

Cases Count: 29

Case Number: 232946

Gender: F

Data Entry Date: 31/08/2007 **Weight (kg)**: 60

Hospitalisation : Age :

Onset Date: 04/07/2007 **DOB**: 27/07/1967

Outcome: 05/07/2007 Causality: Causality possible

Recovered

Information: Patient was on Endep 50mg from 21/06/2007, 100mg from 25/06/2007, 125 mg from

28/06/2007, 100mg from 02/07/2007 to 04/07/2007.

Reaction:			
Preferred Term	Severity	Report Description	Treatment
Dry mouth	Caused or prolonged inpatient hospitalisation	Dry mouth. Bluriness of vision and very quick onset of almost total loss of vision (extremely short-lived, however). Loss of memory over the course of treatment (to about 80%). Disorientation, trembling of hands, involuntary arm and leg jerks, extreme difficulty conveying thoughts into words. Rapid, extreme mood changes including suicidal tendencies, extreme agitation an confusion.	
Affect lability	Caused or prolonged inpatient hospitalisation		
Agitation	Caused or prolonged inpatient hospitalisation		
Amnesia	Caused or prolonged inpatient hospitalisation		
Blindness	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		
Disorientation	Caused or prolonged inpatient hospitalisation		
Mental impairment	Caused or prolonged inpatient hospitalisation		
Myoclonus	Caused or prolonged inpatient hospitalisation		
Suicidal ideation	Caused or prolonged inpatient hospitalisation		

PUTRAN02 Page 1 of 36

Reaction:

Preferred Term Severity **Report Description Treatment**

Tremor Caused or prolonged

inpatient hospitalisation

Vision blurred Caused or prolonged

inpatient hospitalisation

Medicine details:

ENDEP (Suspected) Reason: Depression

Tablet 50 Milligram Daily Oral

Batch: Started: 21/06/2007 Stopped: 04/07/2007

PUTRAN02 Page 2 of 36



Cases Count: 29

Gender: F

Case Number: 234148

Data Entry Date: 09/10/2007 **Weight (kg)**: 0

Hospitalisation: Age: 62Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dizziness Incapacity/disability

Medicine details:

ENDEP (Suspected) Reason :

Batch: Started: Stopped:

LIPITOR (Suspected) Reason : Othr&unspec metabolic diseases

Tablet 40 Milligram Daily Oral

Batch: Started: Stopped: 23/09/2007

PUTRAN02 Page 3 of 36



Cases Count: 29

Case Number: 234213

Gender: F

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

Hospitalisation: Age: 57Y

Onset Date: 07/10/2007 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information: Had a similar reaction to Endep

Reaction:

Preferred Term Severity Report Description Treatment

Aggression aggressive thoughts and

actions

Dry mouth

Fatigue

Self-injurious ideation

Tearfulness

Medicine details:

ENDEP (Suspected) Reason :

Tablet 25 Milligram 1 time Oral

Batch: **Started**: 04/10/2007 **Stopped**:

PUTRAN02 Page 4 of 36



Cases Count: 29

Case Number: 234396

Hospitalisation: Age: 33Y

Onset Date: 09/10/2007 **DOB**:

Outcome : Causality : Causality possible

Unknown

Information: The patient had used Endep 150mg for 18 months previously without problems.

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Delusion		daydreams of people trying to kill him	
Agitation			
Anxiety			
Dysuria			
Nightmare			
Paranoia			

Medicine details :				
ENDEP (Suspected)	Re	ason : Pain		
Tablet	50 Milligram	1 time	Oral	
Batch :	Started : 06/10/2007		Stopped :	0
IBUPROFEN (Other drug)	Re	ason :		

Batch: Started: Stopped:

PANADEINE FORTE (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 5 of 36



Cases Count: 29

Cessation of the lidocaine

infusion. Treated with Atropine.

