

Cases Count: 76

**Case Number: 231443** 

Gender: F

**Data Entry Date:** 02/08/2007 Weight (kg): 62

**Hospitalisation:** Age:

**Onset Date: DOB**: 01/01/1971

Outcome: Causality: Causality possible

Recovered with sequelae

Information:

Reaction:

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

Subdural haematoma Caused or prolonged had a fit and had a severe

inpatient

head injury described as hospitalisation severe intracranial bleed

and hematoma

Convulsion Caused or prolonged

inpatient hospitalisation

Medicine details:

Zeldox (Suspected) Reason: Unspecified psychosis

> 80 Milligram 2 times Oral

Batch: Started: 03/07/2007 **Stopped**: 25/07/2007

**ZYPREXA (Suspected)** Reason:

> 5 Milligram Daily Oral

Batch: Started: 01/07/2007 Stopped:

AMITRIPTYLINE HYDROCHLORIDE (Other drug) Reason:

150 Milligram

Stopped: 0 Batch: Started:

EFEXOR-XR (Other drug) Reason:

250 Milligram

Stopped: 0 Batch: Started:

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**Cases Count: 76** 

**Case Number : 231454** 

Gender: F

Data Entry Date: 02/08/2007 Weight (kg): 0

**Hospitalisation**: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Blood glucose increased prior to starting Zeldox BGL 6-7 mmol/L, after

treatment BGL rose to 9.5

Oral

mmol/L

Medicine details:

Zeldox (Suspected) Reason :

Batch: Started: Stopped:

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**Cases Count: 76** 

**Case Number: 231997** 

Gender: M

Data Entry Date: 15/08/2007 Weight (kg): 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Acute psychosis

Medicine details:

Zeldox (Suspected) Reason: Unspecified schizophrenia

Milligram 2 times

Batch: Started: Stopped: ongoing

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Cases Count: 76

**Case Number: 232105** 

Gender: F

Data Entry Date: 16/08/2007 Weight (kg): 0

Hospitalisation: Admitted to hospital Age: 40Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: patient is improving

Reaction:

Preferred Term Severity Report Description Treatment

Palpitations Caused or prolonged

inpatient hospitalisation

Medicine details:

Zeldox (Suspected) Reason: Unspecified schizophrenia

160 Milligram Daily Oral

Batch: Started: Stopped: 0

SEROQUEL (Other drug) Reason: Unspecified schizophrenia

300 Milligram Daily Oral

Batch: dose reduc. Started: Stopped:

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Cases Count: 76

Case Number: 232107

Gender: F

**Data Entry Date:** 16/08/2007

Weight (kg): 0

**Hospitalisation:** 

**Age:** 35Y

Onset Date: 13/07/2007

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Akathisia

Restlessness

Trismus

Medicine details:

Zeldox (Suspected) Reason: Unspecified schizophrenia

Started: 09/07/2007

80 Milligram

20 Milligram

2 times

Oral

**Stopped**: 16/07/2007

0

FLUOXETINE HYDROCHLORIDE (Other drug)

Reason:

Oral

Batch:

Batch:

Started:

Stopped:

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Cases Count: 76

Case Number: 232286

Gender: M

**Data Entry Date**: 21/08/2007 **Weight (kg)**: 0

Hospitalisation: Age: 99U

**Onset Date**: 15/06/2007 **DOB**:

Outcome: Causality: Causality probable

Unknown

Information: Patient was also having maintenance electroconvulsive therapy.

Reaction:

Preferred Term Severity Report Description Treatment

Tremor Elderly man over 80 years Zeldox ceased

developed shaking and postural hypotension

Orthostatic hypotension

Medicine details:

Zeldox (Suspected) Reason : Depression

Capsule 40 Milligram Daily Oral

Batch: Started: 01/06/2007 Stopped:

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**Cases Count: 76** 

**Case Number : 232409** 

Gender: F

Data Entry Date: 23/08/2007 Weight (kg): 0

Hospitalisation: Age: 25Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Akathisia

Medicine details:

Zeldox (Suspected) Reason: Unspecified psychosis

Tablet 80 Milligram 2 times Oral

Batch: Started: Stopped:

Lexapro (Other drug) Reason :

20 Milligram

Batch: Started: Stopped:

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Cases Count: 76

**Case Number: 232845** 

Gender: F

**Data Entry Date**: 31/08/2007 **Weight (kg)**: 0

**Hospitalisation :** Age: 35Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: Patient had surgery 2 days prior to commencing Zeldox

Reaction:

Preferred Term Severity Report Description Treatment

Blood pressure decreased blood pressure dropped to

80/50

Medicine details:

Zeldox (Suspected) Reason: Unspecified schizophrenia

80 Milligram 2 times Oral

Batch: Started: Stopped: withheld

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Cases Count: 76

**Case Number: 233370** 

Gender: F

**Data Entry Date**: 13/09/2007 **Weight (kg)**: 0

Hospitalisation: Age: 45Y

Onset Date : DOB :

Outcome: 06/09/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Breast engorgement she felt engorged

Breast mass sudden onset of breast

lumps

Breast pain

Galactorrhoea

Menstruation irregular

Medicine details:

Zeldox (Suspected) Reason: Unspecified schizophrenia

80 Milligram As necessary Oral

Batch: Started: Stopped: ongoing

EFEXOR-XR (Other drug) Reason :

150 Milligram

Batch: Started: Stopped:

EPILIM (Other drug) Reason :

700 Milligram

Batch: Started: Stopped: 0

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Cases Count: 76

Case Number: 233371

Gender: M

**Data Entry Date**: 13/09/2007 **Weight (kg)**: 115

**Hospitalisation**: Age: 35Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: patient taking other concomitant medicines not specified

Reaction:

Preferred Term Severity Report Description Treatment

Breast cyst
Breast pain
Gynaecomastia

Medicine details:

Zeldox (Suspected) Reason: Unspecified schizophrenia

80 Milligram 3 times Oral

**Batch**: **Started**: 08/09/2007 **Stopped**: 0

Lexapro (Other drug) Reason :

20 Milligram

Batch: Started: Stopped:

LOSEC (Other drug) Reason :

40 Milligram

Batch: Started: Stopped:

SOLIAN (Other drug) Reason :

1200 Milligram

Batch: Started: Stopped:

THYROXINE SODIUM (Other drug) Reason :

0.2 Milligram

Batch: Started: Stopped:

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**Cases Count: 76** 

Case Number: 233988 Gender: F

**Data Entry Date**: 03/10/2007 **Weight (kg)**: 0

Hospitalisation: Age: 35Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tardive dyskinesia tardive dyskinesia

Medicine details:

Zeldox (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 76

Case Number: 234335

**Data Entry Date**: 12/10/2007 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:			
Preferred Term	Severity	Report Description	Treatment

Delusion delusions, feeling bad

Malaise

Medicine details:

Zeldox (Suspected) Reason :

Batch: Stopped:

RISPERIDONE (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 76

**Case Number : 234426** 

Gender: F

**Data Entry Date**: 16/10/2007 **Weight (kg)**: 75

Hospitalisation: Age:

**Onset Date**: 13/09/2007 **DOB**: 12/09/1961

Outcome: 14/09/2007 Causality: Causality possible

Recovered

Information: No previous exposure, but has had many antipsychiotics in past including risperidone

with no dystonia reported.

Reaction:

Preferred Term Severity Report Description Treatment

Dystonia Caused or prolonged Developed severe oral Benztropine

inpatient dystonia with tongue hospitalisation swelling, dysarthria and

dyspnoea after 3rd dose of Ziprasidone.

