

**Cases Count: 9** 

**Case Number: 232736** 

Gender: F

**Data Entry Date**: 29/08/2007 **Weight (kg)**: 0

Hospitalisation: Age: 22Y

**Onset Date**: 13/08/2007 **DOB**:

Outcome: 13/08/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Sedation Increased sedation.

Medicine details:

DROPERIDOL (Suspected) Reason: Nausea and vomiting

Injection 500 Microgram As necessary Intravenous

**Batch**: **Started**: 13/08/2007 **Stopped**: 13/08/2007

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Cases Count: 9

Case Number: 233228

**Data Entry Date:** 10/09/2007 Weight (kg): 45

**Hospitalisation:** 

Onset Date: 05/06/2007 **DOB**: 18/06/1997

Outcome: 05/06/2007 Causality: Causality possible

Recovered

Information: Patient's diagnosis: appendicectomy

Reaction:

**Preferred Term** Severity **Report Description Treatment** 

**Torticollis** Child developed torticollis Treated with benztropine 0.5mg

after third dose of

droperidol.

IV stat.

Gender: F

Age:

Medicine details:

**DROPERIDOL** (Suspected) Reason:

Injection 0.5 Milligram Daily Intravenous

Batch: Started: 04/06/2007 Stopped: 05/06/2007 0

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**Cases Count: 9** 

**Case Number: 233668** 

Gender: F **Data Entry Date:** 19/09/2007 Weight (kg): 56

**Age:** 63Y **Hospitalisation:** 

Onset Date: 05/09/2007 DOB:

Causality: Causality possible Outcome:

Recovered

Information: Patient has an identical reaction when given Codeine.

Reaction:

**Preferred Term** Severity **Report Description Treatment** 

Chest pain Patient experienced chest

pain and hypotension.

Changed to Fentanyl

Hypotension

Medicine details :					
CLONIDINE HYDROCHLORIDE (	Rea	ason :			
		50 Microgram	Daily		
Batch :	Started: 05	5/09/2007		Stopped :	
DROLEPTAN (Suspected)		Rea	ason :		
		8 Milligram			
Batch :	Started :			Stopped :	
MORPHINE HYDROCHLORIDE (	(Suspected)	Rea	ason : Other	disturbance of sensation	
		10 Millilitre			
Batch :	Started :			Stopped :	
ATACAND (Other drug)		Rea	ason :		
Batch :	Started :			Stopped :	
DROLEPTAN (Other drug)		Reason: Other disturbance of sensation		disturbance of sensation	
		8 Milligram	Daily		
Batch :	Started :			Stopped :	
NEXIUM (Other drug)		Rea	ason :		
Batch :	Started :			Stopped :	
Panadol Osteo (Other drug)			ason :		
Batch :	Started :			Stopped :	
PREMARIN (Other drug)		Rea	ason :		
Batch :	Started :			Stopped :	
TEMAZE (Other drug)		Rea	ason :		
Batch :	Started :			Stanned ·	
Battii .	Jiai ieu .			Stopped :	

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Cases Count: 9

Benztropine prescribed but not

**Case Number : 239712** 

**Data Entry Date**: 08/04/2008 **Weight (kg)**: 31

Hospitalisation: Age:

**Onset Date**: 04/09/2007 **DOB**: 25/01/1992

Outcome: 05/09/2007 Causality: Causality possible

Recovered

Information: Previous single daily doses had not posed any problems.

Reaction:

Preferred Term Severity Report Description Treatment

Eye rolling

Droperidol given 3 x in 12
hours. Eyes rolled back,
jaw pain, deviated jaw and

hours. Eyes rolled back, jaw pain, deviated jaw and shakes, tachycardic and hypertensive, stiffness.

given initially due to tachycardia. Given later.

Droperidol ceased then reinstated at lower dose with Benztropine cover if necessary.

Gender: F

Jaw disorder

Musculoskeletal stiffness

Pain in jaw Tachycardia

Tremor

Medicine details:

DROPERIDOL (Suspected) Reason :

0.2 Milligram Daily Intravenous

**Batch:** Started: 27/08/2007 Stopped: 04/09/2007

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug) Reason:

20 Milligram Intravenous

Batch: Started: 30/08/2007 Stopped:

PARACETAMOL (Other drug) Reason :

3000 Milligram Intravenous

Batch: Started: 27/08/2007 Stopped:

TRAMADOL HYDROCHLORIDE (Other drug) Reason :

300 Milligram Intravenous

Batch: Started: 30/08/2007 Stopped:

TROPISETRON HYDROCHLORIDE (Other drug) Reason :

24 Milligram Intravenous

Batch: Started: 27/08/2007 Stopped:

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Cases Count: 9

Case Number: 240232

Gender: M

**Data Entry Date: 22/04/2008** Weight (kg): 0

Age:

Onset Date: 21/01/2008 **DOB**: 10/07/1978

Outcome: 22/01/2008 Causality: Causality probable

Recovered

Hospitalisation: Required a visit to the doctor

Information:

Reaction:

**Preferred Term** Severity **Report Description Treatment** 

Hot flush Hot flush, agitation, anxiety, decreased

movement, funny

sensation, increased heart

rate.