Case Number : 234845

Gender: F

Data Entry Date: 25/10/2007 **Weight (kg)**: 0

Hospitalisation: Admitted to hospital **Age**: 52Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information: Author: Man-Yiu Cheung Melissa Viney. Title: A Unique case of recurrent asystole

secondary to paroxysmal pain acute herpetic ophthalmicus. Journal: Anaesthesia.

Year: 2007. volume: 105. Pages 1127-1129.

Reaction:

Preferred Term Severity Report Description Treatment

Cardiac arrest Caused or prolonged Patient had episodes of

inpatient asystole varying from 3 to hospitalisation 22 seconds, transient

bradycardic episodes.
These episodes were
associated with

hypotension and brief periods of

unconsciousness. Type 2

respiratory failure secondary to narcosis.

Bradycardia Caused or prolonged

inpatient

hospitalisation

Hypotension Caused or prolonged

inpatient hospitalisation

Loss of consciousness Caused or prolonged

inpatient hospitalisation

Medicine details:

AMITRIPTYLINE HYDROCHLORIDE (Suspected) Reason : Pain

Tablet 50 Milligram Daily Oral

Batch: Started: Stopped: 0

GABAPENTIN (Suspected) Reason : Pain

300 Milligram Daily Oral

Batch: Started: Stopped: 0

Lidocaine (Suspected) Reason :

Injection, intravenous infusion 0.5 Milligram per 1 time

Batch: Started: Stopped: 0

HYDROCHLOROTHIAZIDE (Other drug) Reason : Pain

Batch: Started: Stopped: 0

PUTRAN02 Page 6 of 36

Medicine detai	ls:			
METFORMIN HYDROCHL	ORIDE (Other drug)	Reason :		
Batch :	Started :		Stopped :	

PUTRAN02 Page 7 of 36



Cases Count: 29

Case Number : 235877

Gender: M

Data Entry Date: 04/12/2007 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date: 12/10/2007 **DOB**: 29/06/1958

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Vomiting Caused or prolonged 4/7 history of vomiting, ICU admission required.

inpatient diarrhoea, nil oral intake as hospitalisation he could not tolerate. Probable suspected

SIADH secondary to anitriptyline.

Stopped:

Reason: Diabetes mellitus

Diarrhoea Caused or prolonged

inpatient hospitalisation

Inappropriate antidiuretic Caused or prolonged

hormone secretion inpatient

hospitalisation

Medicine details:

METFORMIN HYDROCHLORIDE (Other drug)

Batch:

AMITRIPTYLINE HYDROCHLORIDE (Suspected) Reason : Depression

Tablet 50 Milligram Daily Oral

Batch: Started: Stopped:

CLONAZEPAM (Other drug) Reason : Anxiety neurosis

Started:

Tablet 0.5 Milligram Daily Oral

Tablet 1 Gram Daily Oral

Batch: Started: Stopped:

PUTRAN02 Page 8 of 36



Cases Count: 29

Case Number: 236192

Gender: F

Data Entry Date: 12/12/2007

Weight (kg): 82

Hospitalisation:

Age: 64Y

Onset Date: 15/11/2007

Outcome:

DOB:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Report Description

Treatment

Headache

Headache, sleepiness, nausea, sweating, shortness of breath,

strange taste, tongue

blisters.

Dysgeusia

Dyspnoea

Hyperhidrosis

Nausea

Somnolence

Tongue blistering

Medicine details:

ACIMAX (Suspected)

Reason:

2 Dose Unspec Daily

Batch:

Started:

Severity

L TERM

Stopped:

ENDEP (Suspected)

Reason: Irritable colon

Tablet

1 Dose Unspec Daily

Oral

Oral

Oral

Batch:

Started:

L TERM

0.3 Dose Unspec Daily

L TERM

Stopped:

MOTILIUM (Suspected)

Reason:

Tablet Batch:

Started:

3 Dose Unspec Daily I TFRM

Stopped:

NOTEN (Suspected)

Batch:

Reason: Essential benign hypertension

Tablet

Started:

Stopped:

PUTRAN02 Page 9 of 36



Cases Count: 29

Gender: M

Case Number: 236808

Data Entry Date: 09/01/2008 **Weight (kg)**: 78

Hospitalisation : Age :

Onset Date: 03/12/2007 **DOB**: 07/11/1929

Outcome: 04/12/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hallucination Hallucinations/felt

unwell/disorientated, after 1 tab of 10mg Endep

taken.

