

Case Number : 233493

Data Entry Date : 18/09/2007

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 27/08/2007

Age :

Outcome : 02/09/2007

DOB : 08/06/1968

Recovered

Causality : Causality possible

Information: Patient received haloperidol 2.5mg-5mg prn 3 doses.
haloperidol 20/08/2007 2 doses, 24/08/2007 one dose, 25/08/2007 one dose,
31/08/2007 2.5mg,
haloperidol 5mg tds reg
haloperidol 3mg tds.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------------|------------------|--|-------------------------|
| Dystonia | Life threatening | Haloperidol induced dystonia possible Neuroleptic Malignant syndrome. | Benztropine. Temazepam. |
| Neuroleptic malignant syndrome | Life threatening | | |

Medicine details :

| | |
|--|----------------------|
| HALOPERIDOL (Suspected) | Reason : |
| Batch : | Started : 21/08/2007 |
| | Stopped : 26/08/2007 |
| CLONAZEPAM (Other drug) | Reason : |
| Batch : | Started : |
| | Stopped : |
| FLUOXETINE HYDROCHLORIDE (Other drug) | Reason : |
| Batch : | Started : |
| | Stopped : |
| MOVICOL (Other drug) | Reason : |
| Batch : | Started : |
| | Stopped : |
| SIMVASTATIN (Other drug) | Reason : |
| Batch : | Started : |
| | Stopped : |
| TIMENTIN (Other drug) | Reason : |
| Batch : | Started : |
| | Stopped : |
| VANCOMYCIN HYDROCHLORIDE (Other drug) | Reason : |
| Batch : | Started : |
| | Stopped : |

Public Case Detail

Cases Count: 14

Case Number : 234539

Data Entry Date : 18/10/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 25/08/1926

Outcome :

Causality : Causality possible

Not yet recovered

Information: This report is a duplicate of 234546

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------|----------|---|---------------------------------------|
| Myocardial infarction | | Heart attack, joint stiffness, gout and fall. | Haloperidol dosed reduced and ceased. |
| Fall | | | |
| Gout | | | |
| Joint stiffness | | | |

Medicine details :

| | | | |
|--------------------------------|------------------|------------------|------|
| HALOPERIDOL (Suspected) | | Reason : | |
| Tablet | 2 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | 0 |
| RISPERDAL (Suspected) | | Reason : | |
| Tablet | 0.1 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | |

Case Number : 237268

Data Entry Date : 24/01/2008

Hospitalisation :

Onset Date :

Outcome :

Recovered

Gender : M

Weight (kg) : 0

Age : 8Y

DOB :

Causality : Causality possible

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--|---|
| Dystonia | | Patient developed dystonia and dyskinesia. Drug ineffective. | Haloperidol stopped, benzatropine started 0.5mg BD, levopda (50mg, with carbidopa 12.5mg TDS). L-dopa weaned. Continued to require lorazepam, phenobarbitone, chloralhydrate, and melatonin to alleviate agitation. |
| Drug ineffective | | | |
| Dyskinesia | | | |

Medicine details :

| | |
|--|--------------------------|
| CLONIDINE HYDROCHLORIDE (Suspected) | Reason : |
| Batch : | Started : Stopped : |
| FENTANYL (Suspected) | Reason : |
| Batch : | Started : Stopped : |
| HALOPERIDOL (Suspected) | Reason : |
| Batch : | Started : Stopped : Oral |
| KETAMINE HYDROCHLORIDE (Suspected) | Reason : |
| Batch : | Started : Stopped : |
| METHYLPREDNISOLONE (Suspected) | Reason : |
| Injection | Intravenous |
| Batch : | Started : Stopped : |
| MIDAZOLAM (Suspected) | Reason : |
| Batch : | Started : Stopped : |
| PREDNISONONE (Suspected) | Reason : |
| Batch : | Started : Stopped : Oral |

Medicine details :

