)	1.0	Percent		Other disturbance of sens	eation	
ISOFLURANE (Susp	pected)	1.0	Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp	pected)	1.0	Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp Batch:		1.0	Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp Batch:		1.0	Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp		1.0	Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp Batch:		1.0	Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp Batch:		1.0	Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp Batch:		1.0	Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp Batch:		1.0	Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp Batch:		1.0	Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp Batch:		1.0	Percent		Other disturbance of sens	sation	
Batch: Laboratory Inv	vestigations:	1.0	Percent		Other disturbance of sens	sation	
ISOFLURANE (Susp Batch:	vestigations:	1.0	Percent		Other disturbance of sens	sation	
Batch: Laboratory Inv	vestigations:	1.0	Percent		Other disturbance of sens	sation	
Batch: Laboratory Inv	vestigations:	1.0	Percent		Other disturbance of sens	sation	
Batch: Laboratory Inv	vestigations:	1.0	Percent		Other disturbance of sens	sation	
Batch: Laboratory Inv	vestigations:	1.0	Percent		Other disturbance of sens	sation	

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 181 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Gender: F Case Number: 122744 Seq: 1 Reported: 25/11/1997 Weight:

Hospitalisation: Age: 45Y **Onset Date:** 14/11/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	<u>toaotion Botanoi</u>			
	Preferred Term	Severity	Report Description	Treatment
	Dystonia		Ocomotor spasm	Benztropine 4mg iv
	Tongue disorder		Tongue rolled back	

Medicine Details:			
MORPHINE NOS (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
DROPERIDOL (Suspected)		Reason: Other disturbance of sensation	
	5.0 Milligram	Daily	
Batch:	Started: 13/11/1997	Stopped: 14/11/1997	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has previous history to maxolon, stemetil and other drugs.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 182 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

-		Seq. 1			nuer. IVI
	ted: 28/07/1998	3		We	eight:
spitalisati					Age : 21
	Date: 06/04/1998				DOB : 17/06/1976
Outco	me: Recovered			Caus	sality: Causality possible
action D	etails:				
Pre	eferred Term	Severity	Rep	ort Description	Treatment
ystonia					
lypertonia					
)pisthotonu					Benztropine iv 1mg.
achycardia	i				
ledicine PANADOL (C			Do.	ason: Pain	
PANADOL (C	other arug)	0.0	Rea	ason: Pain	
Batc	·h·	0.0 Started: 04/	M4/1998	Stopped:	
	(Other drug)	Starteu. 04/		ason: Pain	
ANADEINE	(Julier drug)	0.0	Rec	ason. I am	
Batc	:h:	Started: 04/	04/1998	Stopped:	
		RIDE DIHYDRATE (Other		ason: Nausea and vomiti	ng
Table			Milligram	1 time Ora	_
Batc		Started: 06/	_	Stopped:	
/ENTOLIN (C				ason:	
Inhala		0.0			alation
	:h:	Started: 05/	04/1998	Stopped:	
Batc				•	
	v Investigatio	ons:			
	ry Investigatio	ons: Range Date Test	ted Result		Details

ADRS004 Page 183 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	28/07/1998 06/04/1998 Recovered	Seq: 1		C			
Medicine Deta	ails:						
	DROCHLORIDE (Other	er drug)	Reason:	Otr&nos infect	¶sit dise	eases	
Oral applica	ation	1.2 Gram	Daily		Oral		
Batch:		Started: 04/04/1998		Stopped:			
DICLOXACILLIN S	ODIUM (Other drug)		Reason:	Otr&nos infec	Rparasit dise	eases	
Injection		4.0 Gram	Daily		Intravenous	S	
Batch:		Started: 04/04/1998		Stopped:			
METOCLOPRAMID	E HYDROCHLORIDE	(Other drug)	Reason:	Nausea and vo	omiting		
Injection		40.0 Milligram	Daily		Intravenous	S	
Batch:		Started: 04/04/1998	•	Stopped:	05/04/1998	}	
DROPERIDOL (Sus	spected)		Reason:	Nausea and vo			
		0.0					
Batch:		Started: 03/04/1998		Stopped:	06/04/1998	}	
Laboratory In							
Additional Inf	ormation:						

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 184 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

 Case Number:
 130780
 Seq: 1
 Gender:
 F

 Reported:
 03/09/1998
 Weight:

Hospitalisation: Age: 49

Onset Date: 17/08/1998 **DOB**: 05/09/1948

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tongue oedema		Pulling and swelling at back of tongue.	

Medicine Details:

DIHYDROERGOTAMINE (Other drug) Reason: Migraine

Injection 1.0 Milligram 1 time Intravenous

Batch: Started: 17/08/1998 Stopped:

DROPERIDOL (Suspected)Reason:Nausea and vomitingInjection500.0Microgram1 timeIntravenous

Batch: Started: 17/08/1998 **Stopped:** 17/08/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 185 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:		
Case Number: 130789	Seq: 1	Gender: M

 Reported:
 03/09/1998
 Weight:

 Hospitalisation:
 Age:
 2Y

 Onset Date:
 30/07/1998
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion botano.			
Preferred Term	Severity	Report Description	Treatment
Opisthotonus		Hyperextension of neck	
Dystonia			Cogentin iv 2 doses.

Medicine Details:

DROPERIDOL (Suspected)Reason: Other disturbance of sensation

0.0

Batch: Started: 30/07/1998 **Stopped:** 30/07/1998

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 186 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Gender: F Case Number: 131602 Seq: 1

Weight: 98.00 Reported: 30/09/1998 Hospitalisation: **Age:** 49Y

Onset Date: 09/07/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Extreme hypotention	
Cyanosis			
Flushing			Pt was resuscitated using adrenaline 0.5mg x oxygen and iv fluids.

Medicine Details:

PETHIDINE HYDROCHLORIDE (Su	spected)	Reason: Other disturbance of sensation
	50.0 Milligram	1 time
Batch:	Started: 09/07/1998	Stopped: 09/07/1998
DROLEPTAN (Suspected)		Reason:
	1.0 Milligram	1 time
Batch:	Started: 09/07/1998	Stopped: 09/07/1998
HYPNOVEL (Suspected)		Reason: Other disturbance of sensation
	2.0 Milligram	1 time
Batch:	Started: 09/07/1998	Stopped: 09/07/1998

ESMERON (Suspected) Reason:

> 60.0 Milligram 1 time

Batch: Started: 09/07/1998 **Stopped:** 09/07/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt has allergies to penicillin, amoxil, morphine & furadantin.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 187 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:				
Case Number: 131602 Reported: 30/09/1998 Hospitalisation: Onset Date: 09/07/1998 Outcome: Recovered Reaction Details:	Seq: 1		Gender: Weight: Age: DOB: Causality:	98.00 49Y
Medicine Details: ZOFRAN (Suspected)		Reason:		
ZOFRAN (Suspecteu)	200.0 Milligram	Daily		
Batch:	Started: 09/07/1998		Stopped: 09/07/1998	1
Laboratory Investigations:				
Additional Information: Pt has allergies to penicillin, amoxil, r	morphine & furadantin.			

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 188 of 254



Additional Information:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Do	etails	7.																				
	Number: 134787 Seq: 1 eported: 04/01/1999						Gender: U Weight: 40.00															
ospitalisat	ion:															A	Age:	13				
Onset D																D	OB:	03/	02/1	1984		
Outco	me:	Unknov	vn												C	ausa	ality:	Cau	usal	lity po	ssible)
eaction D					ī																	
		d Term			,	Sev	erity				Repo	ort De	escr	iptio	n		_		T	reatn	nent	
Oculogyratio ∕isual distu																						
/ledicine	Deta	ıils:																				
Medicine PANADEINE											Rea	son:										
							0	.0			Rea	son:										
PANADEINE Bate	(Othe	r drug)				Sta		.0 28/06/	1997		Rea	son:		Stop	pped:							
PANADEINE	(Othe	r drug)	E (Oth	ner d	rug)	Sta			1997			son:		Stop	pped:							
PANADEINE Bate	(Othe h:	r drug)	E (Oth	ner d	rug)		rted: 2	28/06/ .0 Gr	am				,	Stop	pped:		venou	ıs				
PANADEINE Bate AMOXYCILL Inject Bate	(Othe h: IN TRI tion :h:	r drug) HYDRAT		ner d	rug)		rted: 2	28/06/	am		Rea	son: Daily	,	-	oped:		venou	s				
Bato AMOXYCILL Inject Bato METRONIDA	(Othe h: IN TRI tion h: ZOLE	r drug) HYDRAT		ner d	rug)		rted: 2	28/06/ .0 Gr 28/06/	am 1997		Rea	son: Daily son:		-		Intra						
Bate AMOXYCILL Inject Bate METRONIDA	(Othe th: IN TRI tion th: ZOLE	r drug) HYDRAT		ner d	rug)	Sta	4 rted: 2	28/06/ .0 Gr 28/06/	am 1997 Iligra	m	Rea	son: Daily		Stop	pped:	Intra	venou					
PANADEINE Bate AMOXYCILL Inject Bate METRONIDA Inject Bate	(Othe th: IN TRI tion th: ZOLE tion	r drug) HYDRAT (Other di		ner d	rug)	Sta	4 rted: 2	28/06/ .0 Gr 28/06/	am 1997 Iligra	m	Rea	son: Daily son: Daily		Stop		Intra						
Bate AMOXYCILL Inject Bate METRONIDA Inject Bate INDOCID (Or	(Othe th: IN TRI tion th: ZOLE tion th:	r drug) HYDRAT (Other di		ner d	rug)	Sta	4 rted: 2 900 rted: 2	28/06/ .0 Gr 28/06/ .0 Mi 25/06/	am 1997 Iligra 1997	m	Rea	son: Daily son: Daily son:	,	Stop	pped:	Intra	venou					_
Bate AMOXYCILL Inject Bate METRONIDA Inject Bate INDOCID (On	(Othe ch: IN TRI tion ch: ZOLE tion ch: her dr	r drug) HYDRAT (Other di		ner d	rug)	Sta	900 rted: 2	28/06/ .0 Gr 28/06/ .0 Mi 25/06/	am 1997 Iligra 1997	m m	Rea	son: Daily son: Daily	,	Stop	oped:	Intra	venou					
Bate AMOXYCILL Inject Bate METRONIDA Inject Bate INDOCID (Or	(Othe ch: IN TRI tion ch: ZOLE tion ch: her dr	r drug) HYDRAT (Other di		ner d	rug)	Sta	900 rted: 2	28/06/ .0 Gr 28/06/ .0 Mi 25/06/	am 1997 Iligra 1997	m m	Rea	son: Daily son: Daily son:	,	Stop	pped:	Intra	venou					
Bato AMOXYCILL Inject Bato METRONIDA Inject Bato INDOCID (Or Supp	(Othe th: IN TRI tion th: ZOLE tion th: her dr	r drug) HYDRAT	rug)			Sta	900 rted: 2	28/06/ .0 Gr 28/06/ .0 Mi 25/06/	am 1997 Iligra 1997	m m	Rea	son: Daily son: Daily son:	,	Stop	oped:	Intra	venou					
Bate AMOXYCILL Inject Bate METRONIDA Inject Bate INDOCID (Off	(Othe th: IN TRI tion th: ZOLE tion th: her dr pository th:	r drug) HYDRAT	rug)	ons		Star Star	900 rted: 2 200 rted: 3	28/06/ .0 Gr 28/06/ .0 Mi 25/06/	am 1997 Iligra 1997	m m	Rea Rea	son: Daily son: Daily son:	,	Stop	oped:	Intrav Intrav Recta	venou	ıs				