Dysarthria Caused or prolonged

inpatient

hospitalisation

Tongue oedema Caused or prolonged

inpatient hospitalisation

**Medicine details:** 

Ziprasidone (Suspected) Reason :

Capsule 40 Milligram 3 times Oral

Batch: Started: Stopped:

DIAZEPAM (Other drug) Reason : Anxiety neurosis

Tablet 5 Milligram As necessary Oral

Batch: Started: Stopped:

SODIUM VALPROATE (Other drug) Reason :

1 Gram Daily

Batch: Started: L TERM Stopped:

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**Cases Count: 76** 

**Case Number : 234998** 

Gender: M

**Data Entry Date**: 02/11/2007 **Weight (kg)**: 0

**Hospitalisation**: Age: 99u

**Onset Date**: 16/10/2007 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Neuroleptic malignant

syndrome

**Medicine details:** 

Zeldox (Suspected) Reason: Unspecified schizophrenia

160 Milligram Oral

**Batch**: **Started**: **Stopped**: 22/10/2007 0

OLANZAPINE (Other drug) Reason :

Batch: Started: Stopped:

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**Cases Count: 76** 

**Case Number: 235191** 

Gender: U

**Data Entry Date**: 12/11/2007

Weight (kg): 0

**Hospitalisation:** 

**Age:** 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity Report Description

**Treatment** 

Electrocardiogram QT prolonged

experienced a possible QT

elongation

Medicine details:

Zeldox (Suspected)

Reason:

Oral

Batch :

Started:

Stopped:

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**Hospitalisation:** 

#### **Public Case Detail**

Cases Count: 76

**Case Number: 235341** 

Gender: F

**Data Entry Date**: 16/11/2007 **Weight (kg)**: 95

Age:

Onset Date: 01/11/2007

**DOB**: 01/09/1969

Outcome: 01/11/2007

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Malaise Caused or prolonged Patient felt "off colour" for 2 Benztropine 1mg Intramuscular.

inpatient days, eating poorly, had an

hospitalisation oculogyric crisis and

seizure.

Convulsion Caused or prolonged

inpatient

hospitalisation

Oculogyric crisis Caused or prolonged

inpatient hospitalisation

Medicine details :

Zeldox (Suspected) Reason: Hallucinations

Capsule 160 Milligram Daily Oral

**Batch**: **Started**: 15/07/2007 **Stopped**: 02/11/2007

SEREPAX (Other drug) Reason: Anxiety neurosis

Tablet 15 Milligram As necessary Oral

Batch: Started: 15/10/2007 Stopped:

STILNOX (Other drug) Reason : Specific disorders of sleep

Tablet 10 Milligram Daily Oral

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Computerised axial CT head was normal.

tomography

Haematology Blood tests were done and were normal.

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Weight increased

# **Public Case Detail**

**Cases Count: 76** 

Gender: F

**Case Number: 235558** 

**Data Entry Date**: 22/11/2007 **Weight (kg)**: 69

**Hospitalisation**: Hospitalisation prolonged **Age**: 47Y

**Onset Date**: 03/09/2007 **DOB**:

Outcome: Causality: Causality possible

Unknown

Information: The patient had experienced QT prolongation and episodes of bradycardia and atrial

fibrillation prior to Zeldox and this was thought to be due to venlafaxine.

The patient had been previously hospitalised for catatonia and alcohol excess in 2002.

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Anxiety		Anxiety, agitated, pain flank, foot cramps, faint, QT interval prolonged, tardive dyskinesia, back pain, cogwheel rigidity, suicidal ideation, tiredness, insomnia, nightmares, weight gain, shaking, vomiting, dizzy	Zeldox stopped; added benztropine, aripiprazole, diazepam, nortrytiline
Electrocardiogram abnormal		Anxiety, agitated, pain flank, foot cramps, faint, QT interval prolonged, tardive dyskinesia, back pain, cogwheel rigidity, suicidal ideation, tiredness, insomnia, nightmares, weight gain, shaking, vomiting, dizzy	Zeldox stopped
Tardive dyskinesia		tongue flicking	
Bradycardia			
Cogwheel rigidity			
Dizziness			
Electrocardiogram QT prolonged Fatigue			
Flank pain			
Insomnia			
Muscle spasms			
Nightmare			
Suicidal ideation			
Tremor			
Vomiting			

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Medicine details: **RISPERIDONE (Suspected)** Reason: 2 Milligram Oral Started: 03/09/2007 Batch: Stopped: Zeldox (Suspected) Reason: Oral **Stopped**: 10/10/2007 Started: 31/08/2007 Batch: EFEXOR (Other drug) Reason: Stopped: Batch: Started: **METFORMIN HYDROCHLORIDE (Other drug)** Reason:

SERTRALINE HYDROCHLORIDE (Other drug) Reason :

Started:

25 Milligram

Batch: Started: Stopped: 0

SIMVASTATIN (Other drug) Reason :

Batch: Started: Stopped:

**Laboratory Investigations:** 

Batch:

Type Range Date Tested Result Details

Other data 20/08/2007 GGT 78 U/L Unk - 35

GLUCOSE 6.0 mmol/L 3.4 - 5.4

Stopped:

Other data 21/08/2007 BLOOD PRESSURE

90/50 mmHg CALCIUM 2.44 mmol/L 2.13 - 2.63

corrected

**GLOMERULAR 72** 

ml/min

FILTRATION RATE PHOSPHATE 1.54 mmol/L 0.8 - 1.4

HEART RATE 50

irregular

QT INTERVAL 450

milliseconds

Other data 23/08/2007 ANION GAP 22

mmol/L 10 - 20 GGT 69 U/L Unk - 35 SODIUM 148 mmol/L

135 - 145

Other data 03/09/2007 QT INTERVAL 120

milliseconds

Other data 05/10/2007 GGT 93 U/L Unk -

35

Other data 09/10/2007 BLOOD PRESSURE

98/61 mmHg GLUCOSE "Good" HEART RATE 56 QT INTERVAL 482 milliseconds-Widening of QT

interval

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**Laboratory Investigations:** 

Type Range Date Tested Result Details

Other data 10/10/2007 QT INTERVAL 470

milliseconds

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Cases Count: 76

Case Number: 235737

Gender: F

**Data Entry Date**: 28/11/2007 **Weight (kg)**: 0

Hospitalisation : Age :

**Onset Date**: 05/06/2007 **DOB**: 01/08/1967

Outcome: Causality: Causality possible

Recovered

Information: Patient was consuming approximately 10Lit of coke per day.

Reaction:

Preferred Term Severity Report Description Treatment

nephrogenic diabetes insipidus. ? Ziprasidone induced hyperglycaemia. (? Psychogenic

polydipsia). Hyperosmolar

non-ketotic coma?

Hyperglycaemia Life threatening
Nephrogenic diabetes Life threatening

Nephrogenic diabetes insipidus

Medicine details:

LITHIUM CARBONATE (Suspected) Reason :

Tablet 1.5 Gram Daily Oral

Batch: Started: L TERM Stopped: 05/06/2007 0

Ziprasidone (Suspected) Reason : Diabetes mellitus

Capsule 160 Milligram Daily Oral

Batch: Stopped: 05/06/2007

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Serum glucose = 63mmol/L

Sodium Na + = 152 mmol/L.

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Cases Count: 76

Case Number: 235830

Gender : F

**Data Entry Date**: 03/12/2007 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 07/03/1965

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Drug level changed

Preferred Term Severity Report Description Treatment

patient had been stable taking Zeldox, smoking around 30 cigarettes per day, she reduced to 4 per day and psychiatrist agrees that the reaction was due to stopping smoking which increased

Zeldox levels.

Akathisia

Confusional state

Disturbance in attention

Dyskinesia

Hyperhidrosis

Psychotic disorder

Medicine details:

Cigarettes (Interaction) Reason :

Batch: Started: Stopped:

Zeldox (Interaction) Reason :

60 Milligram 2 times Oral

Batch: Started: Stopped: 0

...