THIOPENTONE SODIUM (Suspected)

Reason :

Batch :

Started :

Stopped :

Public Case Detail

Cases Count: 14

Case Number : 237486

Data Entry Date : 01/02/2008

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date : 14/01/2008

Age :

DOB : 21/09/1976

Outcome :
Recovered

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Oedema mouth | | Patient experienced tongue swelling, jaw plus throat swollen. | Benzotropine |
| Tongue oedema | | | |

| Medicine details : | | | |
|--------------------------------|---------------------------------------|-----------------------------|---------------|
| HALOPERIDOL (Suspected) | Reason : Unspecified psychosis | | |
| Injection | 10 Milligram | 1 time | Intramuscular |
| Batch : | Started : 14/01/2008 | Stopped : 14/01/2008 | |

Case Number : 237562

Data Entry Date : 04/02/2008

Gender : M

Hospitalisation : Treated in Accident/Emergency Depar

Weight (kg) : 0

Onset Date : 05/10/2007

Age : 19Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term

Musculoskeletal stiffness

Severity

Dystonia

Muscle twitching

Report Description

Muscle stiffness, twitching, neck stiff toward right jerked and spine twisted in same direction.

Treatment

Ceased chlorpromazine. Treated with a stat dose IM benztropine 2mg then benztropine 2mg tds.

Medicine details :

HALOPERIDOL (Suspected)

Reason :

Injection

10 Milligram

1 time

Intramuscular

Batch :

Started : 04/10/2007

Stopped : 04/10/2007

LARGACTIL (Other drug)

Reason : Unspecified psychosis

100 Milligram

Daily

Batch :

Started :

Stopped :

TEMAZEPAM (Other drug)

Reason : Specific disorders of sleep

10 Milligram

Daily

Batch :

Started :

Stopped :

XANAX (Other drug)

Reason : Anxiety neurosis

2 Milligram

As necessary

Batch :

Started :

Stopped :

Xydep (Other drug)

Reason : Depression

150 Milligram

Daily

Batch :

Started :

Stopped :

Case Number : 239169

Data Entry Date : 20/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 60

Onset Date : 14/12/2007

Age :

DOB : 19/04/1933

Outcome : 19/01/2008

Causality : Causality possible

Death

Information: Past history of ADR to Haloperidol 0.5mg/day-requiring hospitalisation. Patient had history of diabetes, moderate hypertension, moderate hypercholesterolemia and early signs of dementia.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------|--|-----------|
| Stupor | Death | Patient was sedated that he was in a state of stupor. Parkinsonism symptoms were obvious. He was unable to walk or sign his name. His speech was slurred and his vision blurred. About 16 hours later, he had major convulsions and was admitted to hospital where cat -scan revealed intra-cranial bleeding so severe that it had pushed his brain side-ways. Possible side effect of Clexane. He died on 19/01/2008. | |
| Abasia | Death | | |
| Confusional state | Death | | |
| Convulsion | Death | | |
| Haemorrhage intracranial | Death | | |
| Parkinsonism | Death | | |

Medicine details :

CLEXANE (Suspected)

Reason :

Batch :

Started :

Stopped :

HALOPERIDOL (Suspected)

Reason :

3 Milligram Daily

Batch :

Started : 14/12/2007

Stopped : 29/12/2007

AVANDIA (Other drug)

Reason :

Batch :

Started :

Stopped :

| Medicine details : | | |
|---|------------------|------------------|
| AVAPRO (Other drug) | Reason : | |
| Batch : | Started : | Stopped : |
| MELIZIDE (Other drug) | Reason : | |
| Batch : | Started : | Stopped : |
| METFORMIN HYDROCHLORIDE (Other drug) | Reason : | |
| Batch : | Started : | Stopped : |
| ZOCOR (Other drug) | Reason : | |
| Batch : | Started : | Stopped : |

| Laboratory Investigations : | | | | |
|------------------------------------|-------|-------------|--------|---|
| Type | Range | Date Tested | Result | Details |
| Computerised axial tomography | | | | Cat-scan revealed intra-cranial bleeding. |