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 189 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	134787	Seq: 1		Ge	nder: U		
Reported:	04/01/1999	•		We	ight: 40	.00	
lospitalisation:					Age: 13		
Onset Date:	01/07/1997					/02/1984	
Outcome:						usality possible	e
eaction Detai						accanty possible	
cuotion beta							
84 - J	- •1 -						
Medicine Det			Dana and				
DROPERIDOL (Su	spectea)		Reason:				
Injection		1.0 Milligram	1 time		avenous		
Batch:		Started: 01/07/1997		Stopped: 01/0	07/1997		
PROCHLORPERA	ZINE MALEATE (Sus	pected)	Reason:				
Injection		15.0 Milligram	Daily	Intra	avenous		
Batch:		Started: 29/06/1997		Stopped:			
							<u>.</u>
l abanatanı lu							
Laboratory in	vestigations:						
Additional Inf	formation:						
, taaitionai iii							
aport Pup : 01/06/20	07 04:50PM Data	shasa: nusima02	ADDS004			Daga 100 a	

Page 190 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

Case Number: 134855 Seq: 1 Gender: F

Reported: 04/01/1999 **Weight:** 18.00

 Hospitalisation:
 Age: 8

 Onset Date: 22/05/1998
 DOB: 30/01/1990

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction betails.			
Preferred Term	Severity	Report Description	Treatment
Hallucination		Stating she was another person.	
Depersonalisation			
Urinary retention			

Medicine Details:

MORPHINE NOS (Other drug)		Reason: Cong anom	n of spine
Injection	10.0 Milligram	Daily	Intravenous
Batch:	Started: 20/05/1998	Stoppe	d:
DIAZEPAM (Suspected)		Reason: Cong anom	n of spine
Tablet	2.0 Milligram	1 time	Oral
Batch:	Started: 22/05/1998	Stoppe	d:
GENTAMICIN SULPHATE (Suspected)		Reason:	
Injection	50.0 Milligram	1 time	Intravenous
Batch:	Started: 22/05/1998	Stoppe	d:
DROPERIDOL (Suspected)		Reason: Cong anom	n of spine
Injection	1.2 Milligram	Daily	Intravenous

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 191 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:				
Case Number: 134855	Seq: 1		Gender:	F
Reported: 04/01/1999	•		Weight:	
Hospitalisation:			Age:	
Onset Date: 22/05/1998				30/01/1990
Outcome: Recovered				Causality possible
Reaction Details:			- Caucanty.	cadeanty peccione
Medicine Details:				
PANADOL (Suspected)		Reason:	Cong anom of spine	
Suppository	1.5 Gram	Daily	Rectal	
Batch:	Started: 20/05/1998	,	Stopped:	
Laboratory Investigations:				
A 1 100				
Additional Information:				

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 192 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

 Case Number:
 135175
 Seq: 1
 Gender:
 F

 Reported:
 14/01/1999
 Weight:

Hospitalisation: Age: 30Y
Onset Date: 01/10/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Rash			Oxygen given via hudson mask, im phenergan 25mg.
Нурохіа			

Medicine Details:

Keflin Neutral (Suspected)		Reason:		
Injection	1.0 Gram	1 time	Intravenous	
Batch:	Started: 01/10/1998	S	Stopped:	
FENTANYL CITRATE (Suspected)		Reason: Othe	er disturbance of sensation	
Injection	1.0 Dose Unspecif	ied 1 time	Intravenous	
Batch:	Started: 01/10/1998	s	Stopped:	
MIDAZOLAM (Suspected)		Reason: Othe	er disturbance of sensation	
Injection	1.0 Dose Unspecif	ied 1 time	Intravenous	
Batch:	Started: 01/10/1998	S	Stopped:	
DIPRIVAN (Suspected)		Reason: Othe	er disturbance of sensation	
Injection	1.0 Dose Unspecif	ied 1 time	Intravenous	
Batch:	Started: 01/10/1998	S	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data		Saturation oxygen decrease		Saturation oxygen decreased to 89%.

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 193 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number: 135175 Reported: 14/01/1999 Hospitalisation: Onset Date: 01/10/1998 Outcome: Recovered Reaction Details:	Seq: 1	Gender: F Weight: Age: 30Y DOB: Causality: Causality possible
Medicine Details:	December Other	disturbance of connection
DROLEPTAN (Suspected)		disturbance of sensation
Injection Batch:	1.0 Dose Unspecified 1 time Started: 01/10/1998 St	Intravenous copped:
Laboratory Investigations:		
Additional Information:		

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 194 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

 Case Number:
 137338
 Seq: 1
 Gender: M

 Reported:
 16/03/1999
 Weight:

Hospitalisation: Age: 23

Onset Date: 22/10/1998 **DOB**: 15/11/1974

Outcome: Unknown Causality: Causality possible

Reaction Details:

i todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Leukopenia			
Neutropenia			

Medicine Details:

MIDAZOLAM (Suspected)		Reason:	
Injection	10.0 Milligram	1 time	Intramuscular
Batch:	Started: 21/10/1998	Stoppe	d:
DROPERIDOL (Suspected)		Reason:	
Injection	10.0 Milligram	1 time	Intramuscular
Batch:	Started: 20/10/1998	Stoppe	d:
TEMAZEPAM (Suspected)		Reason:	
	10.0 Milligram	As necessary	
Batch:	Started:	Stoppe	d:
EFEXOR (Suspected)		Reason: Depression	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 21/10/1998	Stoppe	d:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		22/10/1998	0.99	
	White blood cells		22/10/1998	2.62	

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 195 of 254



Report Details:

Case Number: 137338

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

	16/03/1999			1	Neight:	
spitalisation:					Age:	23
Onset Date:	22/10/1998				DOB:	15/11/1974
Outcome:	Unknown			Ca	usality:	Causality possible
action Detai	ls:					
ledicine Deta						
DIAZEPAM (Suspe	cted)		Reason:	Anxiety neurosi	S	
Tablet		20.0 Milligram	Daily		Oral	
Batch:		Started: 21/10/1998		Stopped:		
HIAMINE (Suspec	cted)		Reason:			
Oral applica	ation	100.0 Milligram	Daily		Oral	
Batch:		Started: 21/10/1998		Stopped:		
Daten.			Reason:			
	ROCHLORIDE (Suspecte	ed)	Reason.			
	ROCHLORIDE (Suspecte	ed) 40.0 Milligram	Daily			
	ROCHLORIDE (Suspecte			Stopped:	20/10/1998	ı
FLUOXETINE HYD	ROCHLORIDE (Suspecte	40.0 Milligram		Stopped:	20/10/1998	i
FLUOXETINE HYD	ROCHLORIDE (Suspecte	40.0 Milligram		Stopped:	20/10/1998	·
FLUOXETINE HYD Batch:		40.0 Milligram		Stopped:	20/10/1998	
FLUOXETINE HYD Batch:	ROCHLORIDE (Suspecte	40.0 Milligram		Stopped:	20/10/1998	<u>.</u>
Batch:		40.0 Milligram		Stopped:	20/10/1998	
Batch:		40.0 Milligram		Stopped:	20/10/1998	
FLUOXETINE HYD Batch:		40.0 Milligram		Stopped:	20/10/1998	
Batch:		40.0 Milligram		Stopped:	20/10/1998	
FLUOXETINE HYD Batch:		40.0 Milligram		Stopped:	20/10/1998	
FLUOXETINE HYD Batch:		40.0 Milligram		Stopped:	20/10/1998	
FLUOXETINE HYD Batch:		40.0 Milligram		Stopped:	20/10/1998	
FLUOXETINE HYD Batch:		40.0 Milligram		Stopped:	20/10/1998	
Batch: Batch:	vestigations:	40.0 Milligram		Stopped:	20/10/1998	
Batch: Batch:	vestigations:	40.0 Milligram		Stopped:	20/10/1998	
FLUOXETINE HYD Batch:	vestigations:	40.0 Milligram		Stopped:	20/10/1998	
Batch: Batch:	vestigations:	40.0 Milligram		Stopped:	20/10/1998	
Batch: Batch:	vestigations:	40.0 Milligram		Stopped:	20/10/1998	

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 196 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

 Case Number:
 138864
 Seq: 1
 Gender: M

 Reported:
 29/04/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 2

Onset Date: 30/07/1998 **DOB**: 22/07/1996

Outcome: Recovered Causality: Causality possible

Reaction Details:

٠,	todotion Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Rash		Rash upper chest	
	Dystonia			Benztropine 0.24mg iv (0.02mg/kg).

Medicine Details:

DROPERIDOL (Suspected) Reason: Premedication

Injection 3.0 Milligram 1 time Intramuscular

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No known allergies. see original report for details of other drug - paracetamol. date of recovery: 30/7/98.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 197 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

Case Number: 139532 Seq: 1 Gender: F

Reported: 14/05/1999 Weight:
Hospitalisation: Age: 28Y

Onset Date: 14/02/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Ceasded droperidol, given benztropine iv x 4.