ATIVAN (Other drug) Reason :

2 Milligram

Batch: Started: Stopped: 0

METFORMIN HYDROCHLORIDE (Other drug) Reason :

500 Milligram

Batch: Started: Stopped: 0

NARDIL (Other drug) Reason :

Batch: Started: Stopped: 0

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Reaction:
Preferred Term

# **Public Case Detail**

**Report Description** 

Cases Count: 76

Gender: F

**Treatment** 

Case Number: 235836

Severity

**Data Entry Date**: 03/12/2007 **Weight (kg)**: 0

**Hospitalisation**: Required a visit to the doctor Age:

**Onset Date: DOB:** 04/06/1983

Outcome: Causality: Causality possible

Not yet recovered

**Information:** Patient has had torticollis previously with amisulpride.

Dystonia Patient has had dystonic movements of the arm and head. Medicine details: Zeldox (Suspected) Reason: Unspecified schizophrenia Capsule 120 Milligram Oral Daily Batch: Started: 23/10/2007 Stopped: Doxyhexal (Other drug) Reason: Batch: Started: Stopped: OSTELIN 1000 (Other drug) Reason: Stopped: Batch: Started: RHINOCORT AQUEOUS NASAL SPRAY (Other drug) Reason: Batch: Started: Stopped: SOMAC (Other drug) Reason: Started: Stopped: Batch: Symbicort Turbuhaler 200/6 (Other drug) Reason: Batch: Started: Stopped: **TOBRAMYCIN (Other drug)** Reason: Batch: Started: Stopped:

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Cases Count: 76

**Case Number : 236001** 

Gender: F

**Data Entry Date**: 06/12/2007

Weight (kg): 70

**Hospitalisation:** 

**Age:** 47Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Depressed mood

Severity

**Report Description** 

Treatment

Ceased Ziprasidone,

risperidone reduced.

Patient had trouble sleeping, being tired, nightmares, agitated, pain in the right flank radiating to her back, cramps in foot

to her back, cramps in foot, shaking, vomiting,dizzy, QT interval prolonge, depressed mood..

Agitation

Back pain

Dizziness

Electrocardiogram QT

prolonged

Fatigue

Muscle spasms

Nightmare

Sleep disorder

Tremor

Vomiting

Tablet

Medicine details:

RISPERIDONE (Suspected)

Reason:

4 Milligram

40 Milligram

•••

Oral

Batch :

Started :

Daily

Stopped:

Ziprasidone (Suspected)

Reason :

Daily

Oral

Batch :

Capsule

Started: 31/08/2007

Stopped:

**Laboratory Investigations:** 

Type

Range

Date Tested Result

**Details** 

Electrocardiography

ECG-widening of QT interval to 482

msec,

QT interval 10/10/2007 470

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Cases Count: 76

**Case Number: 236265** 

Gender: M

**Data Entry Date:** 13/12/2007

Weight (kg): 0

**Hospitalisation:** 

Age:

**Onset Date:** 

**DOB**: 26/11/1967

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

**Preferred Term** 

Severity

Started: 16/08/2007

**Report Description** 

**Treatment** 

Fatigue

Heart rate decreased

**Palpitations** 

Medicine details:

Zeldox (Suspected)

Reason: Unspecified schizophrenia

2 times

80 Milligram

Oral Stopped: 08/11/2007

0

**EPILIM** (Other drug)

Batch:

Reason:

1.5 Gram

Oral

Batch:

Started:

Stopped:

**Laboratory Investigations:** 

Range Date Tested Result Details Type Electrocardiography 09/10/2007 58 bpm prior to zeldox 90bpm, ECG normal

Electrocardiography 15/10/2007 prior to zeldox 90bpm, ECG normal 64

Electrocardiography 26/10/2007 51 prior to zeldox 90bpm, ECG normal

Electrocardiography 09/11/2007 53 prior to zeldox 90bpm, ECG normal

prior to zeldox 90bpm, ECG normal Electrocardiography 15/11/2007 84

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**Hospitalisation:** 

# **Public Case Detail**

Cases Count: 76

**Case Number: 237520** 

Gender: M

**Data Entry Date**: 04/02/2008 **Weight (kg)**: 100

Age:

Onset Date: 15/07/2007 DOB: 07/05/2007

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Pruritus Intermittent pruritus above

knees down, hair loss.
"Floaty, buzzy" sensation if
misses A.M dose, agitation
and formication when ran

out for 2 days.

Alopecia

Drug withdrawal syndrome

Medicine details:

Zeldox (Suspected) Reason: Unspecified schizophrenia

Capsule 60 Milligram Daily Oral

Batch: Started: 15/07/2007 Stopped:

SERTRALINE HYDROCHLORIDE (Other drug) Reason : Depression

Tablet 400 Milligram Daily Oral

Batch: Started: L TERM Stopped:

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Cases Count: 76

**Case Number : 237802** 

Gender: F

**Data Entry Date**: 11/02/2008 **Weight (kg)**: 0

Hospitalisation: Age: 53Y

**Onset Date**: 01/11/2007 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tardive dyskinesia Incapacity/disability Onset tardive dyskinesia affecting jaw and toes

approximately 4 months after commencing treatment with ziprasidone 80mg bd for diagnosis of

80mg bd for diagnosis of delusional disorder. Prior to commencement of ziprasidone had taken olanzapine for 2 weeks. No other history of

antipsychotic medication

use.

Medicine details:

**Ziprasidone (Suspected)** Reason: Unspecified psychosis

Tablet 80 Milligram 2 times Oral

**Batch**: Unknown **Started**: 28/04/2007 **Stopped**: 07/02/2008

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**Cases Count: 76** 

**Case Number : 238065** 

Gender: F

**Data Entry Date:** 19/02/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 32Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Oculogyric crisis

after several months zeldox use the patient developed oculogyric crisis which recurs every 3 weeks approximately

Medicine details:

Zeldox (Suspected)

Reason:

180 Milligram

Daily

Oral

Batch:

Started:

Stopped:

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**Cases Count: 76** 

Case Number: 238117

Hospitalisation: Age: 53Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tic facial tics

Medicine details:

Zeldox (Suspected) Reason :

80 Milligram 2 times Oral

Batch: Started: Stopped:

COVERSYL (Other drug) Reason :

1.3 Milligram

Batch: Started: Stopped: 0

LUVOX (Other drug) Reason :

200 Milligram

Batch: Started: Stopped:

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Cases Count: 76

Case Number: 238411

Gender: F

Data Entry Date: 28/02/2008 Weight (kg): 0

Hospitalisation: Age: 55Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Nicotine dependence nicotine addiction - obsession with smoking

Medicine details:

CLOPIXOL (Suspected) Reason: Schizo-affective type psychos

400 Milligram Weekly

Batch: Started: Stopped: 0

Zeldox (Suspected) Reason: Schizo-affective type psychos

Capsule 320 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 76

**Case Number: 238506** 

Gender: F

**Data Entry Date**: 03/03/2008

Weight (kg): 0

**Hospitalisation:** 

Age: 99u

Onset Date :

DOB:

Outcome :

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

**Report Description** 

**Treatment** 

Anxiety

When the patient was taking Zeldox 80mg twice daily, she was feeling too stimulated. The dose was reduced and it was working well, however, the

working well, however, patient developed trembling and prickling

under her skin.

