

Cases Count: 15

Case Number: 231711

Gender: M

Data Entry Date: 09/08/2007

Weight (kg): 0

Hospitalisation:

Age: 36Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity **Report Description** **Treatment**

Urticaria

Medicine details:

EDRONAX (Suspected)

Reason:

Oral

Tablet Batch:

Started:

4 Milligram 2 times

40 Milligram

Stopped:

0

CITALOPRAM HYDROBROMIDE (Other drug)

Reason:

Oral

Batch:

Started:

Stopped:

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Cases Count: 15

Case Number: 233954

Gender: M

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

Hospitalisation: Age:

DOB: 09/04/1937 **Onset Date:**

Outcome: Causality: Causality possible

Unknown

Information: Dscharge summary from psychatric hospital-final diagnoses-chronic delirium secondary

to drug and medical causes. No indication of depression.

Reaction:

Preferred Term Severity **Report Description**

Caused or prolonged Disorientation inpatient

hospitalisation

Disoriented, psychotic paranoia, agitated depression. Became delirious. Reported that he had attacked one of the nurses who was tyrying to

restrain him. Oedema.

Treatment

Ceased Panadeine forte. Prescribed Zyprexa. Taken off Zyprexa and Edronax. Put on Risperidone. Had a minder in lock up situation for a week. Taken off Imovane and Risperidone. Given Endone.

Taken off Mirtazapine.

0

Caused or prolonged Aggression

inpatient

hospitalisation

Agitation Caused or prolonged

inpatient

hospitalisation

Confusional state Caused or prolonged

inpatient

hospitalisation

Caused or prolonged Delirium

inpatient

hospitalisation

Oedema Caused or prolonged

inpatient

hospitalisation

Caused or prolonged Paranoia

inpatient

hospitalisation

Psychotic disorder Caused or prolonged

inpatient

hospitalisation

Medicine details:

Batch:

EDRONAX (Suspected) Reason: Depression

Tablet 12 Milligram Daily Oral

Started: Stopped:

IMOVANE (Suspected) Reason: Specific disorders of sleep

Tablet 7.5 Milligram Daily Oral

Batch: Started: Stopped:

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Medicine details :						
PANADEINE FORTE (Suspected)		Reason: Pain				
1 Dose Unspec Daily						
Batch :	Started :		Stopped:			
ASPIRIN (Other drug)		Reason :				
Batch :	Started :		Stopped:			
DILATREND (Other drug)		Reason:				
Batch :	Started :		Stopped :			
NOVORAPID (Other drug)		Reason:				
Batch :	Started :		Stopped :			
PANTOPRAZOLE (Other drug)		Reason :				
Batch :	Started :		Stopped:			
PROTAPHANE (Other drug)		Reason:				
Batch :	Started :		Stopped :			

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Cases Count: 15

Case Number: 234058

Gender: F

Data Entry Date: 05/10/2007 **Weight (kg)**: 74

Hospitalisation: Age: 52Y

Onset Date: 01/06/2007 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hepatitis Incapacity/disability suspected drug induced

hepatitis

Hypertension Incapacity/disability

Visual impairment Incapacity/disability

Medicine details:

EDRONAX (Suspected) Reason : Depression

Tablet 4 Milligram 2 times Oral

Batch: Started: 10/03/2005 Stopped:

Lexapro (Suspected) Reason : Depression

Tablet 30 Milligram 1 time Oral

Batch: Started: 30/06/2006 Stopped:

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Cases Count: 15

Gender: F

Case Number : 235217

Data Entry Date: 13/11/2007 **Weight (kg)**: 62

Hospitalisation: Age:

Onset Date: 25/10/2006 **DOB**: 26/06/1970

Outcome: Causality: Causality possible

Not yet recovered

Information: 235217 is a seq of 235827.

Reaction:

Preferred Term Severity Report Description Treatment

Nausea I am currently treated each symptom

experiencing severe constipation despite eating fibre rich food etc. I also experience headaches over my left eye and still suffer from numbness around my left eye socket. I occasionally get the same tightness in my chest. I am now so loath to return to a doctor about these issues because of my experience late last year and early this year. Just last night I researched on the internet whether or not the Edronax could account for my range of symptoms and discovered that indeed it could! This is why I am now reporting all of them to this website. It's been over a year since I increased the dosage from 8mg to 12mg and it's been within that timeframe that I've experienced all of these symptoms.

Chest pain

Constipation

Dizziness

Headache

Hypoaesthesia

Hypotension

Liver tenderness

Lymphadenopathy

Palpitations

Syncope

Vomiting

Weight decreased

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Medicine details:

EDRONAX (Suspected) Reason: Depression

4 Milligram Oral **Tablet** 3 times

Batch: D832A Started: 06/01/2006 Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Other data Ordered blood tests and CT scans of

chest, abdomen and pelvis, these all came back negative for a cancer

recurrence.

