

Adverse reactions to drugs

Date: 1999-05-27

Search covers total holding

AUS AUT BEL CHL CZE DEN FIN FRA

PANTOPRAZOLE

Body as a whole - general disor

	AUS	AUT	BEL	CHL	CZE	DEN	FIN	FRA
CHEST PAIN								1
MALaise	1							
OEDEMA								1
OEDEMA PERIPHERAL					1			
Centr & periph nervous system d								1
CONVULSIONS GRAND MAL								1
ENCEPHALOPATHY								1
HEADACHE								1
PARAESTHESIA	1							
PARESIS	1							
Gastro-intestinal system disord								
DIARRHOEA								2
TONGUE OEDEMA								1
VOMITING								1
Liver and biliary system disord								1
HEPATITIS								1
Metabolic and nutritional disor								1
HYPERKALAEMIA								1
Musculo-skeletal system disorde								
ARTHRALGIA	1							
MYALGIA	1							
Psychiatric disorders								
IMPOTENCE	1							
LIBIDO DECREASED	1							
Red blood cell disorders								
ANAEMIA HAEMOLYTIC								1
Respiratory system disorders								
LARYNX OEDEMA								1
Skin and appendages disorders								
COLD URTICARIA								1
EPIDERMAL NECROLYSIS								1
FIXED ERUPTION								1
PRURITUS								4
RASH					2			1
RASH ERYTHEMATOUS	1				1			1
RASH MACULO-PAPULAR	1					1		1
White cell and res disorders								
LEUCOPENIA								1

PANTOPRAZOLE SODIUM

Body as a whole - general disor

ALLERGIC REACTION	1							
ASTHENIA	2							
FEVER				1				
MALaise	1							
OEDEMA			1					
RIGORS	1							
SYNCOPE	1							

Cardiovascular disorders, gener
CARDIAC FAILURE 1

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AUS AUT BEL CHL CZE DEN FIN FRA

Centr & periph nervous system d

CEREBELLAR SYNDROME			1					
CRAMPS LEGS	1							
DIZZINESS	1					2		
HEADACHE	5					3	2	
PARAESTHESIA	1							
SPEECH DISORDER	1							
TREMOR	1							

Gastro-intestinal system disord

ABDOMINAL PAIN	1							
CONSTIPATION	1							
DIARRHOEA	3							
HAEMORRHOIDS	1							
MOUTH DRY						1		
NAUSEA	6					1		
PANCREATITIS	1		1					
TONGUE DISCOLOURATION	1							
VOMITING	3							

Hearing and vestibular disorder

TINNITUS	1							
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Heart rate and rhythm disorders

ARRHYTHMIA	1							
EXTRASYSTOLES	1		2					
PALPITATION	1		1			1		
TACHYCARDIA	1							

Liver and biliary system disord

HEPATIC FAILURE	1							
HEPATIC FUNCTION ABNORMAL	1							
HEPATITIS			2					
HEPATITIS CHOLESTATIC			1					
SGPT INCREASED								1

Metabolic and nutritional disor

CREATINE PHOSPHOKINASE INC	1							
OEDEMA GENERALISED	1							
OEDEMA PERIORBITAL								1
XEROPHTHALMIA						1		

Musculo-skeletal system disorde

ARTHRALGIA	2							
ARTHROSIS	1							
MYALGIA	2							
MYOPATHY	1							
RHABDOMYOLYSIS	2							

Platelet,bleeding & clotting di

THROMBOCYTOPENIA	1					1		
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Psychiatric disorders

AMNESIA	1					1		
DEPRESSION	2					2		
IMPOTENCE	1							
INSOMNIA			1					

HEPATIC ENZYMES INCREASED	2							
HEPATITIS	1							
JAUNDICE	1							
Metabolic and nutritional disor								
NPN INCREASED								1
WEIGHT DECREASE								1
Psychiatric disorders								