Public Case Detail

Cases Count: 14

Case Number : 242805

Data Entry Date : 10/07/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/06/2008

Age : 39Y

Outcome :

DOB :

Recovered

Causality : Causality probable

Information: Patient had thoughts of self harm.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--|-----------|
| Pain | | Dermatitis - dental pain, gums infected, gingivitis, gums bleeding, visual problems, can't see face clearly at 5 meters distant. Mouth ulcers and joint stiffness. | |
| Blindness | | | |
| Gingival bleeding | | | |
| Gingivitis | | | |
| Joint stiffness | | | |
| Mouth ulceration | | | |

Medicine details :

| | | | |
|--|-----------------------------|------------------|---------------|
| HALDOL DECANOATE (Suspected) | | Reason : | |
| Injection | 450 Milligram | Daily | Intramuscular |
| Batch : | Started : 17/06/2008 | Stopped : | |
| OMEGA-3 MARINE TRIGLYCERIDES (Other drug) | | Reason : | |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 14

Case Number : 245971

Data Entry Date : 05/11/2008
Hospitalisation : Admitted to hospital
Onset Date : 07/08/2008
Outcome :
 Recovered

Gender : F
Weight (kg) : 0
Age :
DOB : 02/01/1916
Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|---|---|---|
| Preferred Term | Severity | Report Description | Treatment |
| Delirium | Caused or prolonged inpatient hospitalisation | On the 07/08/02, about 2 months after Norspan had been started, patient experienced delirium, tremors of arms and legs, agitation and drowsiness. | Cessation of Norspan patch and haloperidol. |
| Agitation | Caused or prolonged inpatient hospitalisation | | |
| Somnolence | Caused or prolonged inpatient hospitalisation | | |
| Tremor | Caused or prolonged inpatient hospitalisation | | |

| Medicine details : | | | |
|--------------------------------|-----------------------------|---------------------------------------|-------------|
| HALOPERIDOL (Suspected) | | Reason : Unspecified psychosis | |
| | 4 Dose Unspec | Daily | Oral |
| Batch : | Started : | Stopped : 07/08/2008 | |
| Norspan 5 (Suspected) | | Reason : Osteoarthritis | |
| Patch, dermal | 5 Microgram | Daily | Transdermal |
| Batch : | Started : 15/06/2008 | Stopped : 11/08/2008 | |

Public Case Detail

Cases Count: 14

Case Number : 246104

Data Entry Date : 10/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 10/04/2008

Age : 43Y

Outcome : 22/04/2008

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|--|---|--|----------------------------|
| Agitation | Caused or prolonged inpatient hospitalisation | Agitation, dizzy, 1 x fall, 1 weeks history of fever, dystonic, sweaty, shaking, stiff, restless increased inflammatory markers, ck and LFT, HR 170, neuroleptic malignant syndrome. | Midazolam and benztropine. |
| Arthralgia | Caused or prolonged inpatient hospitalisation | | |
| Blood creatine phosphokinase increased | Caused or prolonged inpatient hospitalisation | | |
| C-reactive protein increased | Caused or prolonged inpatient hospitalisation | | |
| Dizziness | Caused or prolonged inpatient hospitalisation | | |
| Dystonia | Caused or prolonged inpatient hospitalisation | | |
| Hepatic function abnormal | Caused or prolonged inpatient hospitalisation | | |
| Hyperhidrosis | Caused or prolonged inpatient hospitalisation | | |
| Neuroleptic malignant syndrome | Caused or prolonged inpatient hospitalisation | | |
| Pyrexia | Caused or prolonged inpatient hospitalisation | | |
| Syncope | Caused or prolonged inpatient hospitalisation | | |
| Tremor | Caused or prolonged inpatient hospitalisation | | |

Medicine details :