Agitation

Hypersensitivity

Paraesthesia

Tremor

Medicine details:

Zeldox (Suspected)

Reason: Unspecifid affective psychosis

Capsule

80 Milligram

Daily

Oral

Batch:

Started:

Stopped:

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Cases Count: 76

**Case Number: 238507** 

Gender: F

Data Entry Date: 03/03/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Psychotic disorder Caused or prolonged P

inpatient

hospitalisation

Psychosis aggravated, family disruption, fever, nausea, vomiting,

diarrhoea, head pressure

Diarrhoea Caused or prolonged

inpatient

hospitalisation

Family stress Caused or prolonged

inpatient

hospitalisation

Headache Caused or prolonged

inpatient hospitalisation

Nausea Caused or prolonged

inpatient

hospitalisation

Pyrexia Caused or prolonged

inpatient

hospitalisation

Vomiting Caused or prolonged

inpatient

hospitalisation

Medicine details:

Zeldox (Suspected) Reason: Unspecified psychosis

Capsule 160 Milligram Daily Oral

Batch: Started: 17/01/2008 Stopped:

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**Cases Count: 76** 

**Case Number: 238509** 

Gender: F

Data Entry Date: 03/03/2008 Weight (kg): 0

**Hospitalisation**: Age: 99u

**Onset Date**: 20/02/2008 **DOB**:

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tardive dyskinesia Zeldox to be stopped

Medicine details:

Zeldox (Suspected) Reason : Depression

160 Milligram Daily Oral

Batch: Started: 20/11/2007 Stopped:

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**Cases Count: 76** 

**Case Number: 238510** 

Gender: F

**Data Entry Date**: 03/03/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 40Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

Report Description

**Treatment** 

Schizophrenia

Caused or prolonged

schizophrenia relapse

Changed back to Risperidone

inpatient hospitalisation

Medicine details:

Zeldox (Suspected)

Reason:

Capsule

Oral

Batch:

Started:

Stopped:

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**Cases Count: 76** 

**Case Number: 238608** 

Gender: F

Data Entry Date: 05/03/2008 Weight (kg): 0

Hospitalisation: Age: 26Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Psychotic disorder psychosis, acne, headache

Acne

Headache

Medicine details:

Zeldox (Suspected) Reason: Schizo-affective type psychos

Capsule 80 Milligram Daily Oral

Batch: Started: 29/11/2007 Stopped:

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**Cases Count: 76** 

**Case Number: 238611** 

Gender: F

**Data Entry Date**: 05/03/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 44Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity Report Description

120 Milligram

**Treatment** 

Electrocardiogram QT

prolonged

QT prolonged

Medicine details:

Zeldox (Suspected)

Reason:

Daily

Oral

Capsule

Batch:

Started:

Stopped:

0

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**Cases Count: 76** 

**Case Number : 238651** 

Gender: M

**Data Entry Date:** 06/03/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 42Y

nospitalisation .

DOB:

Outcome:

**Onset Date:** 

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Report Description

**Treatment** 

Electrocardiogram QT

electrocardiogram QTC

Referred to cardiologist

interval prolonged.

Medicine details:

Zeldox (Suspected)

Reason:

Capsule

prolonged

Oral

Batch: Started: Stopped:

Severity

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Cases Count: 76

**Case Number: 238654** 

Gender: F

**Data Entry Date:** 06/03/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 79Y

**Onset Date:** 

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

**Preferred Term** 

**Report Description** 

**Treatment** 

Electrocardiogram QT prolonged

electrocardiogram QTC

Changed treatment to

interval prolonged. aripiprazole

Medicine details:

Zeldox (Suspected)

Reason:

80 Milligram

Daily

Oral

Batch:

Capsule

Started:

Severity

Stopped:

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Cases Count: 76

**Case Number: 238740** 

Gender: F

**Data Entry Date**: 07/03/2008 **Weight (kg)**: 0

Hospitalisation: Treated in Accident/Emergency Depar Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Psychotic disorder heard voices, was feeling Cogentin

restless and overwhelmed, felt like passing out,

couldnt speak properly and was slurring words.
Fluctuating from being calm to emotional to being

very aggressive.

Aggression

Dysarthria

**Emotional disorder** 

Hallucination, auditory

Insomnia

Presyncope

Restlessness

Speech disorder

Medicine details:

SEROQUEL (Suspected) Reason: Unspecified psychosis

400 Milligram Daily

**Batch**: **Started**: 15/01/2003 **Stopped**:

Zeldox (Suspected) Reason: Unspecified psychosis

Capsule 80 Milligram Daily Oral

Batch: Started: 22/02/2008 Stopped:

LOVAN (Other drug) Reason :

Batch: Started: Stopped:

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**Cases Count: 76** 

Case Number: 238757

Gender: F

**Data Entry Date**: 10/03/2008

Weight (kg): 0

Hospitalisation :

**Age:** 22Y

Onset Date :

DOB:

Outcome : Causa

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Report Description

**Treatment** 

Electrocardiogram QT

prolonged

electrocardiogram QT interval abnormal: corrected QTc >500ms

Zeldox ceased

Medicine details :

LITHIUM CARBONATE (Suspected)

Reason:

Batch :

Started:

Severity

Stopped :

Zeldox (Suspected)

Reason:

Capsule

400 Milligram

Daily

Oral

0

Batch :

Started :

**–** a...,

Stopped :

**QUETIAPINE** (Other drug)

Reason:

Batch :

QT interval

Started :

Stopped:

**Laboratory Investigations:** 

Type

Range

Date Tested Result

Details

QTc greater than 500ms

PUTRAN02



**Cases Count: 76** 

**Case Number: 238828** 

Gender: F

Data Entry Date: 12/03/2008 Weight (kg): 0

**Hospitalisation**: Required a specialist consultation Age:

**Onset Date**: 15/02/2008 **DOB**: 04/06/1983

Outcome: Causality: Causality possible

Not yet recovered

**Information:** ADR to amisulpride (torticollis), lithium (rash).

Reaction:

Preferred Term Severity Report Description Treatment

Acne

Worsening of acne aggravated, despiste multiple dermatological review and interventions. Now on Bactrim DS/bd, Eryacne gel daily, Differin cream daily. Has tried

doxycyctine, minocyctine and

Retin-A cream etc.

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Zeldox (Suspected) Reason: Unspecified schizophrenia

120 Milligram Daily

Batch: Started: 15/10/2007 Stopped:

FERRO-GRADUMET (Other drug) Reason : Unspec vitamin deficien states

Batch: Started: Stopped:

Ostelin Vitamin D and Calcium (Other drug) Reason : Unspec vitamin deficien states

Batch: Started: Stopped: Ongoing.

SOMAC (Other drug) Reason :

Batch: Started: Stopped: 0

Symbicort Turbuhaler 200/6 (Other drug) Reason : Asthma

Batch: Started: Stopped: 0

TOBRAMYCIN (Other drug) Reason : Cystic fibrosis

Batch: Started: Stopped: 0

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Cases Count: 76

Case Number: 238941 Gender: F

Data Entry Date: 13/03/2008 Weight (kg): 0

Hospitalisation: Age: 72Y

**Onset Date**: 20/02/2008 **DOB**:

Outcome: 28/02/0200 Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Rash maculo-papular Maculopapular rash over arms, legs and trunk, very

itchy.

**Pruritus** 

Medicine details: Zeldox (Suspected) Reason: Unspecified schizophrenia 110 Milligram Capsule Daily Oral Batch: Started: 11/02/2008 Stopped: 21/02/2008 Zeldox (Suspected) Reason: Unspecified schizophrenia Oral Capsule 80 Milligram Daily Batch: Started: 18/01/2008 Stopped: 21/02/2008 **ASPIRIN** (Other drug) Reason: Batch: Started: Stopped: **COLOXYL WITH SENNA (Other drug)** Reason: Batch: Started: Stopped: COVERSYL (Other drug) Reason: Batch: Started: Stopped: **DIABEX (Other drug)** Reason: Batch: Started: Stopped: **DIAMICRON MR (Other drug)** Reason: Stopped: Batch: Started: **EPILIM** (Other drug) Reason: Batch: Started: Stopped: **EVISTA (Other drug)** Reason: Started: Stopped: Batch:

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Medicine details :						
LIPITOR (Other drug)		Reason:				
Batch :	Started :		Stopped:			

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**Cases Count: 76** 

**Case Number: 239125** 

Gender: F

Data Entry Date: 19/03/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

**Age:** 57Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hyperkalaemia Caused or prolonged Hyperkalaemia

inpatient hospitalisation

Medicine details:

Zeldox (Suspected) Reason :

Capsule 160 Milligram Daily Oral

**Batch**: **Started**: 15/09/2007 **Stopped**: 0

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Cases Count: 76

Gender: F

**Case Number: 239476** 

**Data Entry Date:** 02/04/2008 Weight (kg): 0

Age: 50Y **Hospitalisation:** 

DOB: **Onset Date:** 

Causality: Causality possible Outcome:

Unknown

Information: Pt also was taking anti-inflammatory drugs for rheumatoid arthrities - not specified.