Was tested for TB and some types of infectous diseases. These were also

negative.

Magnetic Resonance MRI of brain to check that there was no **Imaging**

recurrence of breast cancer and still

every test all came negative.

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Cases Count: 15

Case Number : 236592

Gender: M

Data Entry Date: 02/01/2008

Weight (kg): 0

Hospitalisation:

Age: 67Y

Onset Date:

DOB:

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Dysuria

Urinary retention

Medicine details:

EDRONAX (Suspected)

Reason: Depression

1.5 Dose Unspec Daily

Oral

Batch:

Started :

Stopped:

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Cases Count: 15

Case Number: 238448

Gender: M

Data Entry Date: 29/02/2008 Weight (kg): 68

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 19/11/2007 **DOB**: 02/01/1980

Outcome: 11/02/2008 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment** Penile discharge

Penile discharge started Reduce dose

to 10mg Reboxetine.

after increasing from 8mg

Medicine details:

REBOXETINE MESYLATE (Suspected) Reason: Depression

> 10 Milligram Daily

Batch: Started: 18/11/2007 Stopped: 11/02/2008

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Cases Count: 15

Case Number: 239477

Gender: M

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

Hospitalisation: Age: 99u DOB:

Causality: Causality possible Outcome:

Unknown

Information:

Onset Date:

Reaction:

Preferred Term Severity **Report Description Treatment**

Weight decreased weight loss, fall, increased Sudafed.

> blood pressure, erectile dysfunction, sinus congestion, appetite loss, pulse increased, mood swings, hot flushes, sweating, nausea, vomiting, fatigue, dizziness, chills, itching.

Anorexia

Blood pressure increased

Chills

Dizziness

Erectile dysfunction

Fatigue

Heart rate increased

Hot flush

Hyperhidrosis

Mood swings

Nausea

Pruritus

Sinus congestion

Syncope

Vomiting

Medicine details:

EDRONAX (Suspected) Reason: Depression

Batch: Started: Stopped:

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Cases Count: 15

Case Number: 240434

Gender: M

Data Entry Date: 29/04/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information: Dose of Efexor XR was not decreased gradually before commencing Edronax.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Edronax ceased and Xanax

commenced until he is able to

Suicidal ideation

Switched from Efexor XR to Edronax. Experienced

suicidal thoughts,

see his doctor again.

aggression toward his wife

and dizzy spells.

Aggression

Dizziness

Medicine details:

EDRONAX (Suspected)

Reason:

8 Milligram

Daily

Batch:

Started: 15/04/2008

Stopped:

EFEXOR-XR (Suspected)

Reason:

150 Milligram

Daily

Batch:

Started:

Stopped: 15/04/2008

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Cases Count: 15

Case Number : 241659

Gender: M

Data Entry Date: 06/06/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 31/05/2008

DOB: 15/01/1939

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dry mouth Caused or prolonged

Dry mouth, confusion, increased anxiety, dizziness, increasing

Cessation of Edronax and sodium replacement with IV isotonic saline

inpatient hospitalisation

problems with balance, hyponatraemia (111mmol/L)

Anxiety Caused or prolonged

inpatient

hospitalisation

Balance disorder Caused or prolonged

inpatient

hospitalisation

Confusional state Caused or prolonged

inpatient

hospitalisation

Dizziness Caused or prolonged

inpatient

hospitalisation

Hyponatraemia Caused or prolonged

inpatient

hospitalisation

Medicine details:

EDRONAX (Suspected) Reason :

Tablet 8 Milligram 2 times Oral

CALTRATE (Other drug) Reason :

Tablet 600 Milligram Daily Oral

Batch: Started: Stopped:

COLOXYL WITH SENNA (Other drug) Reason :

As necessary

Batch: Started: Stopped:

NEXIUM (Other drug) Reason :

Tablet 20 Milligram Daily Oral

Batch: Started: Stopped:

PANAMAX (Other drug) Reason :

Batch: Started: Stopped:

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Laboratory Investigations:

Type Range Date Tested Result Details

sodium 128mmol/L on 1.06.08 at 0550 follwoing replacement with isotonic saline. Sodium 31/05/2008 111

sodium 128mmol/L on 1.06.08 at 0550 Sodium 01/06/2008 128

follwoing replacement with isotonic

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Cases Count: 15

Gender: F

Case Number: 242163

Data Entry Date: 20/06/2008 Weight (kg): 0

Hospitalisation: Treated in outpatient department only. Age:

Onset Date: 23/04/2008 **DOB**: 16/03/1976

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment** Urinary retention Caused or prolonged Urinary retention

> inpatient hospitalisation

Prazosin, IDC

Medicine details:

REBOXETINE MESYLATE (Suspected) Reason: Depression

> 8 Milligram Daily Oral

Batch: Started: Stopped: 23/04/2008

ALPRAZOLAM (Other drug) Reason:

> 2 Milligram Daily

Batch: Started: Stopped:

OXYNORM (Other drug) Reason:

> 30 Milligram Daily

Started: Stopped: Batch:

PARACETAMOL (Other drug) Reason:

> 500 Milligram As necessary

Batch: Started: Stopped:

SALAZOPYRIN (Other drug) Reason:

> 2 Gram Daily

Stopped: Batch: Started:

SEROQUEL (Other drug) Reason:

> 200 Milligram Daily

Batch: Started: Stopped:

Zolpidem tartrate (Other drug) Reason:

> 12.5 Milligram Daily

Batch: Started: Stopped:

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Cases Count: 15

Case Number: 242318

Gender: F

Data Entry Date: 26/06/2008 **Weight (kg)**: 45

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 21/05/2008 **DOB**: 02/02/1958

Outcome: 16/06/2008 Causality: Causality possible

Recovered

Information: Was on Edronax 4mg/daily and was fine, problems when dose increased.

Reaction:

Preferred Term Severity Report Description Treatment

Angioedema Angioedema

Medicine details:

EDRONAX (Suspected) Reason : Depression

Tablet 6 Milligram Daily Oral

Batch: **Started**: 21/05/2008 **Stopped**: 30/05/2008

LIPITOR (Other drug) Reason :

Tablet 20 Milligram Daily Oral

 $\textbf{Batch}: \hspace{1cm} \textbf{Started}: \hspace{1cm} \textbf{L} \ \textbf{TERM} \hspace{1cm} \textbf{Stopped}: \\$

LOSEC (Other drug) Reason :

20 Milligram Daily

Batch: Started: L TERM Stopped:

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Cases Count: 15

Case Number: 243260

Gender: M

Data Entry Date: 28/07/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date: 22/09/2007

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Stevens-Johnson syndrome

Stevens-Johnson like

Drug withdrawn

reaction

Erythema multiforme

Urticaria papular

Medicine details:

EDRONAX (Suspected) Reason : Depression

Tablet 16 Milligram Daily Oral

Batch: **Started**: 06/09/2007 **Stopped**: 23/09/2007 0

Escitalopram (Other drug) Reason :

10 Milligram Oral

Batch: Started: 09/08/2007 Stopped:

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Cases Count: 15

Case Number: 244830

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

Hospitalisation: Age:

Onset Date : DOB : 10/09/1951

Outcome : Causality : Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Female sexual arousal Persistent genital arousal Edronax was discontinued.

disorder syndrome

Medicine details:

EDRONAX (Suspected) Reason : Depression

4 Milligram Daily Oral

Batch: **Started**: 15/09/2007 **Stopped**: 01/08/2008 0

EPILIM (Other drug) Reason :

Batch: Started: Stopped:

Lexapro (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 15

Case Number: 244870 Gender: M

Data Entry Date: 25/09/2008 Weight (kg): 0

Hospitalisation: Age:

Onset Date: DOB: 31/12/1949

Outcome: Causality: Causality probable

Recovered

Information:

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Preferred Term Severity **Report Description Treatment**

Urinary retention Urinary Retention after increasing dose from 2mg

Edronax ceased.

daily to 4 mg daily.

Medicine details: **EDRONAX (Suspected)** Reason: Depression Tablet 4 Milligram Daily Oral Batch: Started: 31/07/2008 **Stopped:** 06/08/2008 0 **AVAPRO** (Other drug) Reason: Batch: Started: Stopped: Lexapro (Other drug) Reason: Started: Stopped: Batch: MEGAFOL (Other drug) Reason:

Started: Stopped: Batch:

PARIET (Other drug) Reason:

Batch: Started: Stopped:

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Cases Count: 15

Gender: F

Case Number: 248046

Data Entry Date: 28/01/2009 **Weight (kg)**: 0

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 03/12/2008 DOB: 04/08/1922

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Lethargy, muscle Ceased medication

weakness, abdominal pain.

Abdominal pain

Myalgia

Medicine details:

EDRONAX (Suspected) Reason: Depression

Tablet 8 Milligram Daily Oral

Batch: **Started**: 28/11/2008 **Stopped**: 08/12/2008

COVERSYL (Other drug) Reason :

Batch: Started: Stopped:

INSULIN NOS (Other drug) Reason :

Batch: Started: Stopped:

METFORMIN HYDROCHLORIDE (Other drug) Reason :

Batch: Started: Stopped:

Selection Parameters: Date Range: 01/08/2007 To 31/01/2009 Unclear causality excluded GM medicines Only Medicine Names: EDRONAX, REBOXETINE MESYLATE

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