Disorientation

Malaise

Medicine details :				
ENDEP (Suspected)		Reason : Otr&u	nsp forms neuralg&neurit	
Tablet	10 Milligram	1 time	Oral	
Batch :	Started : 03/04/2007		Stopped : 04/12/2007	
BRICANYL (Other drug)		Reason :		
Batch :	Started :		Stopped :	
COUMADIN (Other drug)		Reason :		
Batch :	Started :		Stopped :	
LIPEX (Other drug)		Reason :		
Batch :	Started :		Stopped :	
PANADEINE FORTE (Other dru	ıg)	Reason :		
Batch :	Started :		Stopped :	
Seretide 250/50 Accuhaler (Oth	er drug)	Reason :		
Batch :	Started :		Stopped :	

PUTRAN02 Page 10 of 36



Cases Count: 29

Case Number: 237006

Gender: F

Data Entry Date: 17/01/2008

Weight (kg): 0

Hospitalisation:

Age: 75Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Trismus

jaw movements, dry mouth, blurred vision.

Dry mouth

Vision blurred

Medicine details:

ENDEP (Suspected)

Reason:

25 Milligram

1 time

Oral

Tablet Batch:

Started:

Stopped:

PUTRAN02 Page 11 of 36



Cases Count: 29

Case Number: 237558 Gender: M

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

Hospitalisation: Age: 33Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: has been referred to neurologist

Reaction:

Preferred Term Severity Report Description Treatment

Convulsion The patient had

experienced 13 seizures in 8 days and they occur during his sleep. Had been taking Enden for

taking Endep for approximately 2 months

prior to event

Medicine details:

ENDEP (Suspected) Reason : Pain

Tablet 35 Milligram 1 time Oral

Batch: Started: Stopped: 0

ENDONE (Other drug) Reason :

Batch: Started: Stopped:

NORFLEX (Other drug) Reason :

Batch: Started: Stopped:

VALIUM (Other drug) Reason :

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Other data CT scan and blood chemistry normal

PUTRAN02 Page 12 of 36



Cases Count: 29

Gender: F

Case Number: 238315

Data Entry Date: 26/02/2008 **Weight (kg)**: 0

Hospitalisation: Age: 55Y

Onset Date: 15/09/2007 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hallucination

Hallucinations, voices in head, sore eyes, dry mouth, difficulty sleeping, difficulty urinating, tingling

and heavy legs.

Dry mouth Dysuria

Eye pain

Hallucination, auditory

Insomnia

Paraesthesia

Sensation of heaviness

Medicine details:

ENDEP (Suspected) Reason: Depression

Tablet 20 Milligram Daily Oral

Batch: **Started**: L TERM **Stopped**: 15/02/2008 0

LIPITOR (Other drug) Reason :

Batch: Started: Stopped:

URAL (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 13 of 36



Cases Count: 29

Case Number: 238451

Gender: F

Data Entry Date: 29/02/2008

Weight (kg): 0

Hospitalisation:

1101911 (119)

Onset Date: 28/02/2008

Age: 54Y

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Diarrhoea Incapacity/disability Diarrhoea stop medication. Fluid

management. Paracetamol

Medicine details:

AMITRIPTYLINE HYDROCHLORIDE (Suspected) Reason :

Tablet 25 Milligram 1 time Oral

Batch: **Started**: 27/02/2008 **Stopped**: 29/02/2008 0

PUTRAN02 Page 14 of 36



Fall, fractured arm and

abnormal electrolytes.