Reaction:

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

Caused or prolonged Anaphylactic reaction Anaphylactic reaction,

> inpatient hospitalisation

oedema.

Medicine details:

Zeldox (Suspected) Reason:

40 Milligram

Batch: Started: Stopped: 0

PROZAC (Other drug) Reason:

Batch: Started: Stopped: 0

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**Cases Count: 76** 

Gender: M

Case Number: 240345

**Data Entry Date**: 24/04/2008 **Weight (kg)**: 0

Hospitalisation: Age: 23Y

Onset Date: 12/03/2008 DOB:

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Akathisia akathisia. the patient was Inde switched using cross Zeld

titration method from Seroquel 1200mg per day to Zeldox 160mg daily. Inderal was administered, Zeldox reduced and given low

dose Seroquel.

Medicine details:

Zeldox (Suspected) Reason: Schizophrenia

Capsule 160 Milligram Daily Oral

Batch: Started: 10/03/2008 Stopped:

FLUOXETINE HYDROCHLORIDE (Other drug) Reason :

Batch: Started: Stopped:

SEROQUEL (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 76

**Case Number: 240673** 

Gender: M

**Data Entry Date**: 07/05/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 18/03/1984

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Nausea Weakness, sedation, dizziness, sleep decreased, nausea,

tiredness.

Asthenia

Dizziness Insomnia

Sedation

Medicine details:

Zeldox (Suspected) Reason : Schizophrenia

Capsule 80 Milligram Daily Oral

Batch: Started: 20/01/2008 Stopped:

LITHIUM CARBONATE (Other drug) Reason :

1350 Milligram

Batch: Started: Stopped:

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Cases Count: 76

**Case Number: 240750** 

Gender: M

Age:

**Data Entry Date**: 08/05/2008 **Weight (kg)**: 85

**Hospitalisation**: Required a visit to the doctor

**DOB**: 11/05/1987

Outcome: Causality: Causality possible

Not yet recovered

Information:

Onset Date: 27/03/2008

Reaction:

Preferred Term Severity Report Description Treatment

Asthenopia Heavy eye lids and excessive blinking.

Excessive eye blinking

Medicine details:

Ziprasidone (Suspected) Reason: Unspecified psychosis

 Capsule
 160 Milligram
 Daily
 Oral

 Batch :
 Started : 14/02/2008
 Stopped : 27/03/2008

ZUCLOPENTHIXOL ACETATE (Other drug) Reason : Unspecified psychosis

Injection 200 Milligram Daily Intramuscular

Batch: Started: Stopped:

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**Cases Count: 76** 

Given one dose of Largactil and

slow reduction of Zeldox. Also

given Anafranil and Invega

Gender: F

**Case Number : 240809** 

**Data Entry Date**: 12/05/2008 **Weight (kg)**: 0

Hospitalisation: Age: 52Y

**Onset Date**: 11/04/2008 **DOB**:

Outcome: 29/04/2008 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Agitation Reported agitation/inner agitation, akathisia, she was pacing and restless and was verbally abusive to physician. Also

butterflies/anxiety and abnormal tongue and mouth movements.

Aggression Akathisia

Anxiety

Drug ineffective

Dyskinesia

Restlessness

Medicine details:

Zeldox (Suspected) Reason : Schizo-affective type psychos

Capsule 320 Milligram Daily Oral

Batch: Started: Stopped:

CLOPIXOL (Other drug) Reason :

400 Milligram

Batch: Started: Stopped:

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Cases Count: 76

**Case Number: 241220** 

Gender: M

**Data Entry Date**: 27/05/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 99U

Onset Date: 08/04/2008

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

**Report Description** 

**Treatment** 

Fall

Caused or prolonged

inpatient hospitalisation

Seen in emergency after a fall the previous night.
Collagpse on the floor

during the night.

Medicine details :

OLANZAPINE (Suspected)

Reason:
10 Milligram Dai

Daily

Batch: Started:

Stopped:

Zeldox (Suspected)

Reason:

80 Milligram

Daily

Batch:

Started: 28/03/2008

Stopped:

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Cases Count: 76

Gender: F

Case Number: 241268

**Data Entry Date: 27/05/2008** Weight (kg): 0

Hospitalisation: Treated in Accident/Emergency Depar Age: 26Y

**Onset Date:** DOB:

Causality: Causality possible Outcome:

Recovered

Information:

Reaction:

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

Dysarthria Caused or prolonged Patient developed slurred Cogentin and valium. Zeldox discontinued.

inpatient speech, akathisia, twitching of limbs and eyes hospitalisation

rolling back in her head

Akathisia Caused or prolonged

inpatient hospitalisation

Caused or prolonged Gaze palsy

inpatient hospitalisation

Muscle twitching Caused or prolonged

inpatient

hospitalisation

Medicine details:

Zeldox (Suspected) Reason: Unspecified schizophrenia

80 Milligram Capsule Daily Oral

Batch: Started: Stopped:

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Cases Count: 76

**Case Number: 241411** 

Gender: F

**Data Entry Date**: 30/05/2008 **Weight (kg)**: 0

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

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Musculoskeletal stiffness Caused or prolonged

inpatient hospitalisation

death experience, parkinsonism, swollen tongue, throat swelling.

Muscle stiffness, near

Apparent death Caused or prolonged

inpatient

hospitalisation

Parkinsonism Caused or prolonged

inpatient hospitalisation

Caused or prolonged

inpatient

hospitalisation
Swollen tongue Caused or prolonged

inpatient

hospitalisation

Medicine details:

Pharyngeal oedema

Zeldox (Suspected) Reason:

Capsule Oral

Batch: Stopped: 13/05/2008

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**Cases Count: 76** 

**Case Number: 241435** 

Gender: M

Data Entry Date: 02/06/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 29Y

...opita..out.on

DOB:

Onset Date : Outcome :

Causality: Causality probable

Recovered

Information:

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Tardive dyskinesia Tardive dyskinesia

Medicine details:

Zeldox (Suspected)

Reason:

160 Milligram

Daily

Oral

Batch:

Capsule

Started:

Stopped:

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Cases Count: 76

**Case Number: 241437** 

Gender: M

Data Entry Date: 02/06/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 34Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Gait disturbance

Preferred Term Severity

Report Description Treatment

Side effects of walking with Dose reduced.

the palm of his hands turned back and cupped, as like a monkey, mouthing and imitating the speech of a person, but not making

any sound, and

cogwheeling with his left side worse than his right

side.

Cogwheel rigidity

Speech disorder

Medicine details:

Zeldox (Suspected) Reason : Schizophrenia

Capsule 160 Milligram Daily Oral

Batch: Started: Stopped: Contin

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**Cases Count: 76** 

**Case Number: 241641** 

Gender: F

**Data Entry Date**: 06/06/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 26Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

**Preferred Term** 

Severity

Report Description Tre

**Treatment** 

Nausea

nausea, feeling unwell, muscle stiffness, stiff neck, photophobia, akathisia

Akathisia

Malaise

Musculoskeletal stiffness

Photophobia

Medicine details:

Zeldox (Suspected)

Reason:

40 Milligram

Daily

Oral

Batch :

Capsule

Started :

Stopped:

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**Cases Count: 76** 

Case Number: 241674 Gender: F

**Data Entry Date**: 06/06/2008 **Weight (kg)**: 0

**Hospitalisation**: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

R	ea	Cti	on	:
K	ea	Cti	on	

Preferred Term Severity Report Description Treatment

Tremor, weight loss, blood

test showed minor abnormalities, hair loss,

drug ineffective.