Agitation Akathisia

Anxiety

Hypokinesia Tachycardia

Medicine details:

**DROLEPTAN (Suspected)** Reason: Nausea and vomiting

5 Milligram Injection Intramuscular

Started: 21/01/2008 21/01/2008 0 Batch: Stopped:

**CLEXANE (Other drug)** Reason:

> 40 Milligram Daily Subcutaneous

Batch: Started: 22/02/2007 Stopped:

**ENDONE** (Other drug) Reason:

> 5 Milligram As necessary

Started: 31/12/2007 Stopped: Batch:

**OXYCONTIN** (Other drug) Reason:

> 10 Milligram Daily

Started: 01/01/2008 Stopped: 22/01/2008 Batch:

PARACETAMOL (Other drug) Reason:

> 1 Gram Daily

Batch: Started: 22/12/2007 Stopped: 22/01/2008

**RANITIDINE** (Other drug) Reason:

> 300 Milligram Daily

Batch: Started: 21/12/2007 Stopped:

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**Hospitalisation:** 

## **Public Case Detail**

**Cases Count: 9** 

**Case Number: 240848** 

Gender: F

**Data Entry Date**: 13/05/2008 **Weight (kg)**: 0

Age:

Onset Date: 05/03/2008

**DOB**: 23/10/1950

Outcome: 05/03/2008

Causality: Causality possible

Recovered

Information: Pinpoint pupils

Reaction:

Preferred Term Severity Report Description Treatment

Unresponsive to stimuli Unresponsiveness Ceased droperidol

**Medicine details:** 

DROPERIDOL (Suspected) Reason :

 Injection
 1 Milligram
 1 time
 Intravenous

 Batch :
 Started : 05/03/2008
 Stopped : 05/03/2008

MORPHINE NOS (Suspected) Reason :

Injection 30 Milligram 1 time Intravenous

**Batch**: **Started**: 05/03/2008 **Stopped**: 05/03/2008

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**Cases Count: 9** 

Gender: M

Case Number: 240948

**Data Entry Date**: 15/05/2008 **Weight (kg)**: 0

Hospitalisation: Age: 13Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: Literature reference copy attached.

Reaction:

Preferred Term Severity Report Description Treatment

Hypertension Patient experienced Droperidol ceased

hypertension, rigidity, neuroleptic malignant

syndrome.

Muscle rigidity

Neuroleptic malignant

syndrome

Medicine details:

DROPERIDOL (Suspected) Reason :

Batch: Started: Stopped:

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**Cases Count: 9** 

**Case Number: 242598** 

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 20/06/2008 DOB: 17/09/1976

Outcome: 20/06/2008 Causality: Causality possible

Recovered

Information:

Reaction:

Hyperhidrosis

Malaise

Preferred Term Severity Report Description Treatment

Tachycardia Uncomfortable, very hot IV midozolam.

and sweaty, tachycardic. Feeling hot

**Medicine details:** 

DROPERIDOL (Suspected) Reason: Nausea and vomiting

Injection 0.5 Millilitre 1 time Intravenous

**Batch**: **Started**: 20/06/2008 **Stopped**: 20/06/2008

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Other data 143 BpM BP 105/82

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Cases Count: 9

**Case Number: 243096** 

Gender: F

**Data Entry Date: 22/07/2008** 

Weight (kg): 0

**Hospitalisation:** 

Age: 27Y

Onset Date: 04/07/2008

DOB:

Outcome: 04/07/2008

Causality: Causality possible

Recovered

Information:

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Confusional state

Stat dose of droperidol post caesarian section symptoms developed

within minutes of injection.

Resolved spontaneously.

Muscle tightness

Tremor

Medicine details:

**DROPERIDOL** (Suspected)

Reason: Nausea and vomiting

Injection

Injection

500 Milligram

1 time

Intravenous

Batch:

Started: 04/07/2008

**Stopped:** 04/07/2008

0

0

TROPISETRON HYDROCHLORIDE (Suspected)

Reason: Nausea and vomiting 2 Milligram

1 time

Intravenous

Batch:

Started: 04/07/2008

**Stopped**: 04/07/2008

Selection Parameters: Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: DROLEPTAN, DROPERIDOL

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