Cases Count: 29

Case Number: 238463

Gender: F

Data Entry Date: 29/02/2008 **Weight (kg)**: 0

Hospitalisation : Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Fall Caused or prolonged

inpatient

hospitalisation

Blood electrolytes abnormal Caused or prolonged

inpatient hospitalisation

Medicine details:

ENDEP (Suspected) Reason :

Tablet 50 Milligram 1 time Oral

Batch : Started : Stopped :

PUTRAN02 Page 15 of 36



Hospitalisation:

Public Case Detail

Cases Count: 29

Age:

Case Number : 238623

Gender: F

Data Entry Date: 05/03/2008 **Weight (kg)**: 46.6

Onset Date: 24/11/2007 DOB: 02/10/1916

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Asthenia Caused or prolonged Patient was admitted to Ceased Tramadol

inpatient hospital confused, slurring hospitalisation speech, weakness in arms and with a headache on

and with a headache on 18/11/07. On 24/11 started having hallucinations and was very confused. Tramadol was ceased on 26/11/07 and confusion

resolved shortly afterwards.

Confusional state Caused or prolonged

inpatient

hospitalisation

Dysarthria Caused or prolonged

inpatient hospitalisation

Hallucination Caused or prolonged

inpatient hospitalisation

Headache Caused or prolonged

inpatient

hospitalisation

Medicine details:

AMITRIPTYLINE HYDROCHLORIDE (Suspected) Reason:

50 Milligram Daily

Batch: Stopped: 24/11/2007

TRAMAL SR (Suspected) Reason :

100 Milligram Daily

Batch: Started: Stopped:

ALLOPURINOL (Other drug) Reason :

300 Milligram

Batch: Started: Stopped:

CLOPIDOGREL (Other drug) Reason :

75 Milligram

Batch: Started: Stopped:

PUTRAN02 Page 16 of 36

Medicine details :		
DEXAMETHASONE (Other drug)		Reason:
		4 Milligram
Batch :	Started :	Stopped :
GABAPENTIN (Other drug)		Reason :
	•	00 Milligram
Batch :	Started :	Stopped :
TEMAZEPAM (Other drug)		Reason :
		20 Milligram
Batch :	Started :	Stopped:

PUTRAN02 Page 17 of 36



Cases Count: 29

Gender: M

Case Number: 239026

Data Entry Date: 17/03/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Pain
Patient reports stinging
wasp-like sensations in the
arms at night. It only
happens at night and

happens at night and occurs every few minutes. It isn't always in the same spot and can be of a very

severe nature.

Medicine details: **ENDEP (Suspected)** Reason: 25 Milligram Oral Tablet Daily Batch: Started: Stopped: ISCOVER (Suspected) Reason: Chron isch heart dis no hyper Tablet 75 Milligram Daily Oral Batch: Started: Stopped: LIPITOR (Suspected) Reason: Chron isch heart dis no hyper 40 Milligram **Tablet** Daily Oral

Batch: Started: Stopped:

OROXINE (Suspected) Reason :

Tablet 100 Microgram Daily Oral

Batch: Started: Stopped:

SOMAC (Suspected) Reason : Other diseases of esophagus

Tablet 40 Milligram Daily Oral

Batch: Started: Stopped:

VOLTAREN (Suspected) Reason :

Tablet 75 Milligram 3 times Oral

Batch: Started: Stopped:

ZANIDIP (Suspected) Reason: Essential benign hypertension

Tablet 10 Milligram Daily Oral

Batch: Started: Stopped:

Zydol (Suspected) Reason :

Capsule 150 Milligram 3 times Oral

Batch: Started: Stopped:

PUTRAN02 Page 18 of 36



Cases Count: 29

Case Number : 239453

Gender: F

Data Entry Date: 01/04/2008 **Weight (kg)**: 0

Hospitalisation: Age: 29Y

Onset Date: 10/02/2008 **DOB**:

Outcome: Causality: Causality possible

Unknown

Information: Past medical history: depression, anxiety, anorexia and postnatal depression. Prior

history of self harm.