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	GFR	IRE	NET	NEZ	POR	SPA	SWE	UNK
ANOREXIA						1		1
CONFUSION				1				
NERVOUSNESS						2		
Skin and appendages disorders								
ALOPECIA					1			1
PRURITUS								1
RASH ERYTHEMATOUS					1			
SEBORRHOEA								1
Urinary system disorders								
NEPHRITIS INTERSTITIAL								1
Vascular (extracardiac) disorde								
PERIPHERAL ISCHAEMIA								1
Vision disorders								
BLINDNESS	1							
PANTOPRAZOLE SODIUM								
Application site disorders								
INJECTION SITE INFLAMMATIO	1							
INJECTION SITE PAIN	1							
INJECTION SITE REACTION	1							
Body as a whole - general disor								
ALLERGIC REACTION	1		1					
ANAPHYLACTIC SHOCK	3							
ANAPHYLACTOID REACTION	1							
BACK PAIN	1							
CHEST PAIN	3							1
CONDITION AGGRAVATED								3
FATIGUE								1
FEVER	4							5
HYPERPYREXIA	1					1		1
INFLUENZA-LIKE SYMPTOMS								
MALAISE	4		2			1		1
OEDEMA	1		1					6
OEDEMA PERIPHERAL							1	2
PAIN								1
RIGORS	2							1
SUDDEN DEATH								1
SYNCOPE	2							1
TEMPERATURE CHANGED SENSAT								1
THERAPEUTIC RESPONSE DECRE								2
UNEXPECTED THERAPEUTIC EFF								1
Cardiovascular disorders, gener								
CARDIAC FAILURE LEFT								1
CIRCULATORY FAILURE	3							

GI HAEMORRHAGE	2						
GINGIVITIS							1
GLOSSITIS	2						
HAEMATEMESIS	1						
MOUTH DRY				1			
NAUSEA	7	2	1				1
OESOPHAGITIS	1	1			1		11
PANCREATITIS	3						
PEPTIC ULCER HAEMORRHAGIC							
STOMATITIS ULCERATIVE							1
TONGUE DISCOLOURATION	1						4

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GFR IRE NET NEZ POR SPA SWE UNK

	GFR	IRE	NET	NEZ	POR	SPA	SWE	UNK
TONGUE DISORDER			1					
TONGUE OEDEMA	1							
VOMITING	3		1					1
Hearing and vestibular disorder								6
TINNITUS	1							
VESTIBULAR DISORDER	1							1
Heart rate and rhythm disorders								
ARRHYTHMIA	2							
BUNDLE BRANCH BLOCK	1							
EXTRASYSTOLES								
PALPITATION	1							1
TACHYCARDIA	1							1
Liver and biliary system disord								
BILIRUBINAEMIA	1							
GAMMA-GT INCREASED	3							
HEPATIC ENZYMES INCREASED	2							
HEPATIC FUNCTION ABNORMAL				1				
HEPATOCELLULAR DAMAGE	1							1
HEPATORENAL SYNDROME	1							
JAUNDICE	3							
SGOT INCREASED	4							
SGPT INCREASED	3							
Metabolic and nutritional disor								
NPN INCREASED	1							
OEDEMA PERIORBITAL								
WEIGHT INCREASE								2
Musculo-skeletal system disorde								1
ARTHRALGIA								
ARTHROPATHY	1							3
MUSCLE WEAKNESS	1			1				
MYALGIA								
Myo endo pericardial & valve di								9
ANGINA PECTORIS								
ANGINA PECTORIS AGGRAVATED				1				
MYOCARDIAL INFARCTION	3							1
Neoplasm								1
BLADDER CARCINOMA	1							
HEPATIC NEOPLASM	1							
LEUKAEMIA GRANULOCYTIC								
LYMPHOMA MALIGNANT	1							1