Medicine Details:

DROPERIDOL (Suspected) Reason:

Injection 1.0 Milligram Daily Intramuscular

Batch: Started: 14/02/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - methadone, dicloxacillin iv & dicolxacillin oral. previous allergies to metoclopramid & haloperidol. four doses of stemetil 12.5mg im given but proved ineffective.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 198 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

 Case Number:
 139883
 Seq: 1
 Gender: M

 Reported:
 24/05/1999
 Weight:

Hospitalisation: Age: 21Y

Onset Date: 12/05/1999

Outcome: Recovered without treatment

Causality: Causality possible

Reaction Details:

caction Details.								
Preferred Term	Severity	Report Description	Treatment					
Delirium								
Vomiting								

Medicine Details:

Medicine Details.				
DROPERIDOL (Suspected)		Reason:		
Injection	10.0 Milligram	2 times Intramu	scular	
Batch:	Started:	Stopped:		
CLOZARIL (Suspected)		Reason: Unspecified schizophre	enia	
Tablet	350.0 Milligram	Daily Oral		
Batch:	Started: 14/04/1999	Stopped:	CONTIN	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Please see original report for details of other drugs - thioridazine. patient has a history of agrressiveness

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 199 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

 Case Number:
 142893
 Seq: 1
 Gender: M

 Reported:
 23/08/1999
 Weight:

Hospitalisation: Age: 26

Onset Date: 18/07/1999 **DOB**: 17/12/1972

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Dystonia			Treated with cogentin 2mg orally.
Agitation		Motor restlessness	

Medicine Details:

ZUCLOPENTHIXOL DECANOATE (S	Suspected)	Reason:	
	200.0 Milligram	Weekly	
Batch:	Started: 12/07/1999	Stopped:	CONTIN
THIORIDAZINE HYDROCHLORIDE (Suspected)	Reason:	
	50.0 Milligram	As necessary	
Batch:	Started: 16/07/1999	Stopped:	CONTIN
DROPERIDOL (Suspected)		Reason:	
	5.0 Milligram	As necessary	
Batch:	Started: 16/07/1999	Stopped:	CONTIN
DIAZEPAM (Suspected)		Reason:	
	5.0 Milligram	As necessary	
Batch:	Started: 16/07/1999	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reduced thioridazine dose to maximum 600mg/d,

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 200 of 254



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Hospitalisation: Onset Date:	23/08/1999 18/07/1999 Not yet recovered	Seq: 1		
Medicine Deta				
COGENTIN (Suspe	ected)	0.5 Milligram	Reason: As necessary	
Batch:		Started: 16/07/1999	Stopped:	CONTIN
Laboratory In	vestigations:			
Additional Inf Reduced thioridazi	f ormation: ne dose to maximun	n 600mg/d,		

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 201 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number: 150478 Reported: 17/03/2000	Seq: 1			
Panartad: 17/03/2000	-		Gender:	
itehorieu. 17/03/2000			Weight:	85.00
ospitalisation:			Age:	
Onset Date: 22/02/2000			DOB:	
Outcome: Recovered			Causality:	Causality possible
action Details:				
Preferred Term	Severity	Report Desc	ription	Treatment
ngina pectoris				
chest pain				
lectrocardiogram abnormal				
lyocardial infarction				
ladiaina Dataila.				
		Reason:		
DROPERIDOL (Suspected)	2.5 M	Reason: Iilligram Daily	Intravenou	s
Medicine Details: DROPERIDOL (Suspected) Injection Batch:	2.5 M Started:	Reason: lilligram Daily	Intravenou Stopped:	s
DROPERIDOL (Suspected) Injection Batch:	Started:			s
DROPERIDOL (Suspected) Injection Batch:	Started:	lilligram Daily		
_aboratory Investigation Date Type Electrocardiograph	Started:	lilligram Daily I Result Marked s	Stopped: Deta	
Injection Batch: Batch: Aboratory Investigation Date Type	Started:	I Result Marked s Troponin	Stopped:	ls

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 202 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 150535 Seq: 1 Gender: F

Reported: 21/03/2000 Weight: 56.00 Hospitalisation: Age: 22

Onset Date: 25/11/1999 **DOB**: 27/11/1976

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Flushing	Life threatening	Generalised skin flush.	
Bronchospasm	Life threatening		Adrenaline and supportive measures. 8 hours icu.
Hypotension	Life threatening		
Tachycardia	Life threatening		

Medicine Details:

MORPHINE NOS (Suspected)	Reason: Other disturbance of sensation	
Injection	1.0 Dose Unspecified 1 time Intravenous	
Batch:	Started: 25/11/1999 Stopped:	
DROPERIDOL (Suspected)	Reason: Other disturbance of sensation	
Injection	1.0 Dose Unspecified 1 time Intravenous	
Batch:	Started: 25/11/1999 Stopped:	
PROPOFOL (Suspected)	Reason: Other disturbance of sensation	
Injection	1.0 Dose Unspecified 1 time Intravenous	
Batch:	Started: 25/11/1999 Stopped:	
LIGNOCAINE (Suspected)	Reason: Other disturbance of sensation	
Injection	1.0 Dose Unspecified 1 time Intravenous	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Immunology				Mast cell tryptase (>200). skin tests positive to rocuronium. also positive to pancuronium, vecuronium and morphine (normal).

Additional Information:

All drugs given as single dose all within 2 minutes prior to reaction. date of recovery: 26/11/1999.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 203 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:		
Case Number: 150535 Reported: 21/03/2000 Hospitalisation: Onset Date: 25/11/1999 Outcome: Recovered Reaction Details:	Seq: 1	Gender: F Weight: 56.00 Age: 22 DOB: 27/11/1976 Causality: Causality possible
Medicine Details:		
ROCURONIUM BROMIDE (Suspected)	Reason:	Other disturbance of sensation
Injection	1.0 Dose Unspecified 1 til	
Batch:	Started: 25/11/1999	Stopped: 25/11/1999
Laboratory Investigations:		

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 204 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 150746 Gender: M Seq: 1

Weight: 118.00 Reported: 24/03/2000

Age: 37Y Onset Date: 25/12/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Hospitalisation:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Agitation			
Confusional state			
Hypertension			
Hypertonia			
Tachycardia			
Tremor			

Medicine Details:

DROPERIDOL (Suspected)		Reason:	
Injection	10.0 Milligram	As necessary	Intramuscular
Batch:	Started: 23/12/1999	Stopped:	26/12/1999
TIMENTIN (Suspected)		Reason:	
Injection	18.6 Gram	Daily	Intravenous
Batch:	Started: 17/12/1999	Stopped:	27/12/1999
RANITIDINE (Suspected)		Reason:	
Injection	150.0 Milligram	Daily	Intravenous
Batch:	Started: 23/12/1999	Stopped:	26/12/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking paracetamol, heparin, nystatin, vancomycin, mianserin, metoclopramide, tramadol. p/h of reaction to stemetil tardive dyskinesia.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 205 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 154154 Seq: 1 Gender: F

Reported: 23/06/2000 Weight: 70.00 Hospitalisation: Age: 60

Onset Date: 16/06/2000 **DOB**: 29/01/1940

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria			Ceased pethidine and droperidol. given phenergan.

Medicine Details:

PETHIDINE HYDROCHLORIDE (Suspected) Reason:

0.0

Batch: Started: 15/06/2000 Stopped: 16/06/2000

DROPERIDOL (Suspected) Reason:

0.0

Batch: Started: 15/06/2000 Stopped: 16/06/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking voltaren, paracetamol. patient recovered 16/6/00.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 206 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

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

 Case Number:
 154883
 Seq: 1
 Gender: M

 Reported:
 17/07/2000
 Weight:

Hospitalisation: Age: 25Y
Onset Date: 22/01/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Bp dropped to 60/40.	
Cardiac arrest	Life threatening		Resuscitated. iv fluids, 5l normal saline, 500ml haemacel, 1.5 l albumin.
Respiratory depression			

Medicine Details:

MEGICINE DELANS.			
HYPNOVEL (Suspected)	•	Reason:	
Injection	7.5 Milligram	Daily	Intravenous
Batch:	Started: 22/01/2000	Stopped:	22/01/2000
DROPERIDOL (Suspected)	ı	Reason:	
Injection	10.0 Milligram	Daily	Intravenous
Batch:	Started: 22/01/2000	Stopped:	22/01/2000

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 207 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 161274 Seq: 1 Gender: U

Reported: 07/02/2001 Weight: 22.00 Hospitalisation: Age: AC

Onset Date: 19/01/2001 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating		Less talkative, staring into space.	

Medicine Details:

DROPERIDOL (Suspected) Reason:

 Injection
 3.0 Milligram
 Total
 Intravenous

 Batch:
 Started: 18/01/2001
 Stopped: 19/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking fentanyl, paracetamol, maxolon, ondansetron.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 208 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Re	po	rt	De	tai	ls:
	\sim		-	u	

Case Number: 161794 Seq: 1 Gender: F

Reported: 21/02/2001 Weight:
Hospitalisation: Age: 42Y

Onset Date: 18/12/2000 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Г	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Malaise		General feeling of unwell.		
	Hyperkinesia		Involuntary muscle restlessness.	Given iv cogentin 4mg and valium iv 2mg.	

Medicine Details:

DROPERIDOL (Suspected) Reason:

Oral Liquid 30.0 Millilitre Total Oral

Batch: Started: 18/12/2000 Stopped: 18/12/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 209 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 165036 Seq: 1 Gender: F

Reported: 01/06/2001 Weight: 43.00 Hospitalisation: Age: 10

Onset Date: 25/05/2001 **DOB**: 08/03/1991

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Hed held in extorsion, jaw clenched shut	Cogentin. date of recovery 25/05/01

Medicine Details:

ONDANSETRON HYDROCHLORIDE DIHYDRATE (Other drug) Reason: Nausea and vomiting

4.0 Milligram As necessary

Batch: Started: 25/05/2001 Stopped: CONTIN

DROPERIDOL (Suspected) Reason: Nausea and vomiting

0.2 Milligram As necessary

Batch: Started: 24/05/2001 Stopped: 25/05/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred 4.5 hrs post droperidol.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 210 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 169227 Seq: 1 Gender: F

Reported: 17/10/2001 Weight:
Hospitalisation: Age: 48Y

Onset Date: 04/10/2001 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Rash erythematous		Face and chest.	
Tachycardia		Increasing tachycardia.	
Hypertension			

Medicine Details:

DROPERIDOL (Suspected) Reason: Nausea and vomiting

 Injection
 1.2
 Milligram
 Daily
 Intravenous

 Batch:
 Started: 04/10/2001
 Stopped: 04/10/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 211 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 171713 Seq: 1 Gender: F

Reported: 04/01/2002 Weight: 18.00 Hospitalisation: Age: 6

Onset Date: 23/12/2001 **DOB**: 08/11/1995

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotton Botanor								
	Preferred Term	Severity	Report Description	Treatment					
	Hypertonia			Date of recovery 23.12.01. patient already in hospital.					
	Staring								

Medicine Details:

MIDAZOLAM (Other drug)		Reason:	
Oral application	4.0 Milligram	Daily	Oral
Batch:	Started: 20/12/2001	Stopped:	
RANITIDINE (Other drug)		Reason:	
Injection	54.0 Milligram	Daily	Intravenous
Batch:	Started: 22/12/2001	Stopped:	CONTIN
PARACETAMOL (Other drug)		Reason:	
Oral application	1.6 Gram	Daily	Oral
Batch:	Started: 20/12/2001	Stopped:	CONTIN
DROPERIDOL (Suspected)		Reason: Nausea and v	omiting
Injection	Injection 2.0 Milligram		Intravenous
Batch:	Started: 22/12/2001	Stonned:	23/12/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient hadhad 2 previous doses of droperidol before reaction. reaction occured when giving relatively close to a dose of metoclopramide.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 212 of 254



metoclopramide.