Medication history: Tramadol, Restavit, Digesic Endep can worsen depression and suicidal ideation.

Endep may enhance the seizure risk in patients taking tramadol

Reaction:

Preferred Term Severity Report Description Treatment

Convulsion A 29 year old female suffered a SEIZURE

(CONVULSION) after taking ENDEP.

The subject also reported Suicidal thoughts, Stress,

and anxiety.

Anxiety Stress

Suicidal ideation

Medicine details:

ENDEP (Suspected) Reason : Depression

Tablet Oral

Batch: **Started**: 08/02/2008 **Stopped**: 0

TRAMADOL HYDROCHLORIDE (Suspected) Reason:

Batch: Started: 08/02/2008 Stopped: 10/02/2008 0

PUTRAN02 Page 19 of 36



Cases Count: 29

Case Number: 240097

Data Entry Date: 16/04/2008 Weight (kg): 0

Hospitalisation: Age:

Onset Date : DOB : 24/02/1944

Outcome: Causality: Causality possible

Unknown

Information:

Reaction :				
Preferred Term	Severity	Report Description	Treatment	
Tachycardia		Tachycardia, aches, fever, chills, inability to walk, shaking, dry mouth, loss of appetite, nausea and drowsiness.		
Anorexia				
Chills				
Dry mouth				
Gait disturbance				
Myalgia				
Nausea				
Pyrexia				
Somnolence				
Tremor				

Medicine details :					
ENDEP (Suspected)		Rea	ason : Depres	sion	
Tablet		50 Milligram	1 time	Oral	
Batch : 7H125	Started : 04/04/	2008		Stopped : 11/04/2008	
METFORMIN HYDROCHLORIDI	E (Other drug)	Rea	ason:		
Batch :	Started :			Stopped :	
MYOCRISIN (Other drug)		Rea	ason :		
Batch :	Started :			Stopped :	
PREDNISONE (Other drug)		Rea	ason:		
Batch :	Started :			Stopped :	
SOMAC (Other drug)		Rea	ason :		
Batch :	Started :			Stopped :	

PUTRAN02 Page 20 of 36

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

PUTRAN02 Page 21 of 36



Cases Count: 29

Case Number: 240119

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 09/04/2008 DOB: 26/11/1953

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Epilepsy had influenza vaccine on Brufen 400mg tid for back pain

9/4/08 am. She had a "black-out" late afternoon on the same day and 3 more on 10/4/08. She said she had fallen over onto her back each time and her

back is sore.

Follow-up 17/4/08: She

had had 2 more

?black-outs? with falls on 11 & 12/4/08. A locum doctor visited her 12/4/08. said her blood pressure was fairly low (did not tell her the reading), and said she had internal bruising, but he thought her spine was all right. On 16/4/08 she had seen her GP who prescribed Brufen 400mg tid for her back pain. Her blood pressure was OK then. doctor did not think she needed further treatment or change of treatment for the

?blackouts?. She says she

is still in a lot of pain

Fall

Loss of consciousness

Medicine details:

ENDEP (Suspected) Reason: Depression

50 Milligram Daily

Batch: **Started**: 07/04/0110 **Stopped**: 0

INFLUENZA VACCINE (Suspected) Reason: Prophylactic inoculation and vaccination

1 Dose Unspec 1 time

Batch: **Started**: 09/04/2008 **Stopped**: 0

PUTRAN02 Page 22 of 36

Medicine details: Lexapro (Suspected) Reason: 25 Milligram Daily Started: 01/10/2007 0 Stopped: Batch: Reason: Epilepsy **EPILIM (Other drug)** 200 Milligram Daily Batch: Started: Stopped: FEMARA (Other drug) Reason: Malignant neoplasm of breast 2.5 Milligram Daily Batch : Stopped: Started:

PUTRAN02 Page 23 of 36



Report Description

hallucinations, bitter taste, dry mouth, dry lips,

Experienced

sweating.