HALOPERIDOL (Suspected)

Reason : Unspecified psychosis

Tablet 1.5 Milligram Daily Oral

Batch : Started : Stopped : 10/04/2008

FLUOXETINE HYDROCHLORIDE (Other drug)

Reason : Depression

Tablet 20 Milligram Daily Oral

Batch : Started : Stopped : 22/04/2008

Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|------------------------|-------|-------------|--------|---------|
| Creatine phosphokinase | | 11/04/2008 | 1531 | |
| Creatine phosphokinase | | 16/04/2008 | 1151 | |
| Creatine phosphokinase | | 18/04/2008 | 512 | |
| C-Reactive Protein | | 11/04/2008 | 6.4 | |
| C-Reactive Protein | | 17/04/2008 | 15.9 | |
| C-Reactive Protein | | 20/04/2008 | 12.0 | |
| ALT = SGPT | | 12/04/2008 | 64 | |
| ALT = SGPT | | 20/04/2008 | 48 | |
| Bilirubin | | 12/04/2008 | 39 | |
| Bilirubin | | 20/04/2008 | 18 | |

Public Case Detail

Cases Count: 14

Case Number : 246129

Data Entry Date : 11/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 85Y

Outcome :

DOB :

Causality : Causality possible

Recovered

Information: The patient was admitted to the hospital for treatment of depression. Upon admission, his drug therapy included doxepin, clonazepam, morphine, prednisolone, omeprazole, cisapride, and betaxalol eye drops. Doxepin was discontinued, and nefazodone was started on hospital day 6. The nefazodone dosage was slowly increased to 150mg twice daily by hospital day 17. Prednisolone was tapered and stopped on hospital day 20. Clonazepam was decreased to 0.5 mg twice daily on day 20, and was discontinued on day 25. Three doses of haloperidol were administered on days 26 and 27 for treatment of increased confusion and paranoia.

No specific treatment was administered and the fever, tachycardia, and rigidity resolved within two days. His mental state improved, although he remained confused.

CITATION: This case was described in the articles: Nyfort-Hansen K, Alderman C. Possible neuroleptic malignant syndrome associated with olanzapine. The annals of pharmacotherapy. 2000; 34:667. Stevens D L. associated between selective serotonin-reuptake inhibitors, second-generation antipsychotics and neuroleptic malignant syndrome. The annals of pharmacotherapy. 2008; 42: 1290-1297.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------------|----------|---|---|
| Neuroleptic malignant syndrome | | 85 year old caucasian male who experienced neuroleptic malignant syndrome. He received olanzapine. The patient has a history of rheumatoid arthritis, depression, peptic ulcer disease, glaucoma, and possible parkinson's disease. Olanzapine 10mg every night was started in hospital day 28. Two days after the addition of olanzapine to nefzodone, the patient was disoriented and hallucinating, and developed a fever of 38 degrees celsius. Over the next three days, he was confused and paranoid, became tachycardic (heart rate 100-110 beats/min), and developed urinary incontinence. Body temperature ranged from 37.5 to 38.5. Hyperreflexia, hypertonia, and clonus were noted. | Intravenous ceftriaxone and erythromycin. |

Medicine details :

HALOPERIDOL (Suspected)

Reason :

Batch :

Started :

Stopped :

ZYPREXA (Suspected)

Reason :

10 Milligram

Daily

Oral

Batch :

Started :

Stopped :

BETAXOLOL HYDROCHLORIDE (Other drug)

Reason :

Batch :

Started :

Stopped :

CISAPRIDE (Other drug)

Reason :

Batch :

Started :

Stopped :

CLONAZEPAM (Other drug)

Reason :

Batch :

Started :

Stopped :

MORPHINE NOS (Other drug)

Reason :

Batch :

Started :

Stopped :

NEFAZODONE HYDROCHLORIDE (Other drug)

Reason :

Batch :

Started :

Stopped :

OMEPRAZOLE (Other drug)