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

eport Details:		
Case Number: 171713	Seq: 1	Gender: F
Reported: 04/01/2002		Weight: 18.00
spitalisation:		Age : 6
Onset Date: 23/12/2001		DOB : 08/11/1995
Outcome: Recovered		Causality: Causality possible
action Details:		
edicine Details:		
edicine Details:	E (Suspected)	Reason: Nausea and vomiting
	E (Suspected) 8.0 Milligram	Reason: Nausea and vomiting Daily Intravenous
METOCLOPRAMIDE HYDROCHLORID		
METOCLOPRAMIDE HYDROCHLORID	8.0 Milligram	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORID	8.0 Milligram	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORID	8.0 Milligram	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORID	8.0 Milligram	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORID	8.0 Milligram	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORID	8.0 Milligram	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORID	8.0 Milligram	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORID	8.0 Milligram	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORID	8.0 Milligram	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORIDI Injection Batch:	8.0 Milligram Started: 21/12/2001	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORID	8.0 Milligram Started: 21/12/2001	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORIDI Injection Batch:	8.0 Milligram Started: 21/12/2001	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORIDI Injection Batch:	8.0 Milligram Started: 21/12/2001	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORIDI Injection Batch:	8.0 Milligram Started: 21/12/2001	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORIDI Injection Batch:	8.0 Milligram Started: 21/12/2001	Daily Intravenous
METOCLOPRAMIDE HYDROCHLORIDI Injection Batch:	8.0 Milligram Started: 21/12/2001	Daily Intravenous

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 213 of 254

Patient hadhad 2 previous doses of droperidol before reaction. reaction occured when giving relatively close to a dose of



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 172415 Seq: 1 Gender: F

Reported: 05/02/2002 Weight: 85.00 Hospitalisation: Age: 43Y

Onset Date: 03/12/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment				
Flushing		Facial flushing.					
Hypotension							
Tachycardia							

Medicine Details:

ESMERON (Suspected)			Reason:		
Injection	50.0	Milligram	Daily		Intravenous
Batch:	Started:			Stopped:	
DROPERIDOL (Suspected)			Reason:		
Injection	0.5	Milligram	Daily		Intramuscular
Batch:	Started:			Stopped:	
THIOPENTONE SODIUM (Suspected)			Reason:		
Injection	350.0	Milligram	Daily		Intravenous
Batch:	Started:			Stopped:	
FENTANYL (Suspected)			Reason:	Pain	
Injection	200.0	Milligram	Daily		Intravenous
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Recent ga with all same agents, except droperidol, 3 months ago uneventful. vecuron used instead of esmeron.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 214 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details	S:					
Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	05/02/2002 03/12/1997 Recovered	Seq: 1			Gender: Weight: Age: DOB: Causality:	85.00 43Y
Medicine Deta		25	Milligram	Reason:	Introveneur	
Injection Batch:		2.5 Started:	Milligram	Daily	Intravenous Stopped:	5
Laboratory In	vestigations:					
Additional Inf Recent ga with all s		t droperidol, 3 ı	months ago ι	uneventful. ved	uron used instead of	esmeron.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 215 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number:173278Seq: 1Gender:FReported:01/03/2002Weight:98.00Hospitalisation:Admitted to hospitalAge: 43Y

Onset Date: 24/01/2002 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity Report Description		Treatment	
Hypotension		Decreased bp.		
Blood creatine phosphokinase incr		Elevated ck.		
Anuria		Not passing urine.		
Dyspnoea				
Generalised oedema			Patient was hospitalised. medication was reviewed and some withdrawn with polypharmacy being the major factor.	
Peripheral ischaemia				

Medicine Details:

DERALIN (Other drug)		Reason:	Anxiety neuros	sis
Tablet	40.0 Milligram	Daily		Oral
Batch:	Started: 24/01/2002		Stopped:	CONTIN
DERALIN (Suspected)		Reason:	Anxiety neuros	sis
Tablet	80.0 Milligram	Daily		Oral
Batch:	Started: 17/01/2002		Stopped:	24/01/2002
CIPRAMIL (Suspected)		Reason:	Depression	
Tablet	40.0 Milligram	Daily		Oral
Batch:	Started: 17/01/2002		Stopped:	24/01/2002
PAXAM (Suspected)		Reason:	Other disturba	nce of sensation
Tablet	4.0 Milligram	Daily		Oral
Batch:	Started: 17/01/2002		Stopped:	24/01/2002

Laboratory Investigations:

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

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 216 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number:173278Seq: 1Gender:FReported:01/03/2002Weight:98.00Hospitalisation:Admitted to hospitalAge: 43Y

Onset Date: 24/01/2002 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

PAXAM (Suspected)		Reason:	Other disturba	nce of sensation
Tablet	2.0 Milligram	Daily		Oral
Batch:	Started: 24/01/2002		Stopped:	24/01/2002
NEURONTIN (Suspected)		Reason:		
Capsule	1.8 Gram	Daily		Oral
Batch:	Started: 21/01/2002		Stopped:	24/01/2002
NEURONTIN (Suspected)		Reason:		
Capsule	300.0 Milligram	Daily		Oral
Batch:	Started: 24/01/2002		Stopped:	28/01/2002
DROLEPTAN (Suspected)		Reason:	Otr spec symp	psychopathol nec
Injection	5.0 Milligram	Daily		Intravenous
Batch:	Started: 17/01/2002		Stopped:	26/01/2002

Laboratory Investigations:

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 217 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	173278	Seq: 1				Gender:	F	
	01/03/2002					Weight:		
-	Admitted to hospi	tal				Age:		
Onset Date:	•	ıaı				DOB:		
					•			
Outcome:					C	ausanty:	Causality possible	
Reaction Detai	IS:							
Medicine Deta								
ZYPREXA (Suspec				Reason:	Unspecified so			
Oral applica	ation	20.0	Milligram	Daily		Oral		
Batch:		Started: 15/	01/2002		Stopped:	24/01/2002	2	
SEROQUEL (Susp	ected)			Reason:	Unspecified so	hizophrenia		
Tablet		400.0	Milligram	Daily		Oral		
Batch:		Started: 21/	01/2002		Stopped:	24/01/2002	2	
SERENACE (Suspe	ected)			Reason:	Unspecified ps	ychosis		
Tablet		10.0	Milligram	Daily		Oral		
Batch:		Started: 21/	-	·	Stopped:	24/01/2002		
					•			
Laboratory In	vestigations:							
Additional Inf	ormation:							
Additional iiii	omation.							

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 218 of 254



Case Number: 173703

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

S	Severity equired pecialist onsultation	F Mild fever.	Report De		Age: 30 DOB: 22/01/1971 ausality: Causality possible Treatment
Onset Date: 06/01/2002 Outcome: Recovered eaction Details: Preferred Term Pyrexia RSi Co Blood creatine phosphokinase incr Confusional state Dystonia	equired pecialist		Report De		DOB: 22/01/1971 ausality: Causality possible Treatment
Preferred Term Pyrexia Richard Signature Phosphokinase incred State Pystonia	equired pecialist		Report De		Treatment
Preferred Term Pyrexia Riscord Blood creatine phosphokinase incr Confusional state Dystonia	equired pecialist		Report De	scription	
Preferred Term Pyrexia Richard Signature Blood creatine phosphokinase incr Confusional state Dystonia	equired pecialist		Report De	scription	
Si Co Blood creatine phosphokinase incr Confusional state Dystonia	pecialist	Mild fever.			
Confusional state Dystonia					Translation (II) (I) (I)
Confusional state Dystonia					Transferd with 6 the sec
					The standard of the second
					Treated with fluids. seroque
Hypertonia					and droperidol ceased.
Medicine Details:			Passani		
SEROQUEL (Suspected)	100.0		Reason:		
		Milligram	Daily		
Batch:	Started: 15/1	2/2001			06/01/2002
DROPERIDOL (Suspected)			Reason:	Otr spec symp	psychopathol nec
		Milligram	Daily		
Batch:	Started: 05/0	1/2002		Stopped:	06/01/2002
_aboratory Investigations: Date Type Range	Date Teste	ed Resul	t		Details

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 219 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 175129 Seq: 1 Gender: M

Reported: 06/05/2002 Weight: 0.00 Hospitalisation: Age: 25

Onset Date: 22/03/2002 **DOB:** 18/01/1977

Outcome: Death 22/03/2002 Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Arrhythmia	Life threatening		
Sudden death			

Medicine Details:

Medicine Details.			
DROPERIDOL (Suspected)		Reason:	
Injection		As necessary	Intramuscular
Batch:	Started:	Stoppe	d:
CLOZARIL (Suspected)		Reason:	
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 03/08/1999	Stoppe	d:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
06/05/2002	Autopsy report				

Additional Information:

Patient died approximately 2 and half years after commencing Clozaril. He had been receivine droperidol for some time and had received an IM injection half an hour prior to his death.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 220 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 175870 Seq: 1 Gender: F

Reported: 03/06/2002 Weight: 71.00 Hospitalisation: Age: 39

Onset Date: 08/05/2002 **DOB:** 15/01/1963

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	toaction Dotaile			
	Preferred Term	Severity	Report Description	Treatment
	Bradycardia			
	Cardiac arrest			

Medicine Details:

MORPHINE SULPHATE (Suspected)		Reason: Other disturbance of sensation	
Injection	0.0	Intravenous	
Batch:	Started:	Stopped:	
MIDAZOLAM (Suspected)		Reason: Premedication	
Injection	5.0 Milligram	1 time Intramuscular	
Batch:	Started: 08/05/2002	Stopped:	
PROPOFOL (Suspected)		Reason: Other disturbance of sensation	
Injection	1.0 Dose Unspe	ecified 1 time Intravenous	
Batch:	Started: 08/05/2002	Stopped:	
VECURONIUM BROMIDE (Suspected)		Reason: Other disturbance of sensation	
Injection	1.0 Dose Unspe	ecified 1 time Intravenous	
Batch:	Started: 08/05/2002	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No reaction to previous anaesthetics.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 221 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 175870 Seq: 1 Gender: F

Reported: 03/06/2002 Weight: 71.00 Hospitalisation: Age: 39

Onset Date: 08/05/2002 **DOB:** 15/01/1963

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

DROPERIDOL (Suspected)		Reason	Other disturba	ance of sensation
Injection	1.0	Dose Unspecified 1 ti	me	Intramuscular
Batch:	Started:		Stopped:	
MAXOLON (Suspected)		Reason	Nausea and v	omiting
Injection	1.0	Dose Unspecified 1 ti	me	Intravenous
Batch:	Started:		Stopped:	
DUCENE (Suspected)		Reason		
Tablet	15.0	Milligram Da	ly	Oral
Batch:	Started: 08/	05/2002	Stopped:	

Laboratory Investigations:

Additional Information:

No reaction to previous anaesthetics.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 222 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 182338 Seq: 1 Gender: F

Reported: 04/02/2003 Weight: 0.00 Hospitalisation: Age: 30

Onset Date: 04/10/2002 **DOB**: 25/01/1972

Outcome: Recovered Causality: Causality probable

Reaction Details:

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Dystonia		Patient became shakey, anxious and developed dystonia	Droperidol ceased.
Anxiety			
Tremor			

Medicine Details:

PARACETAMOL (Other drug)		Reason:	
	4.0 Gram	Daily	
Batch:	Started:	Stopped:	contin
MS CONTIN (Other drug)		Reason:	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	Contin
DROPERIDOL (Suspected)		Reason: Nausea and vomiting	
	250.0 Microgram	1 time	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Morphine.