Cases Count: 29

Treatment

Case Number: 240839 Gender: F

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

Hospitalisation: Age: 69Y

Onset Date: 15/01/2007 DOB:

Outcome: Causality: Causality possible

Unknown

Severity

Information:

Reaction:
Preferred Term

Hallucination

Batch:

Dry mouth			
Dysgeusia			
Hyperhidrosis			
Lip dry			
Medicine details :			
ENDEP (Suspected)	Re	ason: Anxiety neurosis	
Tablet	50 Milligram	Daily	Oral
Batch :	Started : 01/01/2007	Stopped :	
ARATAC (Other drug)	Re	ason :	
Batch :	Started :	Stopped :	
AVAPRO (Other drug)	Re	ason:	
Batch :	Started :	Stopped :	
BRUFEN (Other drug)	Re	ason:	
Batch :	Started :	Stopped :	
Protos (Other drug)	Re	ason:	
Batch :	Started :	Stopped :	
RANI 2 (Other drug)	Re	ason :	
Batch :	Started :	Stopped :	
WARFARIN SODIUM (Other drug)	Re	ason :	

Stopped:

PUTRAN02 Page 24 of 36

Started:

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

PUTRAN02 Page 25 of 36



Cases Count: 29

Case Number: 241054

Gender: F

Data Entry Date: 19/05/2008 **Weight (kg)**: 0

Hospitalisation: Treated in Accident/Emergency Depart Age:

Onset Date: 15/07/2007 DOB: 12/01/1965

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Urinary retention Started having bladder Given analgesia problems including

difficulty with initiation of urine flow and two episodes of urinary retention. Also since starting Endep, she has had a very dry mouth, gingivitis, sensitive teeth and decay at gum line.

Dental caries

Dry mouth Gingivitis

Sensitivity of teeth

Medicine details:

ENDEP (Suspected) Reason : Pain

Tablet 150 Milligram Daily Oral

Batch: Started: 15/12/2005 Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Ultrasound Ultrasound showed a 10cm fibroid leaning on the bladder. A repeat ultrasound refuted the original findings,

showing a 3 cm fibroid not touching the

bladder.

PUTRAN02 Page 26 of 36



Cases Count: 29

Case Number: 244006 Gender: F

Data Entry Date: 21/08/2008 **Weight (kg)**: 0

Hospitalisation: Age: 60Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

K	е	a	C	τı	O	n	1	-

Preferred Term Severity Report Description Treatment

Delirium Delirious and sweating.

Hyperhidrosis

Medicine details:

AMITRIPTYLINE HYDROCHLORIDE (Suspected) Reason : Depression

Batch: Started: Stopped: 0

Cymbalta (Suspected) Reason: Depression

Capsule 60 Milligram 1 time Oral

Batch: Started: Stopped:

LOVAN (Suspected) Reason : Depression

Batch: Started: Stopped:

PUTRAN02 Page 27 of 36



Cases Count: 29

Case Number: 245050

Gender: F

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

Hospitalisation: Age: 53Y

Onset Date: 15/06/2008 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Open angle glaucoma Wide angle glaucoma

Medicine details:

ENDEP (Suspected) Reason : Headache

Tablet 50 Milligram 1 time Oral

Batch: Started: L TERM Stopped:

PUTRAN02 Page 28 of 36



Cases Count: 29

Case Number: 246837

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

Hospitalisation: Age: 73Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Depression Depressed, teary, shaky. Endep ceased and Xanax

increased.