AGRANULOCYTOSIS
LEUCOPENIA

5

1

Adverse reactions to drugs

Date: 1999-05-27

Search covers total holding

Summary on investigated terms

PANTOPRAZOLE

ALOPECIA	2
ANAEMIA HAEMOLYTIC	1
ANOREXIA	2
ARTHRALGIA	1
BLINDNESS	1
CHEST PAIN	1
COLD URTICARIA	1
COMA	1
CONFUSION	1
CONVULSIONS GRAND MAL	1
DEAFNESS	1
DIARRHOEA	3
DIZZINESS	1
ENCEPHALOPATHY	1
EPIDERMAL NECROLYSIS	1
FIXED ERUPTION	1
HEADACHE	1
HEPATIC ENZYMES INCREASED	2
HEPATITIS	2
HYPERKALAEMIA	1
IMPOTENCE	1
JAUNDICE	1
LARYNX OEDEMA	1
LEUCOPENIA	1
LIBIDO DECREASED	1
MALaise	1
MYALGIA	1
NEPHRITIS INTERSTITIAL	1
NERVOUSNESS	2
NEUROPATHY	2
NPN INCREASED	1
OEDEMA	1
OEDEMA PERIPHERAL	1
PARAESTHESIA	2
PARESIS	1
PERIPHERAL ISCHAEMIA	1
PRURITUS	7
RASH	2
RASH ERYTHEMATOUS	2
RASH MACULO-PAPULAR	3
SEBORRHOEA	1
SUDDEN DEATH	1
TONGUE OEDEMA	1
VOMITING	2
WEIGHT DECREASE	1

PANTOPRAZOLE SODIUM
ABDOMINAL PAIN
ABORTION

17
2

Adverse reactions to drugs

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Search covers total holding
Summary on investigated terms

ACNE	1
AGGRESSIVE REACTION	1
AGITATION	2
AGRANULOCYTOSIS	1
ALLERGIC REACTION	3
ALOPECIA	4
AMNESIA	2
ANAEMIA HAEMOLYTIC	1
ANAESTHESIA MOUTH	1
ANAL FISSURE	1
ANAPHYLACTIC SHOCK	3
ANAPHYLACTOID REACTION	1
ANGINA PECTORIS	1
ANGINA PECTORIS AGGRAVATED	1
ANGIOEDEMA	7
ANXIETY	4
APPETITE INCREASED	1
ARRHYTHMIA	3
ARTHRALGIA	5
ARTHROPATHY	1
ARTHROSIS	1
ASPIRATION	1
ASTHENIA	1
ASTHMA	2
ATAXIA	2
BACK PAIN	3
BILIRUBINAEMIA	2
BLADDER CARCINOMA	1
BLINDNESS TEMPORARY	1
BREAST ENLARGEMENT	1
BRONCHOSPASM	4
BRONCHOSPASM AGGRAVATED	3
BULLOUS ERUPTION	1
BUNDLE BRANCH BLOCK	3
CARDIAC FAILURE	1
CARDIAC FAILURE LEFT	1
CEREBELLAR SYNDROME	1
CEREBROVASCULAR DISORDER	1
CHEST PAIN	4
CIRCULATORY FAILURE	6
COAGULATION TIME DECREASED	3
COAGULATION TIME INCREASED	1
COMA	3
CONDITION AGGRAVATED	2
CONFUSION	1
CONSTIPATION	4
CONVULSIONS	3
	1

CONVULSIONS GRAND MAL	2
COUGHING	1
CRAMPS LEGS	1
CREATINE PHOSPHOKINASE INC	1
CYSTITIS	2
DEPRESSION	17

Adverse reactions to drugs

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Summary on investigated terms

DERMATITIS	1
DERMATITIS EXFOLIATIVE	1
DIARRHOEA	31
DIARRHOEA BLOODY	1
DIPLOPIA	2
DIZZINESS	30
DREAMING ABNORMAL	2
DYSAESTHESIA	6
DYSPEPSIA	4
DYSPHAGIA	3
DYSPNOEA	8
DYSURIA	1
ECZEMA	3
EMBOLISM PULMONARY	1
EMOTIONAL LABILITY	1
EPIDERMAL NECROLYSIS	1
EPIDIDYMITIS	1
EPISTAXIS	3
ERUCTATION	2
ERYTHEMA MULTIFORME	1
EXTRAPYRAMIDAL DISORDER	1
EXTRASYSTOLES	4
EYE ABNORMALITY	1
EYE BURNS	1
FACE OEDEMA	10
FAECES DISCOLOURED	2
FATIGUE	5
FEVER	7
FLATULENCE	8
FLUSHING	4
FURUNCULOSIS	1
GAIT ABNORMAL	1
GAMMA-GT INCREASED	3
GASTRIC ULCER	2
GASTRIC ULCER HAEMORRHAGIC	2
GASTROESOPHAGEAL REFLUX	3
GI HAEMORRHAGE	2
GINGIVITIS	1
GLAUCOMA	1
GLOSSITIS	2
GYNAECOMASTIA	3
HAEMATEMESIS	1
HAEMATURIA	1
HAEMORRHAGE NOS	1
HAEMORRHOIDS	1