Alopecia

Blood test abnormal

Drug ineffective

Weight decreased

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•	···			M-CL	-	

Zeldox (Suspected) Reason :

Capsule

Batch: Started: Stopped:

EFEXOR (Other drug) Reason :

Batch: Started: Stopped:

SEROQUEL (Other drug) Reason :

Batch: Started: Stopped:

SODIUM VALPROATE (Other drug) Reason :

Batch: Started: Stopped:

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**Cases Count: 76** 

Gender: F

Case Number: 242057

Data Entry Date: 18/06/2008 Weight (kg): 0

Hospitalisation : Age :

**Onset Date: DOB:** 17/09/1962

Outcome: Causality: Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Throat tightness	Life threatening	Difficulty swallowing and three episodes of constriction in throat associated with difficulty breathing to the extent of loss of consciousness	Spontaneously resolved after a period of about five minutes
Dysphagia	Life threatening		
Dyspnoea	Life threatening		
Loss of consciousness	Life threatening		
Medicine details :			
Ziprasidone (Suspected)		Reason :	
Capsule	180 Milligram	Daily	Oral

Medicine details :						
Ziprasidone (Suspected)		Re	ason:			
Capsule		180 Milligram	Daily	Oral		
Batch :	Started :			Stopped :		
EFEXOR (Other drug)		Re	ason :			
Batch :	Started :			Stopped :		
EPILIM (Other drug)		Re	ason :		_	
Batch :	Started :			Stopped :		
MICARDIS (Other drug)		Re	ason :			
Batch :	Started :			Stopped :		

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**Cases Count: 76** 

Ziprasidone & phenelzine

stopped.

Gender: F

**Case Number : 242396** 

**Data Entry Date**: 30/06/2008 **Weight (kg)**: 0

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

Onset Date: 10/06/2008 DOB: 13/06/1962

Outcome: 14/06/2008 Causality: Causality probable

Recovered

Information: Previous serotonin syndrome several years ago when commenced on amisulpride

(resolved when amisulpride ceased).

Reaction:

Preferred Term Severity Report Description Treatment

Hyperreflexia Caused or prolonged Hyper reflexia, ankle

inpatient clonus, tremor, dilated hospitalisation pupils, tachycardia,

increasing agitation and restlessness, sweating.

Agitation Caused or prolonged

inpatient

hospitalisation

Clonus Caused or prolonged

inpatient hospitalisation

Hyperhidrosis Caused or prolonged

inpatient hospitalisation

Caused or prolonged

Neuroleptic malignant

syndrome

inpatient

hospitalisation

Restlessness Caused or prolonged

inpatient hospitalisation

Tachycardia Caused or prolonged

inpatient

hospitalisation

Tremor Caused or prolonged

inpatient

hospitalisation

Medicine details:

LAMOTRIGINE (Interaction) Reason: Unspecified schizophrenia

400 Milligram Daily

Batch: Started: L TERM Stopped: 0

LITHIUM CARBONATE (Interaction) Reason: Unspecified schizophrenia

675 Milligram Daily

Batch: Started: L TERM Stopped: 0

PHENELZINE SULPHATE (Interaction) Reason: Unspecified schizophrenia

90 Milligram Daily

Batch: Started: L TERM Stopped: 0

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Medicine details: **QUETIAPINE** (Interaction) Reason: Unspecified schizophrenia 100 Milligram Daily LTERM Batch: Started: Stopped: Reason: Unspecified schizophrenia Ziprasidone (Interaction) 160 Milligram Daily Batch: Started: 05/06/2008 **Stopped**: 12/06/2008 0 **ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)** Reason: 40 Milligram Daily L TERM Started: Stopped: Batch: **INDAPAMIDE HEMIHYDRATE (Other drug)** Reason: 40 Milligram Daily Started : Stopped: Batch: **LEVLEN ED (Other drug)** Reason: 40 Milligram Daily

L TERM

Stopped:

Batch:

Started:

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**Cases Count: 76** 

Case Number: 242682 Gender: F

**Data Entry Date**: 08/07/2008 **Weight (kg)**: 0

**Hospitalisation**: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Loss of consciousness 2 episodes of loss of

consiousness, once with associated loss of bladder

control

Dysphagia Sedation

Medicine details:

Zeldox (Suspected) Reason :

160 Milligram Daily Oral

Batch: Started: 12/05/2008 Stopped:

EFEXOR (Other drug) Reason:

Batch: Started: Stopped:

EPILIM (Other drug) Reason :

Batch: Started: Stopped:

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**Cases Count: 76** 

Case Number: 243117

Data Entry Date: 22/07/2008 Weight (kg): 0

Hospitalisation: Age: 32Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Serotonin syndrome Suspected Serotonin

syndrome

Medicine details:

Zeldox (Suspected) Reason: Unspecified schizophrenia

Capsule 120 Milligram Daily Oral

Batch: Started: Stopped:

FLUVOXAMINE MALEATE (Other drug) Reason :

Batch: Started: Stopped:

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**Cases Count: 76** 

**Case Number: 243169** 

Gender: F

**Data Entry Date**: 23/07/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 99U

Onset Date :

DOB:

Outcome:

Causality: Causality probable

Unknown

Information:

Reaction:

**Preferred Term** Hypomania Severity

Report Description Treatment

hypomania on increasing dose of Zeldox to 60mg daily. Symptoms reduced on reduction of dose to

40mg.

Medicine details:

Zeldox (Suspected) Reason : Schizo-affective type psychos

Capsule 60 Milligram Daily Oral

Batch: Started: Stopped:

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**Cases Count: 76** 

Gender: M

Age:

Case Number: 243414

**Data Entry Date**: 01/08/2008 **Weight (kg)**: 110

**Hospitalisation**: Required a visit to the doctor

**Onset Date**: 08/07/2008 **DOB**: 12/04/1949

Outcome : Causality : Causality probable

Recovered

Information:

Reaction	า :
D ( 17	

Preferred Term Severity Report Description Treatment

Atrial fibrillation Developed AF and Ceased Ziprasidone

increased QT.

Electrocardiogram QT

prolonged

Medicine details :			
Ziprasidone (Suspected)		Reason: Otr spec s	symp psychopathol nec
Capsule	80 Milligra	m Daily	Oral
Batch :	<b>Started</b> : 04/07/2008		<b>Stopped</b> : 07/07/2008
CELLCEPT (Other drug)		Reason :	
Batch :	Started :		Stopped:
Escitalopram (Other drug)		Reason :	
Batch :	Started :		Stopped:
PREDNISOLONE (Other drug)		Reason :	
Batch :	Started :		Stopped:
SODIUM VALPROATE (Other drug)		Reason :	
Batch :	Started :		Stopped:
TACROLIMUS (Other drug)		Reason :	
Batch :	Started :		Stopped:
TOPIRAMATE (Other drug)		Reason :	
Batch :	Started :		Stopped:

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**Cases Count: 76** 

Case Number: 243457

Gender: M

Data Entry Date: 04/08/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 70Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity Report Description

**Treatment** 

Extrapyramidal disorder

Cogwheel rigidity

Parkinsonian gait

**Medicine details:** 

Zeldox (Suspected)

Reason:

Oral

Capsule Batch :

Started :

Stopped :

Extrapyramidal disorder

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Cases Count: 76

**Case Number: 244083** 

Gender: M

**Data Entry Date: 22/08/2008** 

Weight (kg): 77

**Hospitalisation:** 

Age:

Onset Date: 17/07/2008

**DOB**: 24/09/1927

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

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

Electrocardiogram QT prolonged

Electrocardiogram QT

Zeldox weaned and ceased.

prolonged

Medicine details:

Zeldox (Suspected) Reason: Unspecified psychosis

Capsule 120 Milligram Daily Oral

Batch: Started: 16/07/2008 Stopped: 17/07/2008

**DIAFORMIN (Other drug)** Reason:

> 1 Gram Daily

Batch: Started: Stopped:

MAGMIN (Other drug) Reason:

> 1 Gram Daily

Started: Stopped: Batch:

MIXTARD 30/70 (Other drug) Reason:

> 10 Unit Daily

Batch: Started: Stopped:

**ZOLOFT (Other drug)** Reason:

> 50 Milligram Daily

Started: 14/07/2008 Stopped: Batch:

**ZYPREXA (Other drug)** Reason:

> 10 Milligram Daily

Batch: Started: Stopped:

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**Cases Count: 76** 

**Case Number : 244219** 

Gender: F

**Data Entry Date:** 28/08/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 99U

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Dyskinesia

Preferred Term

Severity

**Report Description** 

**Treatment** 

Experienced muscle twitch, rahs slurred speech,

dizziness, faint,

dehydration and her veins also feel painful. Also noticed abnormal movements of her face,

tongue and lips.