Nervousness

Tearfulness

Medicine details:

ENDEP (Suspected) Reason : Anxiety neurosis

Tablet 5 Milligram Daily Oral

Batch: **Started**: 25/11/2008 **Stopped**: 28/11/2008

CARDIZEM (Other drug) Reason :

Batch: Started: Stopped:

XANAX (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 29 of 36



Cases Count: 29

Case Number : 246852

Gender: F

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

Hospitalisation: Age: 64Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Nausea Has experienced 4

episodes of fainting over the last six years while on Endep. Episodes always occur first thing in the morning upon arising. First experiences nausea and a hot sensation, then faints.

Feeling hot Syncope

Medicine details:

ENDEP (Suspected) Reason : Depression

Tablet 25 Milligram Daily Oral

Batch: Started: L TERM Stopped:

ZOMIG (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 30 of 36



Cases Count: 29

Endep discontinued.

Case Number : 246930

Gender: F

Data Entry Date: 08/12/2008 Weight (kg): 0

Age: 64Y **Hospitalisation:**

Onset Date: 25/10/2008 DOB:

Outcome: Causality: Causality possible

Recovered

Information: History of nerve pain, insomnia, atrial fibrillation and hypercholesterolaema. Patient had

open heart surgery on 25/08/08.

Reaction:

Preferred Term Severity **Report Description Treatment**

Confusional state On three ocassions, patient experienced confusion while driving after taking Endep. For

brief moments she didn't

now where she was.

Medicine details:

ENDEP (Suspected) Reason: Pain

Tablet 25 Milligram Oral Daily

Stopped: 01/11/2008 Started: 25/10/2008 Batch: 0

AMIODARONE HYDROCHLORIDE (Other drug) Reason:

Batch: Started: 10/09/2008 Stopped:

FOSINOPRIL (Other drug) Reason:

Batch: Started: L TERM Stopped:

NORMISON (Other drug) Reason:

Started: 15/09/2008 Stopped: Batch: Ongoing.

WARFARIN SODIUM (Other drug) Reason:

Batch: Started: 15/06/2008 Stopped:

ZOCOR (Other drug) Reason:

L TERM Batch: Started: Stopped:

PUTRAN02 Page 31 of 36



Cases Count: 29

Case Number: 247014

Gender: F

Data Entry Date: 09/12/2008

Weight (kg): 0

Hospitalisation:

Age: 55Y

....

Onset Date: 03/11/2008 DOB:

Outcome:

Causality: Causality certain

Recovered

Information: Cert (Rechall)

Reaction:

Preferred Term Severity

Palpitations

Report Description Treatment
She reported heart

palpitations to the pharmacist after taking tablets from a new pack of Endep 25mg. The event occured on two ocassions. The patient took a tablet from a different pack and

had no problem.

Medicine details:

ENDEP (Suspected) Reason :

Tablet 25 Milligram Daily Oral

Batch: 8A120 **Started**: **Stopped**: 04/11/2008

PUTRAN02 Page 32 of 36



Cases Count: 29

Case Number: 247657	F
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Data Entry Date: 13/01/2009 **Weight (kg)**: 0

Hospitalisation: Age: 48Y

Onset Date: 03/10/2008 **DOB**:

Outcome : Causality : Causality possible

Not yet recovered

Information:

Preferred Term	Severity	Report Description	Treatmen

Delirium, hallucinations. Olanzapine stat wafer with good

effect.

Hallucination

Reaction:

Medicine detai	ls:			
AMITRIPTYLINE HYDROCHLORIDE (Suspected)		Reason :		
Batch :	Started :		Stopped :	
CITALOPRAM HYDROBROMIDE (Suspected)		Reason :		
Batch :	Started :		Stopped :	
FENTANYL TRANSDERMAL (Suspected)		Reason :		_
Batch :	Started :		Stopped :	

PUTRAN02 Page 33 of 36



Cases Count: 29

Case Number: 248007

Gender: F

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

Hospitalisation: Admitted to hospital Age: 89Y

Onset Date: 09/10/2008 DOB:

Outcome: Causality: Causality possible

mouth.