HALLUCINATION	2
HEADACHE	49
HEART DISORDER	1
HEPATIC ENZYMES INCREASED	2
HEPATIC FAILURE	1
HEPATIC FUNCTION ABNORMAL	3
HEPATIC NEOPLASM	1
HEPATITIS	2

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Summary on investigated terms

HEPATITIS CHOLESTATIC	1
HEPATOCELLULAR DAMAGE	1
HEPATORENAL SYNDROME	1
HERNIA CONGENITAL	1
HYPERAESTHESIA	1
HYPERKINESIA	1
HYPERPYREXIA	1
HYPERTENSION	2
HYPERTONIA	1
HYPOAESTHESIA	1
HYPOTENSION	2
HYPOTENSION POSTURAL	2
HYSTERIA	1
IMPOTENCE	3
INFECTION	1
INFECTION VIRAL	1
INFLUENZA-LIKE SYMPTOMS	1
INJECTION SITE INFLAMMATIO	1
INJECTION SITE PAIN	1
INJECTION SITE REACTION	1
INSOMNIA	4
JAUNDICE	3
LACRIMATION ABNORMAL	1
LARYNGISMUS	1
LEUCOPENIA	6
LEUKAEMIA GRANULOCYTIC	1
LEUKORRHOEA	1
LYMPHOMA MALIGNANT	1
MALAISE	14
MICTURITION FREQUENCY	3
MIGRAINE	4
MONILIASIS	2
MOUTH DRY	3
MUSCLE CONTRACTIONS INVOLU	1
MUSCLE WEAKNESS	2
MYALGIA	11
MYOCARDIAL INFARCTION	4
MYOPATHY	1
NAUSEA	29
NERVOUSNESS	2
NEUROPATHY	2
NIPPLE ULCERATION	1
NPN INCREASED	1

OEDEMA	6
OEDEMA GENERALISED	1
OEDEMA PERIORBITAL	3
OEDEMA PERIPHERAL	1
OESOPHAGITIS	2
OPTIC ATROPHY	1
PAIN	1
PALPITATION	5
PANCREATITIS	5
PANCYTOPENIA	3

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Summary on investigated terms

PARAESTHESIA	6
PARALYSIS	2
PARESIS	1
PARKINSONISM AGGRAVATED	1
PARONIRIA	2
PAROSMIA	2
PEPTIC ULCER HAEMORRHAGIC	1
PHLEBITIS	1
PHOTOSENSITIVITY REACTION	4
PLEURAL MESOTHELIOMA	1
PRURITUS	28
PSORIASIS AGGRAVATED	2
PSYCHOSIS	2
PURPURA	1
RASH	28
RASH ERYTHEMATOUS	15
RASH MACULO-PAPULAR	10
RASH PUSTULAR	1
RENAL FAILURE ACUTE	1
RENAL FUNCTION ABNORMAL	1
RENAL PAIN	1
RESPIRATORY DEPRESSION	1
RETROBULBAR NEURITIS	1
RHABDOMYOLYSIS	2
RHINITIS	2
RIGORS	4
SEXUAL FUNCTION ABNORMAL	1
SGOT INCREASED	4
SGPT INCREASED	4
SKIN COLD CLAMMY	2
SKIN DISCOLOURATION	1
SKIN DISORDER	2
SKIN DRY	2
SKIN ULCERATION	1
SLEEP DISORDER	1
SOMNOLENCE	4
SPEECH DISORDER	1
STOMATITIS ULCERATIVE	4
SUBARACHNOID HAEMORRHAGE	1
SUDDEN DEATH	1
SWEATING INCREASED	4