Previous reactions:-24/8/02-dystonic reaction to metoclopramide, requiring benztropine iv prn.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 223 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:

 Case Number:
 186485
 Seq: 1
 Gender:
 M

 Reported:
 02/06/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 27Y

Onset Date: 20/03/2003 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		Ceased Seroquel and Chlorpromazine, no further Droperidol given.

Medicine Details:

SEROQUEL (Suspected)		Reason:		
Tablet			Oral	
Batch:	Started:	Sto	pped: 21/03/2003	
DROPERIDOL (Suspected)		Reason: Otr spe	c symp psychopathol nec	
Injection	10.0 Milligram	1 time	Intramuscular	
Batch:	Started:	Sto	pped:	
CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason: Otr spe	c symp psychopathol nec	
Tablet	100.0 Milligram	Daily	Oral	
Batch:	Started: 18/03/2003	Sto	pped: 21/03/2003	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
02/06/2003	Creatinine				
02/06/2003	Neutrophils	(2-7.5)	03/04/2003	1.24	
02/06/2003	Neutrophils	(2-7.5)	28/03/2003	1.09	
02/06/2003	Neutrophils	(2-7.5)	20/03/2003	1.61	
02/06/2003	White blood cells		20/03/2003	3.5	
02/06/2003	White blood cells		28/03/2003	2.8	
02/06/2003	White blood cells		03/04/2003	2.7	

Additional Information:

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 224 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 190616 Seq: 1 Gender: F

Reported: 18/09/2003 Weight: 0.00 Hospitalisation: Age: 31Y

Onset Date: 12/09/2003 DOB:

Outcome: Recovered 12/09/2003 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Dystonic reaction		Cogentin 1 mg IV

Medicine Details:

DROPERIDOL (Suspected)

1.0 Dose Unspecified Daily

Batch: Started: Stopped:

STEMETIL (Suspected) Reason:

1.0 Dose Unspecified Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Other medications taken: Zofran, Na Heparin.

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 225 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 193274 Seq: 1 Gender: F

Reported: 17/12/2003 Weight: 0.00 Hospitalisation: Age: 17

Onset Date: 05/12/2003 **DOB**: 15/01/1986

Outcome: Recovered 05/12/2003 Causality: Causality possible

Reaction Details:

teaction Details.				
Preferred Term	Severity	Report Description	Treatment	
Depressed level of consciousness		'	Required ICU admission, given Flumazenil 500mg iv with rapid response.	

Medicine Details:

SEROQUEL (Interaction)		Reason: Otr spec symp psychopathol nec	
Batch:	Started:	Stopped:	
MIDAZOLAM (Interaction)		Reason: Otr spec symp psychopathol nec	
Injection	10.0 Milligram	As necessary Intramuscular	
Batch:	Started:	Stopped:	
DROPERIDOL (Interaction)		Reason: Otr spec symp psychopathol nec	
Injection	5.0 Milligram	As necessary Intramuscular	
Batch:	Started:	Stopped:	
Abilify (Interaction)		Reason: Otr spec symp psychopathol nec	
Tablet	15.0 Milligram	Daily Oral	
Batch:	Started: 26/11/2003	Stopped: 05/12/2003	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Levlen, Ferro-Gradmet, Nicabate, Mylanta. Aripiprazole commenced 1 week prior (26/11/03). Multiple drug interactions many have pre this event.cipitated

Report Run: 01/06/2007 04:50PM Database: pusime02 ADRS004 Page 226 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 193274 Seq: 1 Gender: F

Reported: 17/12/2003 Weight: 0.00 Hospitalisation: Age: 17

Onset Date: 05/12/2003 **DOB**: 15/01/1986

Outcome: Recovered 05/12/2003 Causality: Causality possible

Reaction Details:

Medicine Details:

LAMICTAL (Interaction)		Reason:		
Tablet	137.0	Milligram Daily	Oral	
Batch:	Started:		Stopped:	
DIAZEPAM (Interaction)		Reason:	Otr spec symp psychopathol nec	
Tablet	20.0	Milligram Daily	Oral	
Batch:	Started:		Stopped:	
EPILIM (Interaction)		Reason:		
Tablet	1000.0	Milligram Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Additional Information:

Patient was also taking Levlen, Ferro-Gradmet, Nicabate, Mylanta. Aripiprazole commenced 1 week prior (26/11/03). Multiple drug interactions many have pre this event.cipitated

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 227 of 254



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Number:	193653	Seq : 1				Gender	: F	
Reported	: 06/01/200	14				Weight:	0.00	
lospitalisation:						Age	: 9	
Onset Date	: 13/11/200	3				DOB	: 30/03/1994	
Outcome:	Recovere	d		13/11/2003		Causality	: Causality proba	able
Reaction Deta	ils:							
	red Term	Seve	erity	Repo	ort Description		Treatmer	ıt
Oculogyration			Ос	ulogyric crisis	•			
Medicine De			Doo	Rea	son:			
Batch:		Star		se Unspecified	Stonno	d : 13/11/200	12	
Laboratory I	nvestigat _{Type}		ate Tested	Result		Deta	nile	
Date	Турс	range E	ate rested	resuit		DCIE		
Additional In	ıformatio	n:						
eport Run: 01/06/20	007 04:51PN	1 Database: pusir	me02	Α	DRS004		Page 228	of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 196398 Seq: 1 Gender: F

Reported: 13/04/2004 Weight: 50.00 Hospitalisation: Age: 15

 pitalisation:
 Age: 15

 Onset Date: 24/03/2004
 DOB: 06/01/1989

Outcome: Recovered 26/03/2004 Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Hypotension		Hypotensive (66/26).	Aripiprazole withheld then ceased. IV fluids given but was hard to re-establish BP.
Drug interaction			

Medicine Details:

Medicine Details.			
DROPERIDOL (Interaction)		Reason: Otr spec symp psychopathol nec	
Injection	10.0 Milligram	As necessary Intramuscular	
Batch:	Started:	Stopped:	
Abilify (Interaction)		Reason: Anxiety neurosis	
Tablet	15.0 Milligram	Daily Oral	
Batch:	Started: 04/03/2004	Stopped: 24/03/2004	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Buspirone, Lamictal, Centrum and Olanzapine.

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 229 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 197256 Seq: 1 Gender: U

Reported: 11/05/2004 Weight: 0.00 Hospitalisation: Age: 51

Onset Date: 12/02/2004 **DOB**: 04/10/1952

Outcome: Recovered 15/02/2004 Causality: Causality possible

Reaction Details:

Eaction Details.								
Preferred Term	Severity	Report Description	Treatment					
	Caused or prolonged inpatient hospitalisation		Augmentin duo forte ceased. Lomotil 1 tds prn					

Medicine Details:

DROPERIDOL (Suspected)	Reason: Nausea and vomiting				
Injection	1.2 Milligram	As necessary	Intravenous		
Batch:	Started: 09/02/2004	Stopped:	11/02/2004		
AUGMENTIN DUO FORTE (Suspected)	R	eason:			
	2.0 Dose Unspecifie	ed Daily			
Batch:	Started: 10/02/2004	Stopped:	11/02/2004		
ZOFRAN (Suspected)	R	eason: Nausea and v	omiting		
Injection	16.0 Milligram	Daily			
Batch:	Started: 09/02/2004	Stopped:	11/02/2004		
KEFLEX (Suspected)	R	eason:			
Capsule	2.0 Gram	Daily	Oral		
Batch:	Started: 09/02/2004	Stopped:	11/02/2004		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking panadol, maxolon,

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 230 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

_		_		
Dana	\ ret	$\mathbf{D}^{\mathbf{A}}$	tai	~ :
Repo)I L	υt	Lai	15.

Case Number: 197414 Seq: 1 Gender: F

Reported: 17/05/2004 Weight: 0.00 Hospitalisation: Age: 15Y

Onset Date: 13/05/2004 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Extrapyramidal reaction	Benztropine

Medicine Details:

DROPERIDOL (Suspected)

Reason:

Dose Unspecified

Batch: Started: Stopped:

MAXOLON (Suspected) Reason: Nausea and vomiting

Injection40.0MilligramDailyIntravenousBatch:Started: 13/05/2004Stopped: 13/05/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 231 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN.DROPERIDOL

Report Details:

Case Number: 198190 Seq: 1 Gender: M

Reported: 16/06/2004 Weight: 0.00 Hospitalisation: Age: 42

Onset Date: 13/03/2004 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism		Priapism and agitation.	Nebulised 5mg salbutamol with no effect (twice). Transfered to A & E. Withdraw blood and fluid from penile area to resolve the situation. Injected adrenaline 1:10,000 diluted 1 in 10ml. Urologist injected aramine to subside.
Agitation			

Medicine Details:

DROPERIDOL (Suspected)	Reason:
Injection	10.0 Milligram Daily

Batch: Started: 13/03/2004 Stopped:

QUETIAPINE (Suspected) Reason:

Tablet 300.0 Milligram Daily Oral

Batch: Started: Stopped:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Tablet 200.0 Milligram Daily Oral

Batch: Started: 13/03/2004 Stopped:

DIAZEPAM (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral Batch: Started: 13/03/2004 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Large amounts of alcohol injested previous night (18 schooners). Priapism resolved but was exacerbated by chlorpromazine.

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 232 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 198674 Seq: 1 Gender: F

Reported: 02/07/2004 Weight: 0.00 Hospitalisation: Age: 37

Onset Date: 30/05/2004 DOB: 25/05/1967

Outcome: Recovered Causality: Causality probable

Reaction Details:

100.00.00.00.00.			
Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Sad and suicidal thoughts, pain, dysphoria.	Counselling and reassurance.
Dysphoria			
Pain			

Medicine Details:

DROPERIDOL (Suspected) Reason: Nausea and vomiting

Injection 625.0 Microgram 1 time Intravenous

Batch: Started: 30/05/2004 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking tramadol, Paracetamol, Metronidazole, Omeprazole, Enoxaparin, Ondansetron, Nicotine patch, Promethazine.