Dehydration

Dizziness

Dysarthria

Muscle twitching

Rash

Syncope

Vein pain

Medicine details:

Zeldox (Suspected)

Reason:

Batch:

Started:

**Stopped:** 15/03/2008

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Cases Count: 76

Gender: F

Case Number: 244272

**Data Entry Date**: 01/09/2008 **Weight (kg)**: 0

Hospitalisation : Age :

**Onset Date**: 08/07/2008 **DOB**: 27/11/1972

Outcome: 11/07/2008 Causality: Causality probable

Recovered

Information:

Reaction:

Preferred TermSeverityReport DescriptionTreatmentVomitingCaused or prolongedVomiting, diarrhoea,Drug ceased

inpatient

hospitalisation

Diarrhoea Caused or prolonged

inpatient hospitalisation

Muscle tightness Caused or prolonged

inpatient hospitalisation

Nausea Caused or prolonged

inpatient hospitalisation

Tremor Caused or prolonged

inpatient hospitalisation

Medicine details:

Zeldox (Suspected) Reason :

360 Milligram Oral

tightness in jaw, leg

tremors, nausea

Batch: Started: Stopped: 0

VENLAFAXINE HYDROCHLORIDE (Other drug) Reason :

450 Milligram

Batch: Started: Stopped:

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**Cases Count: 76** 

**Case Number: 244393** 

Gender: F

**Data Entry Date**: 04/09/2008 **Weight (kg)**: 0

Hospitalisation: Age: 40Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

**Information:** Previously on risperidone and similar reaction.

Reaction:

Preferred Term Severity Report Description Treatment

Hyperprolactinaemia Prolactin levels increased

Medicine details:

Zeldox (Suspected) Reason :

120 Milligram Daily

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Prolactin Prolactin levels up to 2000

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Cases Count: 76

**Case Number : 244397** 

Gender: F

**Data Entry Date**: 04/09/2008 **Weight (kg)**: 0

**Hospitalisation**: Admitted to hospital Age:

**Onset Date**: 14/08/2008 **DOB**: 18/06/1938

Outcome: Causality: Causality possible

Unknown

Information: past history of TIA and tinnitus; continues herbal medicines. against doctor's advice

Reaction: **Preferred Term** Severity **Report Description Treatment** Convulsion Caused or prolonged seizure, tinnitus, insomnia, drug ceased. inpatient shakiness and collapse. hospitalisation Caused or prolonged Insomnia inpatient hospitalisation **Tinnitus** Caused or prolonged inpatient hospitalisation Tremor Caused or prolonged inpatient hospitalisation

Medicine details: Zeldox (Suspected) Reason: Unspecifid affective psychosis Capsule Oral Batch: Started: 12/08/2008 Stopped: 0 **ZYPREXA (Suspected)** Reason: Unspecifid affective psychosis Started: Stopped: Batch: **HERBAL MEDICINES (Other drug)** Reason: Batch: Started: Stopped: **MELATONIN** (Other drug) Reason: Batch: Started: Stopped: **THYROXINE SODIUM (Other drug)** Reason: Batch: Started: Stopped:

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**Cases Count: 76** 

**Case Number: 244403** 

Gender: M

Data Entry Date: 05/09/2008

Weight (kg): 70

**Hospitalisation:** 

**Age:** 18Y

Onset Date: 06/08/2008

DOB:

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term
Muscle twitching

Severity Report Description

**Treatment** 

Facial twitching and

numbness.

Hypoaesthesia

Medicine details:

Zeldox (Suspected) Reason: Unspecifid affective psychosis

Capsule 20 Milligram Daily Oral

Batch: Started: Stopped:

**Lexapro (Other drug)** Reason : Depression

10 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 76

Gender: M

Case Number: 244583

Data Entry Date: 12/09/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

**Information:** Past history of recreational drugs.

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Preferred Term Severity Report Description Treatment

Psychomotor hyperactivity Hyperactivity, general discomfort, quality of life

decreased, dry mouth,

drowsiness

Discomfort Dry mouth

Quality of life decreased

Somnolence

Medicine details:

Zeldox (Suspected) Reason : Other psychoses

Capsule Oral

Batch: Started: Stopped: 0

COGENTIN (Other drug) Reason :

Batch: Started: Stopped:

GINSENG (Other drug) Reason :

Batch: Started: Stopped:

Lexapro (Other drug) Reason :

Batch: Started: Stopped:

TEMAZEPAM (Other drug) Reason :

Batch: Started: Stopped:

VALIUM (Other drug) Reason :

Batch: Started: Stopped:

ZINC (Other drug) Reason :

Batch: Started: Stopped:

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**Cases Count: 76** 

Case Number: 244621

Gender: F

**Data Entry Date**: 15/09/2008

Weight (kg): 0

**Hospitalisation:** Admitted to hospital

**Age:** 45Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Malaise

Myoclonus

Preferred Term Severity

Report Description Tre

Treatment

Serotonin syndrome

Caused or prolonged

General physical health deterioration, serotonin

admitted to ICU, monitored in

inpatient hospitalisation

syndrome, sever myoclonic

clinic for 2 weeks

Caused or prolonged

inpatient

hospitalisation

Caused or prolonged

inpatient

hospitalisation

Medicine details:

PHENELZINE SULPHATE (Suspected)

Reason:

jerks

Daily

Batch :

Started :

Stopped:

Zeldox (Suspected)

Reason :

75 Milligram

160 Milligram

Batch :

Started:

Stopped:

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**Cases Count: 76** 

Gender: M

Case Number: 244646

Data Entry Date: 16/09/2008 Weight (kg): 0

Hospitalisation: Age: 25Y

**Onset Date**: 27/08/2008 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred TermSeverityReport DescriptionTreatmentPsychiatric decompensationPsychiatricZeldox ceased

decompensation

Medicine details :

Zeldox (Suspected) Reason: Unspecified schizophrenia

Capsule 160 Milligram Daily Oral

Batch: Started: Stopped: 0

LITHIUM CARBONATE (Other drug) Reason :

Batch: Started: Stopped:

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**Cases Count: 76** 

Zeldox stopped

Case Number: 244831

Gender: F

**Data Entry Date**: 24/09/2008 **Weight (kg)**: 0

**Hospitalisation**: Required a specialist consultation **Age**: 51Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Influenza like illness ACUTE MYOCARDIAL INFARCTION;CYANOSIS

PERIPHERAL; SEROTONIN

SYNDROME; FLU LIKE

SYMPTOMS; DIARRHOEA

Cyanosis Diarrhoea

Myocardial infarction Serotonin syndrome

Medicine details:

Zeldox (Suspected) Reason : Depression

Capsule Oral

**Batch**: **Started**: 20/05/2008 **Stopped**: 05/06/2008

PROTHIADEN (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 76

**Case Number : 245052** 

Gender: F

**Data Entry Date**: 02/10/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Electrocardiogram QT

prolonged

After a baseline ECG
Zeldox was commenced at
40mg and titrated up to
80mg twice daily. On
follow-up the ECG found a
prolongation in QT interval.
The dose was reduced to
40mg and ECG was

reported as OK at the time

of reporting.