SYNCOPE	4
TACHYCARDIA	2
TASTE LOSS	1
TASTE PERVERSION	3
TEMPERATURE CHANGED SENSAT	2
THERAPEUTIC RESPONSE DECRE	1
THROMBOCYTHAEMIA	1
THROMBOCYTOPENIA	5
THROMBOPHLEBITIS	2
THROMBOPHLEBITIS ARM	1
THROMBOPHLEBITIS PELVIC VE	1
TINNITUS	2

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Adverse reactions to drugs

Date: 1999-05-27

Search covers total holding

Summary on investigated terms

TONGUE DISCOLOURATION	2
TONGUE DISORDER	1
TONGUE OEDEMA	2
TONGUE PARALYSIS	1
TRANSIENT ISCHAEMIC ATTACK	1
TREMOR	3
UNEXPECTED THERAPEUTIC EFF	1
URTICARIA	13
UTERINE HAEMORRHAGE	2
VASCULITIS	1
VASOSPASM	1
VERTIGO	3
VESICULAR RASH	1
VESTIBULAR DISORDER	2
VISION ABNORMAL	25
VISUAL FIELD DEFECT	3
VITREOUS DETACHMENT	1
VOMITING	13
WEIGHT INCREASE	2
XEROPHTHALMIA	1

785

Search performed on:

Year(s): All

Countries: All

Drug(s): PANTOPRAZOLE
PANTOPRAZOLE SODIUM

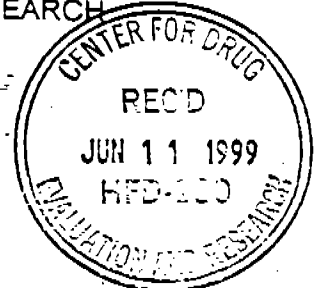
Reaction(s): All

NDA 20987

Walsh

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH



DATE: JUN 9 1999

FROM: Ann Corken, RPh, MPH, Safety Evaluator
Division of Drug Risk Evaluation II (DDRE II)

THROUGH: Evelyn Rodriguez, M.D., M.P.H., Director
DDRE II, HFD-738

/S/

TO: Lilia Talarico, M.D., M.P.H., Division Director
Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECT: Consult:
Drug: Pantoprazole (Protonix®)
Reaction: Evidence of Carcinogenicity

INTRODUCTION:

This memorandum is in response to a verbal consult received from Maria Walsh of HFD-180 requesting information on the evidence of carcinogenicity associated with use of pantoprazole, a drug which has not been approved in the U.S. Specifically, Ms. Walsh requested a search of reports from the FDA's Adverse Event Reporting System (AERS) database and asked for any reported cases from Australia, Canada, Germany, and the United Kingdom. In addition, the medical literature was searched.

AERS CASES

On May 27, 1999, a search was performed in AERS using pantoprazole as suspect and concomitant drug and *neoplasms benign and malignant (including cysts and polyps)* as the MedDRA SOC term. The search produced 2 foreign cases of carcinogenicity (metastatic renal cell carcinoma and lingula fibrosis), both listing pantoprazole as a concomitant drug. Duration of therapy for either the concomitant or suspect drug was not provided in the reports, making causality with pantoprazole difficult to establish. These reports are attached for your review.

WHO DATA

A report (by organ system) of adverse reactions to pantoprazole from the WHO database is attached for your review. As you can see, there are a total of six cases of neoplasm, with the following breakdown: bladder carcinoma, hepatic neoplasm, granulocytic leukaemia, malignant lymphoma, pleural mesothelioma, and thrombocythaemia. Note from the attachment that there are no reports of neoplasm from Australia and Canada.

LITERATURE

As of May 27, 1999, a MEDLINE search of the published English-language literature using the term pantoprazole produced no individual case reports of carcinogenicity. However, a review article reported that patients receiving long-term (up to 36 months) therapy with pantoprazole reported a slight (and statistically insignificant) increase in enterochromaffin-like (ECL) cell density (1.58-fold) (1).