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 233 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 200055 Seq: 1 Gender: F

Reported: 17/08/2004 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 50

Onset Date: 12/08/2004 **DOB**: 26/07/1954

Outcome: Recovered 12/08/2004 Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Muscle rigidity	Caused or prolonged inpatient hospitalisation	Patient experienced muscle rigidity and akathesia.	
Akathisia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MAXOLON (Suspected) Reason: Nausea and vomiting

30.0 Milligram Daily

Batch: Started: 11/08/2004 Stopped: 12/08/2004

DROPERIDOL (Suspected) Reason: Nausea and vomiting

Daily

Batch: Started: 11/08/2004 Stopped: 12/08/2004

Laboratory Investigations:

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

Additional Information:

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 234 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 201682 Seq: 1 Gender: U

Reported: 13/10/2004 Weight: 0.00 Hospitalisation: Age: 99U

Onset Date: 29/06/2004 DOB:

Outcome: Recovered 30/06/2004 Causality: Causality probable

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Agitation		Agitated behaviour, uncontollable screaming, hallucinations	Frequent observation. Medical review - nil medical intervention. Droperidol ceased.
Hallucination			
Screaming			

Medicine Details:

BUSCOPAN (Other drug)		Reason:
Injection	60.0 Milligram	Intravenous
Batch:	Started:	Stopped:
PARACETAMOL (Other drug)		Reason:
	4.0 Gram	Oral
Batch:	Started:	Stopped:
COLOXYL (Other drug)		Reason:
Oral Liquid	120.0 Milligram	Oral
Batch:	Started:	Stopped: 30/06/2004
AGAROL (Other drug)		Reason:
Oral Liquid	20.0 Millilitre	Oral
Batch:	Started:	Stopped: 30/06/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Mother states had similar reaction x 1 before to Maxalon (Metoclopramide). Patient appeared to be hallucinating.

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 235 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number: 201682 Seq: 1 Gender: U

Reported: 13/10/2004 Weight: 0.00 Hospitalisation: Age: 99U

Onset Date: 29/06/2004 DOB:

Outcome: Recovered 30/06/2004 Causality: Causality probable

Reaction Details:

Medicine Details:

ONDANSETRON HYDROCHLORIDE	Reason:			
Injection	12.0 Milligram	Daily	Intravenous	
Batch:	Started: 22/06/2004	St	topped:	0
DROPERIDOL (Suspected)		Reason:		
DROPERIDOL (Suspected) Injection	5.0 Milligram	Reason: 1 time	Intravenous	

Laboratory Investigations:

Additional Information:

Mother states had similar reaction x 1 before to Maxalon (Metoclopramide). Patient appeared to be hallucinating.

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 236 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

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

Case Number:203329Seq: 1Gender:MReported:07/12/2004Weight:8.00Hospitalisation:Admitted to hospitalAge: 0

Onset Date: 25/11/2004 DOB: 16/05/2004

Outcome: Recovered 25/11/2004 Causality: Causality possible

Reaction Details:

Dreferred Term	Coverity	Depart Description	Tractment
Preferred Term	Severity	Report Description	Treatment
Oculogyration	Caused or prolonged inpatient hospitalisation	Oculogynic dystonic reaction.	Required IV Benztropine
Dystonia	Caused or prolonged inpatient hospitalisation		

		ne		

DROPERIDOL (Suspected)	Reason:				
Injection	1.0	Dose Unspecified	1 time	Intravenous	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 237 of 254



Hospitalisation:

Case Number: 203664

Reported: 20/12/2004

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Age: 38

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

Onset D	oate: 30/11/200	14		DOB:				
Outco	me: Not yet re	covered		Causality: Causality possible				
Reaction D	etails:							
	eferred Term		everity	Repo	ort Description	Treatment		
Supraventrio	cular tachycardi	a	Patient experienced a cardiac event twenty years ago. On the 30/11/04 was administered Ondansetron HCL. At the same time, she also received Droperidol injection, almost straight after she was administered both medications, she experienced supraventricular tachycardia					
Medicine ZOFRAN (Su				Rea	son:			
Bato	ch:	s	started: 30/11	/2004	Stopped:			
DROLEPTAN	l (Suspected)			Rea	son:			
Bato	ch:	S	started:		Stopped:	0		
Laborato	ry Investigat	ions:						
Date	Туре	Range	Date Tested	d Result	l	Details		
Additiona	ıl Informatio	n:						
eport Run: 01/	06/2007 04:51PN	1 Database: po	usime02	Α	DRS004	Page 238 of 254		



Hospitalisation:

Case Number: 207252

Reported: 19/04/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 58.00

Age: 16

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

Outcome: Recovered eaction Details: Preferred Term Severity Report Description Treatm Muscle twitching Caused or prolonged inpatient hospitalisation Vomiting Caused or			
Preferred Term Severity Report Description Treatm Muscle twitching Caused or prolonged inpatient hospitalisation Twitching legs and arms after 1 dose of droperidol, vomiting. Benztropine 1mg	 nent		
Muscle twitching Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged droperidol, vomiting. Benztropine 1mg	nent		
prolonged droperidol, vomiting. inpatient hospitalisation			
Vomiting Caused or	im.		
prolonged inpatient hospitalisation			
Medicine Details: MORPHINE SULPHATE (Other drug) Reason:			
Batch: Started: Stopped:			
OXYCODONE HYDROCHLORIDE (Other drug) Reason:			
Batch: Started: Stopped:			
TROPISETRON HYDROCHLORIDE (Other drug) Reason:			
Batch: Started: Stopped:			
AMPICILLIN (Other drug) Reason:			
Batch: Started: Stopped:			
- Constant C			
aboratory Investigations:			
- Constant C			
aboratory Investigations:			
aboratory Investigations:			
_aboratory Investigations:			
_aboratory Investigations:			
_aboratory Investigations:			
_aboratory Investigations: Date Type Range Date Tested Result Details			
Laboratory Investigations:			
Laboratory Investigations: Date Type Range Date Tested Result Details			
_aboratory Investigations: Date Type Range Date Tested Result Details			
_aboratory Investigations: Date Type Range Date Tested Result Details			



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Hospitalisation: Onset Date: Outcome: Reaction Detai	19/04/2005 20/02/2005 Recovered ils:	Seq: 1			58.00
GENTAMICIN SUL	PHATE (Other drug)		Reason:		
Batch:		Started:		Stopped:	
METRONIDAZOLE	(Other drug)		Reason:		
Batch:		Started:		Stopped:	
DROPERIDOL (Su	spected)		Reason:		
Injection		5.0 Milligram	1 time	Intravenou	s
Batch:		Started: 20/02/2005		Stopped:	
Laboratory In	vestigations:				
Additional Inf	formation:				

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 240 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Rep	oort	Deta	ils:
-----	------	------	------

Case Number: 210461 Seq: 1 Gender: M

Reported: 05/08/2005 Weight: 80.50 Hospitalisation: Age: 72

Onset Date: 18/05/2005 **DOB:** 13/11/1932

Outcome: Recovered 18/05/2005 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	Dystonic reaction, restlessness, anxiety, felt out of control, could not focus.	Treated with Cogentin IV/1mg.
Anxiety	Caused or prolonged inpatient hospitalisation		
Feeling abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DROPERIDOL (Suspected) Reason: Other disturbance of sensation

As necessary

Batch: Started: Stopped:

MORPHINE SULPHATE (Suspected) Reason: Nausea and vomiting

30.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 241 of 254



Case Number: 210461

Reported: 05/08/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 80.50

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

Hospitalisation:			Ag	e : 72	
Onset Date: 18/05/2005		DOB : 13/11/1932			
Outcome: Recovered		18/05/2005	Causalit	ty: Causality possib	ole
Reaction Details:					
Preferred Term	Severity	Report Des	scription	Treatment	
Restlessness	Caused or prolonged inpatient hospitalisation				
Medicine Details:					
DROPERIDOL (Suspected)		Reason:	Other disturbance of se	ensation	
		As neo	essary		
Batch:	Started:		Stopped:		
MORPHINE SULPHATE (Suspected)		Reason:	Nausea and vomiting		
	30.0 M	lilligram Daily			
Batch:	Started:		Stopped:		
Laboratory Investigations:					
Additional Information:					
eport Run: 01/06/2007 04:51PM Data	abase: pusime02	ADRS00	4	Page 242	of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report	t Detail	s:
--------	----------	----

Case Number: 210462 Seq: 1 Gender: M

Reported: 05/08/2005 Weight: 72.00 Hospitalisation: Age: 13

Onset Date: 18/05/2005 **DOB**: 24/10/1991

Outcome: Recovered 18/05/2005 Causality: Causality possible

Reaction Details:

7	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
			in normal saline PCA.	Treated with Cogentin 1mg/IV.

Medicine Details:

MORPHINE SULPHATE (Suspected)		Reason: Pain	
	1.0 Milligram	Per hour	
Batch:	Started:	Stopped:	0
DROPERIDOL (Suspected)		Reason: Nausea and vomiting	
	1.0 Milligram	Per hour	

Batch: Started: Stopped: 18/05/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 243 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

anaut Dataila					
Report Details	S :				
Case Number:	215059	Seq: 1			Gender: F
Reported:	18/01/2006				Weight: 46.00
lospitalisation:					Age: 12
Onset Date:	14/11/2005				DOB : 26/09/1993
Outcome:	Recovered		14/11/2005	С	ausality: Causality possible
<u>eaction Detail</u>		_	1		
Preferre	d Term	Severity	<u> </u>	ort Description	Treatment
Gaze palsy			After the first dos had difficulty clo- gaze.	se of Droperidol, pa sing eyes with an up	tient oward
Medicine Deta			Rea	son:	
Injection	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	0.5	Milligram	1 time	Intravenous
Batch:		Started: 14		Stopped:	0
_aboratory Inv	vestigations				
Laboratory Inv		: ange Date Tes	ted Result		Details
I aboratory Inv	vestigations				

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 244 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

 Case Number:
 215576
 Seq: 1
 Gender:
 M

 Reported:
 06/02/2006
 Weight:
 0.00

Hospitalisation: Required a visit to the doctor **Age**: 56

Onset Date: 27/01/2006 DOB: 22/12/1949
Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Trismus	prolonged	The patient developed lock jaw, thick tongue, restlessness, anxiousness and dystonic movements with arching back.	Droperidol ceased. Given oral Valium 5mg.
Anxiety	Caused or prolonged inpatient hospitalisation		
Dystonia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DROPERIDOL (Suspected)
Injection
2.5 Milligram
Daily
Intravenous