Reason :

Batch :

Started :

Stopped :

Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|---------|-------|-------------|--------|--|
| Lactate | | | | Lactate dehydrogenase was elevated at 289 U/L. |

Public Case Detail

Cases Count: 14

Case Number : 246506

Data Entry Date : 25/11/2008

Hospitalisation :

Onset Date :

Outcome :

Recovered

Gender : F

Weight (kg) : 0

Age :

DOB : 20/01/1973

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---|--|
| Preferred Term | Severity | Report Description | Treatment |
| Dyskinesia | | Given Haloperidol in conjunction with Seroquel which led to dyskinesia. | Haloperdol ceased and Seroquel increased to 800mg. |

| Medicine details : | | | |
|--------------------------------|------------------|------------------|------|
| HALOPERIDOL (Suspected) | | Reason : | |
| Tablet | | | Oral |
| Batch : | Started : | Stopped : | 0 |
| SEROQUEL (Suspected) | | Reason : | |
| Tablet | | | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 14

Case Number : 247169

Data Entry Date : 16/12/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 13/11/2008

Age :

DOB : 01/06/1990

Outcome :

Causality : Causality possible

Recovered

Information: Patient administered haloperidol post OD attempt. OD of ethylene glycol (anti-freeze).

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--|-----------------------------------|
| Oculogyric crisis | | In ICU exhibiting hallucinations, developed oculogyric crisis. | Benztropine injection 0.5mg IV x3 |

Medicine details :

| | | | |
|---|------------------|---------------------------------------|-------------|
| HALOPERIDOL (Suspected) | | Reason : Unspecified psychosis | |
| Injection | 1 Milligram | Daily | Intravenous |
| Batch : | Started : | Stopped : | |
| ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug) | | Reason : | |
| Injection | Milligram | Daily | |
| Batch : | Started : | Stopped : | |
| PYRIDOXINE HYDROCHLORIDE (Other drug) | | Reason : | |
| Tablet | Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | |
| THIAMINE (Other drug) | | Reason : | |
| Injection | Milligram | Daily | |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 14

Case Number : 247351

Data Entry Date : 22/12/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/10/2008

Age :

DOB : 18/07/1985

Outcome :

Causality : Causality probable

Recovered

Information:

| Reaction : | | | |
|-----------------------|-----------------|--|--------------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Dystonia | | Agitation then had dystonic reaction with decerebrate posturing. | Haloperidol not given further. |
| Posturing | | | |

| Medicine details : | | | |
|--|-----------------------------|-----------------------------|--|
| HALOPERIDOL (Suspected) | | | |
| Injection | 2.5 Milligram | 1 time | Reason : Otr spec symp psychopathol nec |
| Batch : | Started : 01/10/2008 | Stopped : 01/10/2008 | |
| CYPROHEPTADINE HYDROCHLORIDE (Other drug) | | | |
| Tablet | Milligram | 1 time | Reason : |
| Batch : | Started : | Stopped : | Oral |
| MIDAZOLAM (Other drug) | | | |
| Injection | Milligram | 1 time | Reason : |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 14

Case Number : 247855

Data Entry Date : 21/01/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 55Y

Outcome : 21/11/2008

DOB :

Recovered

Causality : Causality probable

Information:

| Reaction : | | | |
|-----------------------|-----------------|---|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Dystonia | | Dystonia left masseter muscle, caused pain at temporo mandibular joint on that side | |

| Medicine details : | | | |
|--------------------------------|--|-----------------------------|------|
| HALOPERIDOL (Suspected) | Reason : Otr spec symp psychopathol nec | | |
| Tablet | 250 Microgram | Daily | Oral |
| Batch : | Started : 07/11/2008 | Stopped : 20/11/2008 | 0 |

Selection Parameters : Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: HALDOL DECANOATE, HALOPERIDOL, HALOPERIDOL DECANOATE, PACEDOL, SERENACE