DISCUSSION/CONCLUSION:

This document describes the results of a search of the AERS database, the WHO database, and the medical literature for reports of carcinogenicity associated with use of pantoprazole. Based on the information from these three sources, it appears that there have been few cases of carcinogenicity associated with pantoprazole use. However, since pantoprazole has not been approved in the U.S., reports in AERS would not be expected. We will continue to monitor pantoprazole reports for additional evidence of carcinogenicity and update you if more information becomes available.

REFERENCES:

1. Fitton A, Wiseman L. Pantoprazole. A review of its pharmacological properties and therapeutic use in acid-related disorders. Drugs 1996; 51 (3): 460-82.

 / S /
Ann Corken, RPh, MPH

Concur:

 / S /
Toni Piazza-Hepp, Pharm.D., Team Leader

cc:
HFD-180 Walsh/ Gallo-Torres/ NDA# 20987
HFD-730 Lillie
HFD-738 Rodriguez/ Chron/ Consult file/ Piazza-Hepp/ Corken
HF-2 Lumpkin

**APPEARS THIS WAY
ON ORIGINAL**

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AUS AUT BEL CHL CZE DEN FIN FRA

PANTOPRAZOLE

	AUS	AUT	BEL	CHL	CZE	DEN	FIN	FRA
Body as a whole - general disor								
CHEST PAIN								1
MALAISE		1						
OEDEMA								1
OEDEMA PERIPHERAL					1			
Centr & periph nervous system d								
CONVULSIONS GRAND MAL								1
ENCEPHALOPATHY								1
HEADACHE								1
PARAESTHESIA		1						
PARESIS		1						
Gastro-intestinal system disord								
DIARRHOEA								2
TONGUE OEDEMA								1
VOMITING								1
Liver and biliary system disord								
HEPATITIS								1
Metabolic and nutritional disor								
HYPERKALAEMIA								1
Musculo-skeletal system disorde								
ARTHRALGIA		1						
MYALGIA		1						
Psychiatric disorders								
IMPOTENCE		1						
LIBIDO DECREASED		1						
Red blood cell disorders								
ANAEMIA HAEMOLYTIC								1
Respiratory system disorders								
LARYNX OEDEMA								1
Skin and appendages disorders								
COLD URTICARIA								1
EPIDERMAL NECROLYSIS								1
FIXED ERUPTION								1
PRURITUS								1
RASH					2			4
RASH ERYTHEMATOUS					1			1
RASH MACULO-PAPULAR		1						1
White cell and res disorders					1			1
LEUCOPENIA								1

PANTOPRAZOLE SODIUM

Body as a whole - general disor								
ALLERGIC REACTION		1						
ASTHENIA		2						
FEVER					1			
MALAISE		1						
OEDEMA								1
RIGORS		1						
SYNCOPE		1						

Cardiovascular disorders, gener
 CARDIAC FAILURE 1

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AUS AUT BEL CHL CZE DEN FIN FRA

Centr & periph nervous system d

CEREBELLAR SYNDROME		1					
CRAMPS LEGS	1						
DIZZINESS	1				2		
HEADACHE	5				3	2	
PARAESTHESIA	1						
SPEECH DISORDER	1						
TREMOR	1						

Gastro-intestinal system disord

ABDOMINAL PAIN	1						
CONSTIPATION	1						
DIARRHOEA	3						
HAEMORRHOIDS	1						
MOUTH DRY					1		
NAUSEA	6				1		
PANCREATITIS	1		1				
TONGUE DISCOLOURATION	1						
VOMITING	3						

Hearing and vestibular disorder

TINNITUS	1						
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Heart rate and rhythm disorders

ARRHYTHMIA	1						
EXTRASYSTOLES	1		2				
PALPITATION	1		1		1		
TACHYCARDIA	1						

Liver and biliary system disord

HEPATIC FAILURE	1						
HEPATIC FUNCTION ABNORMAL	1						
HEPATITIS			2				
HEPATITIS CHOLESTATIC			1				
SGPT INCREASED						1	

Metabolic and nutritional disor

CREATINE PHOSPHOKINASE INC	1						
OEDEMA GENERALISED	1						
OEDEMA PERIORBITAL						1	
XEROPHTHALMIA					1		

Musculo-skeletal system disorde

ARTHRALGIA	2						
ARTHROSIS	1						
MYALGIA	2						
MYOPATHY	1						
RHABDOMYOLYSIS	2						

Platelet, bleeding & clotting di

THROMBOCYTOPENIA	1						
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Psychiatric disorders