Medicine details:

Zeldox (Suspected) Reason: Unspecified schizophrenia

Capsule 160 Milligram Daily Oral

Batch: Started: 12/07/2007 Stopped: Contin

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Electrocardiography

ECG reported a mildly prolongated QTc interval of 475 to 476 msec. The first ECG prior to treatment showed QTc of 462 msec on 2/7/07. third ECG on

462 msec on 2/7/07. third ECG on 6/7/08 showed a QTc of 470 msec which was passed as normal by another

cardiologist.

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**Cases Count: 76** 

Gender: F

**Case Number : 245318** 

**Data Entry Date**: 10/10/2008 **Weight (kg)**: 0

Hospitalisation : Admitted to hospital Age :

Onset Date: 01/09/2008 DOB: 16/10/1942

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hyponatraemia Life threatening Type 2 respiratory failure Normal saline infusion

secondary to

hyponatraemia (sodium 107mmol/l on admission) caused by antiphyschotics.

Respiratory failure Life threatening

Medicine details:

BENZHEXOL HYDROCHLORIDE (Suspected) Reason :

5 Milligram Daily

Batch: Started: Stopped:

Champix (Suspected) Reason :

2 Milligram Daily

**Batch**: **Started**: 01/05/2008 **Stopped**:

DIAZEPAM (Suspected) Reason :

2.5 Milligram Daily

Batch: Started: Stopped:

FLUPENTHIXOL DECANOATE (Suspected) Reason:

20 Milligram Fortnightly

Batch: Started: Stopped:

Ziprasidone (Suspected) Reason :

80 Milligram Daily

Batch: Started: 15/07/2008 Stopped:

CALTRATE (Other drug) Reason :

1 Dose Unspec Daily

Batch: Started: Stopped:

COLOXYL WITH SENNA (Other drug) Reason :

2 Dose Unspec Daily

Batch: Started: Stopped:

SERETIDE ACCUHALER NOS (Other drug) Reason :

2 Dose Unspec Daily

Batch : Started : Stopped :

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Medicine details	•		
SPIRIVA (Other drug)		Reason:	
		1 Dose Unspec Daily	
Batch :	Started :	Stopped :	
VENTOLIN (Other drug)		Reason :	
		6 Dose Unspec Daily	
Batch :	Started :	Stopped :	

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Cases Count: 76

Gender: M

**Case Number : 245439** 

**Data Entry Date**: 14/10/2008 **Weight (kg)**: 0

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

Onset Date: 17/09/2008 DOB: 01/03/1974

Outcome: Causality: Causality possible

Recovered

Information:

Medicine details:

Batch:

Reaction: **Preferred Term** Severity **Report Description Treatment** Neuroleptic malignant Caused or prolonged Patient developed fever, Ceased ziprasidone. Treated syndrome inpatient and later in the day had a with bromocriptine hospitalisation grand mal seizure. Patient had also developed Neuroleptic malignant syndrome on an unknown date and symptoms of fever and cardiovascular instability persisted for some days and creatine kinase peaked at 13000 Blood creatine phosphokinase Caused or prolonged inpatient increased hospitalisation Caused or prolonged Cardiovascular insufficiency inpatient hospitalisation Grand mal convulsion Caused or prolonged inpatient hospitalisation Pyrexia Caused or prolonged inpatient hospitalisation

**CLOZAPINE (Suspected)** Reason: Started: Stopped: Batch: Lexapro (Suspected) Reason: Depression Oral 10 Milligram Daily Started: 30/03/2008 Batch: Stopped: **PERIACTIN (Suspected)** Reason: 4 Milligram Oral Daily Batch: Started: Stopped: Zeldox (Suspected) Reason: Unspecified schizophrenia Capsule 160 Milligram Daily Oral

Stopped:

0

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Started: 17/07/2008

Laboratory In	Laboratory Investigations :						
Туре	Range	Date Tested	Result	Details			
Creatine phosphokinase	<200	29/09/2008	13000				
Creatine phosphokinase	<200	22/09/2008	4000				
Creatine phosphokinase	<200	29/09/2008	164				

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**Cases Count: 76** 

**Case Number : 245847** 

Gender: F

Data Entry Date: 27/10/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

**Preferred Term** 

Severity Report Description

**Treatment** 

Dystonic reaction, jaw

spasm

Trismus

Dystonia

Medicine details:

Zeldox (Suspected)

Reason:

120 Milligram

Batch : Started :

Stopped:

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**Cases Count: 76** 

Case Number: 245988

Gender: M

**Data Entry Date**: 05/11/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 35Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

**Preferred Term** 

Severity Ro

160 Milligram

Report Description

**Treatment** 

Mania

manic symptoms, experienced falls and a

wide-based gait.

Gait disturbance

Syncope

Medicine details:

Zeldox (Suspected)

Reason:

cason.

Daily

Batch :

Started :

Stopped:

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**Cases Count: 76** 

Gender: F

Case Number: 246054

**Data Entry Date**: 07/11/2008 **Weight (kg)**: 0

Hospitalisation: Age:

**Onset Date**: 30/09/2008 **DOB**: 21/03/1973

Outcome : Causality : Causality possible

Not yet recovered

Started:

Started:

Started:

Information:

Batch:

Batch:

Batch:

**OXYCONTIN** (Other drug)

QUILONUM SR (Other drug)

Reaction:				
Preferred Term	Severity	Report Description	Treatment	
Mania		Patient was becoming Manic, depressed with noticable dyskinetic movements of jaw and small movement of toes bilaterally.		
Depression				
Dyskinesia				
Medicine details :				
SEROQUEL (Suspected)	1	Reason :		
Batch :	Started :	Stopped :		
Zeldox (Suspected)	ı	Reason: Unspecifid affective psyc	chosis	
	80 Milligram	Daily	Oral	
Batch :	Started: 26/08/2008	Stopped :		0
Cymbalta (Other drug)		Reason :		

Stopped:

Stopped:

Stopped:

Reason:

Reason:

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**Cases Count: 76** 

Gender: F

**Case Number: 247167** 

**Data Entry Date**: 16/12/2008 **Weight (kg)**: 0

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

**Onset Date**: 12/06/2008 **DOB**: 26/12/1957

Outcome: 19/06/2008 Causality: Causality possible

Recovered

Information: The cardiologist diagnosis was increased anteroapical infarction diagnosis due to Left

Anterior Descending occlusion not due to thrombosis but spasm.

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Preferred Term	Severity	Report Description	Treatment
Cyanosis	Caused or prolonged inpatient hospitalisation	In 2005, the patient began Prothiaden therapy for agitated depression. On 3 June 2008, the patient began Zeldox for agitated depression. Hours after increasing Zeldox the patient developed nausea, vomiting and heartburn, then tightness in the chest and dizziness. On 10 June patient ceased Zeldox therapy. On 12 June 2008, the patient noticed blue lips and fingernails and was admitted to the Coronary Care Unit with acute myocardial infarction with cardiogenic shock.	Medication ceased.
Acute myocardial infarction	Caused or prolonged inpatient hospitalisation		
Arteriospasm coronary	Caused or prolonged inpatient hospitalisation		
Cardiogenic shock	Caused or prolonged inpatient hospitalisation		
Dizziness	Caused or prolonged inpatient hospitalisation		
Dyspepsia	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		
Transient ischaemic attack	Caused or prolonged inpatient hospitalisation		

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Reaction:

Preferred Term Severity Report Description Treatment

Vomiting Caused or prolonged

inpatient hospitalisation

Medicine details:

PROTHIADEN (Suspected) Reason : Depression

250 Milligram Daily Oral

Batch: Started: Stopped: 12/06/2008

Ziprasidone (Suspected) Reason : Depression

60 Milligram Daily Oral

Batch: Started: 03/06/2008 Stopped:

Selection Parameters: Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE, Zeldox, Ziprasidone

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