Started: 26/01/2006
Stopped: 27/01/2006

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 245 of 254



Case Number: 215576

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

Reported: 06/02/2006			Weight: 0.00
Hospitalisation: Required a vi	isit to the doctor		Age: 56
Onset Date: 27/01/2006			DOB : 22/12/1949
Outcome: Recovered		(Causality: Causality possible
Reaction Details:			
Preferred Term	Severity	Report Description	Treatment
Restlessness	Caused or prolonged inpatient hospitalisation		
Tongue disorder	Caused or prolonged inpatient hospitalisation		
Medicine Details: DROPERIDOL (Suspected)		Reason: Nausea and	vomiting
Injection	2.5 Milligran		Intravenous
Batch:	Started: 26/01/2006		27/01/2006
Laboratory Investigation	ns:		
Additional Information:			
Report Run: 01/06/2007 04:51PM I	Database: pusime02	ADRS004	Page 246 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Case Numb	er: 219433	Seq: 1				Gend	der: M
Report	ed: 23/06/20	06				Weig	jht: 44.00
ospitalisati	on:					Α	ge: 10
Onset Da	ite: 05/05/20	06				D	OB : 01/01/1996
Outcor	ne: Recovere	ed				Causal	lity: Causality probable
action De		1					_
	ferred Term	Seve		•	rt Description		Treatment
luscle spasi	ns		Pati and bac	ent develope neck, archin k.	d spasm of l g of the back	egs, fingers k, eye rolled	Droperidol ceased and observed.
ye rolling							
pisthotonus	i						
ain							
ledicine l	Details:						
				Reas	son:		
			3.5 Gran		son:	Oral	
	her drug)	Start	3.5 Gran	n		Oral	
PANADOL (O Batch TROPISETRO	her drug) :: N HYDROCHLO	Starte RIDE (Other drug)	ed: 03/05/20	n 106 Reas	Sto	opped:	
PANADOL (Or Batch TROPISETRO Injecti	her drug) :: N HYDROCHLO	RIDE (Other drug)	ed: 03/05/20	n 106 Reas gram	Sto	opped:	enous
PANADOL (Or Batch TROPISETRO Injecti Batch	ther drug) I: N HYDROCHLO DO I:	RIDE (Other drug) Start	ed: 03/05/20	n 106 Rea s gram 106	Sto son:	opped:	enous
TROPISETRO Injecti Batch	ther drug) I: N HYDROCHLO DO I:	RIDE (Other drug)	2.0 Millig	n 1066 Reas gram 1066 Reas	Sto son:	Intravi	enous
Batch TROPISETRO Injecti Batch OXYCODONE	ther drug) HYDROCHLO On HYDROCHLOR	RIDE (Other drug) Starte IDE (Other drug)	2.0 Millig ed: 02/05/20	n 106 Reas gram 106 Reas	Sto son: Sto son:	Intravo	enous
PANADOL (Or Batch TROPISETRO Injecti Batch OXYCODONE Batch	ther drug) N HYDROCHLO On HYDROCHLOR HYDROCHLOR	RIDE (Other drug) Starte IDE (Other drug)	2.0 Millig	n 106 Reas gram 106 Reas	Sto son: Sto son:	Intravi	enous
PANADOL (Or Batch TROPISETRO Injecti Batch OXYCODONE	ther drug) N HYDROCHLO On HYDROCHLOR HYDROCHLOR	Starte Starte Starte Starte	2.0 Millig ed: 02/05/20	rn 1066 Reas 1066 Reas 1066	Sto son: Sto son:	Intravion popped: Oral	enous
PANADOL (Or Batch TROPISETRO Injecti Batch OXYCODONE Batch	ther drug) I: N HYDROCHLOGOR I: HYDROCHLOR I: (Suspected)	RIDE (Other drug) Starte DE (Other drug) Starte	2.0 Milliged: 02/05/20 5.0 Milliged: 03/05/20	n 1006 Reas gram 1006 Reas gram 1006 Reas gram 1006 Reas gram 1006	Storeson: Storeson: Storeson: As necessary	Intravion popped: Oral	
PANADOL (Or Batch TROPISETRO Injecti Batch OXYCODONE Batch DROPERIDOL	ther drug) HYDROCHLO HYDROCHLOR CONTROL HYDROCHLOR CONTROL C	Starte Starte Starte Starte Starte	2.0 Millig ed: 02/05/20 5.0 Millig ed: 03/05/20 500.0 Micro	n 1006 Reas gram 1006 Reas gram 1006 Reas gram 1006 Reas gram 1006	Storeson: Storeson: Storeson: As necessary	Intravopped: Oral	
PANADOL (Or Batch TROPISETRO Injecti Batch OXYCODONE Batch DROPERIDOL	ther drug) I: N HYDROCHLOGOR I: HYDROCHLOR I: (Suspected)	Starte Starte Starte Starte Starte Starte	2.0 Millig ed: 02/05/20 5.0 Millig ed: 03/05/20 500.0 Micro	n 1006 Reas gram 1006 Reas gram 1006 Reas gram 1006 Reas gram 1006	Storeson: Storeson: Storeson: As necessary	opped: Intravious Oral Oral opped: Opped:	

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 247 of 254



Case Number: 219441

Reported: 23/06/2006

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 50.00

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Seq: 1

lospitalisation:						Ag	je: 14
Onset Date:	23/12/200	5				DC	DB : 20/07/1991
Outcome:	Recovered	t		24/12/2006		Causali	ty: Causality possible
eaction Detai	ls:						
Preferre	ed Term	Se	everity	Rep	ort Description		Treatment
Anxiety			s	pasm feeling o	very anxious, dev ver entire body, oc ement of upper lim	casional bs.	Treated with 2 x Benztropine 1mg IV- no response 1 x Diazepam 5 mg IV-settled after 30 min.
Dyskinesia							
Muscle spasms							
Medicine Deta				D			
OXYCODONE HYD	ROCHLORIE	E (Other drug)		Rea	son:		
Batch:		Si	tarted:		Stopped	i:	
METRONIDAZOLE	(Other drug)			Rea	son:		
Batch:		Si	tarted:		Stopped	l:	
GENTAMICIN SULI	PHATE (Othe		<u> </u>	Rea	son:	•	
Batch:		e	tarted:		Stopped		
DICLOFENAC SOD	IUM (Other o		tarteu.	Rea	son:		
	(3,					
Batch:		Si	tarted:		Stopped	l:	
_aboratory In	vestigati	ons:					
	Туре	Range	Date Tested	Result		D	etails
Additional Inf	ormation	1:					