Not yet recovered

Information:

Reaction:

Dry mouth

Preferred Term Severity **Report Description Treatment** Buzzing in both ears, Endep ceased

Tinnitus Caused or prolonged

inpatient hospitalisation

Caused or prolonged

inpatient hospitalisation

Caused or prolonged Hallucination

inpatient hospitalisation

visual hallucinations, dry

Medicine details:

ENDEP (Suspected) Reason: Otr&unsp vertebrogen pain synd

Tablet 10 Milligram Daily Oral

Started: Stopped: Batch:

FRUSEMIDE (Other drug) Reason:

Batch: Started: Stopped:

POTASSIUM NOS (Other drug) Reason:

Batch: Started: Stopped:

QUININE (Other drug) Reason:

Stopped: Batch: Started:

PUTRAN02 Page 34 of 36



Cases Count: 29

Gender: M

Case Number: 248152

Data Entry Date: 30/01/2009 **Weight (kg)**: 0

Hospitalisation : Age :

hospitalisation

Onset Date : DOB : 25/09/1928

Outcome: Causality: Causality possible

Recovered

Information:

Reaction: **Preferred Term** Severity **Report Description Treatment** Confusional state Caused or prolonged Report of drug induced Gabpentin dose was decreased inpatient confusion and drowsiness to 100mg/day. Carbamazepine hospitalisation (thought to be gabapentin was ceased. MS contin dose but carbamazepine and was decreased from 10mg amitriptylline may have nocte to 5mg nocte. Endone contributed also). He was also prescribed for reported increased breakthrough pain. lethargy and somnolence and an epidsode of altered behaviour upon starting gabapentin (although pain had improved) Abnormal behaviour Caused or prolonged inpatient hospitalisation Caused or prolonged Lethargy inpatient hospitalisation Somnolence Caused or prolonged inpatient

Medicine details :						
AMITRIPTYLINE HYDROCHLORID	Re	ason : Pain				
Tablet		50 Milligram	Daily	Oral		
Batch :	Started :			Stopped :		
CARBAMAZEPINE (Suspected)		Re	ason : Pain			
Tablet		100 Milligram	Daily	Oral		
Batch :	Started :			Stopped : 25/10/20	008	
GABAPENTIN (Suspected)		Re	ason : Pain			
Capsule		300 Milligram	Daily	Oral		
Batch :	Started : 24/09/2008		Stopped :	0		
MS CONTIN (Suspected)		Re	ason:			
Batch :	Started :			Stopped :		
ASPIRIN (Other drug)		Re	ason:			
Batch :	Started :			Stopped :		

PUTRAN02 Page 35 of 36

Medicine details	:			
ATORVASTATIN (Other drug))	Reason :		
Batch :	Started :		Stopped :	
DIGOXIN (Other drug)		Reason :		_
Batch :	Started :		Stopped :	
F.G.F. (Other drug)		Reason :		_
Batch :	Started :		Stopped :	
FRUSEMIDE (Other drug)		Reason :		_
Batch :	Started :		Stopped :	
GLYCERYL TRINITRATE (Other drug)		Reason :		_
Patch, dermal				
Batch :	Started :		Stopped :	
METOCLOPRAMIDE HYDROCHLORIDE (Other drug)		Reason :		_
Batch :	Started :		Stopped :	
MIXTARD 30/70 (Other drug)		Reason :		
Batch :	Started :		Stopped :	
OSTELIN 1000 (Other drug)		Reason :		_
Batch :	Started :		Stopped :	
PERINDOPRIL (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: AMITRIP, AMITRIPTYLINE HYDROCHLORIDE, ELAVIL, ENDEP, LAROXYL, SAROTEN, TRYPTANOL, TRYPTINE

PUTRAN02 Page 36 of 36