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 248 of 254



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Onset Date: 23/12/2005 DOB: 20/07/1991 Outcome: Recovered 24/12/2006 Causality: Causality possible Bedicine Details: ARACETAMOL (Other drug) Reason: Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 IROPERIDOL (Suspected) Reason: Reason: Intravenous Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	## Age: 14 Dobs: 23/12/2005 Dobs: 20/07/1991	## Age: 14 Onset Date: 23/12/2005 DOB: 20/07/1991	## Age: 14	Danastad. 0	19441	Seq: 1			Gender:	F
Onset Date: 23/12/2005 DOB: 20/07/1991 Outcome: Recovered 24/12/2006 Causality: Causality possible Bedicine Details: ARACETAMOL (Other drug) Reason: Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 IROPERIDOL (Suspected) Reason: Reason: Intravenous Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Onset Date: 23/12/2005 DOB: 20/07/1991 Outcome: Recovered 24/12/2006 Causality: Causality possible Bedicine Details: ARACETAMOL (Other drug) Reason: Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection Batch: Started: 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Reason: ROPERIDOL (Suspected) Reason: Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Onset Date: 23/12/2005 DOB: 20/07/1991 Outcome: Recovered 24/12/2006 Causality: Causality possible edicine Details: edicine Details: PARACETAMOL (Other drug) Reason: Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: ROPISETRON HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 IROPERIDOL (Suspected) Reason: Reason: Injection 500.0 Microgram As necessary Intravenous Batch: 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Onset Date: 23/12/2005 DOB: 20/07/1991 Outcome: Recovered 24/12/2006 Causality: Causality possible edicine Details: Paracetanol (Other drug) Reason: Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: ROPISETRON HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 IROPERIDOL (Suspected) Reason: Intravenous Reason: Intravenous Batch: Started: 20.0 Microgram As necessary Intravenous Batch: Started: 20.0 Microgram As necessary Intravenous Batch: Started: 20.0 Stopped: 23/12/2005	•	3/06/2006				_	
Outcome: Recovered 24/12/2006 Causality: Causality possible action Details: Bedicine Details: ARACETAMOL (Other drug) Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: ROPERIDOL (Suspected) Roperid Reason: Roperid Reason: ROPERIDOL (Suspected) Roperid Reason: R	Outcome: Recovered 24/12/2006 Causality: Causality possible action Details: Bedicine Details: ARACETAMOL (Other drug) Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: ROPERIDOL (Suspected) Batch: Started: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Outcome: Recovered 24/12/2006 Causality: Causality possible action Details: Pedicine Details: PARACETAMOL (Other drug) Batch: Started: Stopped: PROPISETRON HYDROCHLORIDE (Other drug) Batch: Started: Stopped: PROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: Stopped: 23/12/2005 PROPERIDOL (Suspected) Batch: Started: Stopped: 23/12/2005 PROPERIDOL (Suspected) Reason: Reason: PROPERIDOL (Suspected) Reason:	Outcome: Recovered 24/12/2006 Causality: Causality possible action Details: Pedicine Details: PARACETAMOL (Other drug) Batch: Started: Stopped: Reason: ROPISETRON HYDROCHLORIDE (Other drug) Batch: Started: Stopped: PROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: Stopped: 23/12/2005 PROPERIDOL (Suspected) Batch: Started: 23/12/2005 Reason: Reason: Reason: Reason: Reason: R	-					_	
edicine Details: ARACETAMOL (Other drug) Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: ROPERIDOL (Suspected) Reason: ROPERIDOL (Suspected) Reason: Roperid As necessary Intravenous	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Suspected) Reason: ROPISETRON Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Stopped: 23/12/2005	PARACETAMOL (Other drug) Batch: Started: Stopped: PROPISETRON HYDROCHLORIDE (Other drug) Batch: Started: Stopped: PROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 PROPERIDOL (Suspected) Reason: PROPISETRON HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 PROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Action Details: Comparison							
edicine Details: ARACETAMOL (Other drug) Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Started: 20/12/2005 Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Ropected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Roped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	PROMETHAZINE HYDROCHLORIDE (Suspected) Batch: Started: Stopped: PROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 PROPERIDOL (Suspected) Reason: Reason: Reason: Reason: Reason: Reason: Reason: As necessary Intravenous Stopped: 23/12/2005 Reason: Injection 500.0 Microgram As necessary Intravenous Stopped: 23/12/2005	PARACETAMOL (Other drug) Batch: Started: Stopped: TROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: PROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 PROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005				24/12/200	06	Causality:	Causality possible
Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	iction Details).					
Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005 Roperidon 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005							
Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005							
Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	RARACETAMOL (Other drug) Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	RARACETAMOL (Other drug) Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005							
Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	RARACETAMOL (Other drug) Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	RARACETAMOL (Other drug) Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005							
Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005							
Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005							
Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005							
Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005							
Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: Stop	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: Stop							
Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: Reason: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: Stop	Batch: Started: Stopped: Reason: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: PROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 PROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005							
RARACETAMOL (Other drug) Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: Stop	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	adiaina Data:	lo					
Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: Romethazine Hydrochloride (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Intravenous Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: Romethazine Hydrochloride (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Intravenous Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROPISETRON HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005				R	leason:		
ROPISETRON HYDROCHLORIDE (Other drug) Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	ROPISETRON HYDROCHLORIDE (Other drug) Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	ROPISETRON HYDROCHLORIDE (Other drug) Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	ROPISETRON HYDROCHLORIDE (Other drug) Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	(33	3,					
Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: ROMETHAZINE HYDROCHLORIDE (Suspected) Reason: Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: PROMETHAZINE HYDROCHLORIDE (Suspected) Injection Batch: Started: 23/12/2005 PROPERIDOL (Suspected) Injection Stopped: 23/12/2005 Reason: Injection Stopped: 23/12/2005 Reason: Injection Stopped: 23/12/2005 Reason: Injection Stopped: 23/12/2005 Stopped: 23/12/2005	Batch: Started: Stopped: PROMETHAZINE HYDROCHLORIDE (Suspected) Injection Batch: Started: 23/12/2005 PROPERIDOL (Suspected) Injection Stopped: 23/12/2005 Reason: Injection Stopped: 23/12/2005 Reason: Injection Stopped: 23/12/2005 Reason: Injection Stopped: 23/12/2005 Stopped: 23/12/2005 Stopped: 23/12/2005	Batch:		Started:		Stoppe	d:	
ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous As necessary Intravenous Stopped: 23/12/2005 Reason: Injection 500.0 Microgram As necessary Intravenous Stopped: 23/12/2005	ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous As necessary Intravenous Stopped: 23/12/2005 Reason: Injection 500.0 Microgram As necessary Intravenous Stopped: 23/12/2005	ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous As necessary Intravenous Stopped: 23/12/2005 Reason: Injection 500.0 Microgram As necessary Intravenous Stopped: 23/12/2005	ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous As necessary Intravenous Stopped: 23/12/2005 Reason: Injection 500.0 Microgram As necessary Intravenous Stopped: 23/12/2005	ROPISETRON HYD	ROCHLORIDE (Ot	her drug)	R	leason:		
ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous As necessary Intravenous Stopped: 23/12/2005 Reason: Injection 500.0 Microgram As necessary Intravenous Stopped: 23/12/2005	ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous As necessary Intravenous Stopped: 23/12/2005 Reason: Injection 500.0 Microgram As necessary Intravenous Stopped: 23/12/2005	ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	ROMETHAZINE HYDROCHLORIDE (Suspected) Injection 25.0 Milligram As necessary Intravenous Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous As necessary Intravenous Stopped: 23/12/2005 Reason: Injection 500.0 Microgram As necessary Intravenous Stopped: 23/12/2005							
Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Injection 25.0 Milligram As necessary Intravenous Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005					Stoppe	d:	
Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Reason: Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: 23/12/2005 Stopped: 23/12/2005 ROPERIDOL (Suspected) Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005		DROCHLORIDE (S					
ROPERIDOL (Suspected) Injection Started: 20/12/2005 Reason: Intravenous Stopped: 23/12/2005	ROPERIDOL (Suspected) Injection Started: 20/12/2005 Reason: As necessary Intravenous Stopped: 23/12/2005	DROPERIDOL (Suspected) Injection Started: 20/12/2005 Reason: As necessary Intravenous Stopped: 23/12/2005	DROPERIDOL (Suspected) Injection Source Started: 20/12/2005 Reason: Intravenous Stopped: 23/12/2005							
Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005	Injection 500.0 Microgram As necessary Intravenous Batch: Started: 20/12/2005 Stopped: 23/12/2005		4D	Started: 23/12/			d : 23/12/2005	5
Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch: Started: 20/12/2005 Stopped: 23/12/2005	Batch : Started : 20/12/2005 Stopped : 23/12/2005		ectea)	500.0 M			Introvonou	•
······································	······································									
nboratory Investigations:	aboratory Investigations:	aboratory Investigations:	aboratory Investigations:			Starteu. 20/12/	2003	Эторре	u. 23/12/2003	,
				Dateii.						
					estigations:					
					estigations:					
					estigations:					
					estigations:					
iditional Information:	iditional Information:	dditional Information:	dditional Information:	aboratory Inv						
ditional Information:	ditional Information:	dditional Information:	dditional Information:	aboratory Inv						
ditional Information:	dditional Information:	dditional Information:	dditional Information:	aboratory Inv						
ditional Information:	dditional Information:	dditional Information:	dditional Information:	aboratory Inv						
dditional Information:	dditional Information:	dditional Information:	dditional Information:	aboratory Inv						

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 249 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 219583 Seq: 1 Gender: F

Reported: 30/06/2006 Weight: 0.00 Hospitalisation: Age: 48

Onset Date: 08/04/2006 **DOB**: 02/08/1957

Outcome: Recovered 08/04/2006 Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Hypotension		,,	IV fluid, IV increments Aramine, IV Adrenaline total 0.8mg.
Rash			
Tachycardia			

Medicine Details:

PROPOFOL (Suspected)		Reason: Other disturbance of sensation	
Injection	200.0 Milligram	1 time Intravenous	
Batch:	Started: 08/04/2006	Stopped:	
ROCURONIUM BROMIDE (Suspected)		Reason: Other disturbance of sensation	
Injection	50.0 Milligram	1 time Intravenous	
Batch:	Started: 08/04/2006	Stopped:	
Keflin Neutral (Suspected)		Reason: Other disturbance of sensation	
Injection	100.0 Milligram	1 time Intravenous	
Batch:	Started: 08/04/2006	Stopped:	
DROPERIDOL (Suspected)		Reason: Other disturbance of sensation	
Injection	1.0 Milligram	1 time Intravenous	
Batch:	Started: 08/04/2006	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Allergies: Sulphurs, Penicillin, Ceforoxamine, Erythromycin. Previous exposure to Cephalothin with OA in 2005- no problem.

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 250 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 219583 Seq: 1 Gender: F

Reported: 30/06/2006 Weight: 0.00 Hospitalisation: Age: 48

Onset Date: 08/04/2006 **DOB**: 02/08/1957

Outcome: Recovered 08/04/2006 Causality: Causality possible

Reaction Details:

Medicine Details:

DEXAMETHASONE (Suspected)		Reason:	Other disturbance of sensation
Injection	8.0 Milligram	1 time	Intravenous
Batch:	Started: 08/04/2006		Stopped:
GRANISETRON (Suspected)		Reason:	Other disturbance of sensation
Injection	1.0 Milligram	1 time	Intravenous
Batch:	Started: 08/04/2006		Stopped:
MORPHINE SULPHATE (Suspected)		Reason:	Other disturbance of sensation
Injection	5.0 Milligram	1 time	Intravenous
Batch:	Started: 08/04/2006	ted: 08/04/2006 Stopped:	
MIDAZOLAM (Suspected)	Reason:		
Injection	5.0 Milligram	1 time	Intravenous
Batch:	Started: 08/04/2006		Stopped:

Laboratory Investigations:

Additional Information:

Allergies: Sulphurs, Penicillin, Ceforoxamine, Erythromycin. Previous exposure to Cephalothin with OA in 2005- no problem.

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 251 of 254



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Laboratory Investigatio	PNS: Range Date Tes	sted Result	Detai	ls		
Batch:	Started:		Stopped:			
, , ,	0.5	Milligram				
Medicine Details: DROPERIDOL (Suspected)		Reason:				
Oculogyration		Oculogyric crisis.	inj.	tient required benztropine ection.		
Preferred Term	Severity	Report Descr		Treatment		
eaction Details:			Causanty.	Causality possible		
Outcome: Recovered			DOB: 19/05/1995 Causality: Causality possible			
Onset Date: 10/09/2006			Age:	11		
Reported: 16/11/2006 lospitalisation: Onset Date: 10/09/2006			Weight:			



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Ospitalisation: Onset Date: Outcome:	18/12/2006	Seq: 1	Gender: F					
Onset Date: Outcome:		•						
Outcome:			Age: 57					
	Onset Date: 20/10/2006			DOB : 19/01/1949				
11 .	Unknown			C	Causality: Causality possible			
<u>action Detai</u>								
Preferre	Severity		Report Description	Treatment				
naphylactic read		Developed hypotensid bronchosp	d rash over body, acute on, decreased saturation, pasm.	Adrenaline, dexamethasone fluids and promethazine.				
Medicine Deta				Reason:				
(3.5.4)	,							
Batch:		Started: 20	/10/2006					
ROCURONIUM BR	OMIDE (Suspected)			Reason:				
Dotaha		0 44 d- 00	14010000	Stopped:				
Batch:	I BROMIDE (Suspecte	Started: 20	/10/2006					
SUXAWETHONIUW	BROWIDE (Suspecte	;u)		Reason:				
Batch:		Started: 20	/10/2006	Stopped:				
	DIUM (Suspected)	Otantoa : 20	10/2000					
, <u> </u>	, <u></u>			Reason:				
Batch:		Started: 20	/10/2006	Stopped:	Stopped:			
	vestigations: Type Rang	ge Date Tes	sted Res	nult	Details			
	Type Rang	je Date les	ieu nes	Buit	DEIGIIS			

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 253 of 254



Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN, DROPERIDOL

Report Details:				
Case Number: 224140 S Reported: 18/12/2006 Hospitalisation: Onset Date: 20/10/2006 Outcome: Unknown Reaction Details:	eq: 1			0.00
Medicine Details: DROPERIDOL (Suspected)		Reason:		
Batch:	Started: 20/10/2006		Stopped:	
FENTANYL (Suspected)	Startour 23/10/2000	Reason:	Сторрош	
Batch:	Started: 20/10/2006		Stopped:	
MORPHINE HYDROCHLORIDE (Suspected	1)	Reason: 1 time		
Batch:	Started: 20/10/2006		Stopped:	
Laboratory Investigations:				
Additional Information:				

Report Run: 01/06/2007 04:51PM Database: pusime02 ADRS004 Page 254 of 254