AMNESIA	1						
DEPRESSION	2					2	
IMPOTENCE	1						
INSOMNIA			1				

HEPATIC ENZYMES INCREASED	2						
HEPATITIS	1						
JAUNDICE	1						
Metabolic and nutritional disor							
NPN INCREASED							1
WEIGHT DECREASE							1
Psychiatric disorders							

Adverse reactions to drugs

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	GFR	IRE	NET	NEZ	POR	SPA	SWE	UNK
ANOREXIA						1		1
CONFUSION				1				
NERVOUSNESS						2		
Skin and appendages disorders								
ALOPECIA					1			1
PRURITUS								1
RASH ERYTHEMATOUS					1			
SEBORRHOEA								1
Urinary system disorders								
NEPHRITIS INTERSTITIAL								1
Vascular (extracardiac) disorde								
PERIPHERAL ISCHAEMIA								1
Vision disorders								
BLINDNESS	1							
PANTOPRAZOLE SODIUM								
Application site disorders								
INJECTION SITE INFLAMMATIO	1							
INJECTION SITE PAIN	1							
INJECTION SITE REACTION	1							
Body as a whole - general disor								
ALLERGIC REACTION	1		1					
ANAPHYLACTIC SHOCK	3							
ANAPHYLACTOID REACTION	1							
BACK PAIN	1							
CHEST PAIN	3							
CONDITION AGGRAVATED								
FATIGUE								
FEVER	4							
HYPERPYREXIA	1					1		
INFLUENZA-LIKE SYMPTOMS								
MALAISE	4		2					
OEDEMA	1		1			1		
OEDEMA PERIPHERAL							1	
PAIN								
RIGORS	2							
SUDDEN DEATH								
SYNCOPE	2							
TEMPERATURE CHANGED SENSAT								
THERAPEUTIC RESPONSE DECRE								
UNEXPECTED THERAPEUTIC EFF								
Cardiovascular disorders, gener								
CARDIAC FAILURE LEFT								
CIRCULATORY FAILURE	3							

GI HAEMORRHAGE	2							
GINGIVITIS								1
GLOSSITIS	2							
HAEMATEMESIS	1							
MOUTH DRY			1					1
NAUSEA	7	2	1		1			11
OESOPHAGITIS	1	1						
PANCREATITIS	3							
PEPTIC ULCER HAEMORRHAGIC								1
STOMATITIS ULCERATIVE								4
TONGUE DISCOLOURATION	1							

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Adverse reactions to drugs

Date: 1999-05-27

Search covers total holding

	GFR	IRE	NET	NEZ	POR	SPA	SWE	UNK
TONGUE DISORDER			1					
TONGUE OEDEMA	1							1
VOMITING	3		1					6
Hearing and vestibular disorder								
TINNITUS	1							
VESTIBULAR DISORDER	1							1
Heart rate and rhythm disorders								
ARRHYTHMIA	2							
BUNDLE BRANCH BLOCK	1							
EXTRASYSTOLES								1
PALPITATION	1							1
TACHYCARDIA	1							
Liver and biliary system disord								
BILIRUBINAEMIA	1							
GAMMA-GT INCREASED	3							
HEPATIC ENZYMES INCREASED	2							
HEPATIC FUNCTION ABNORMAL			1					1
HEPATOCELLULAR DAMAGE	1							
HEPATORENAL SYNDROME	1							
JAUNDICE	3							
SGOT INCREASED	4							
SGPT INCREASED	3							
Metabolic and nutritional disor								
NPN INCREASED	1							
OEDEMA PERIORBITAL								2
WEIGHT INCREASE			1					1
Musculo-skeletal system disorde								
ARTHRALGIA								3
ARTHROPATHY	1							
MUSCLE WEAKNESS	1		1					
MYALGIA								9
Myo endo pericardial & valve di								
ANGINA PECTORIS			1					
ANGINA PECTORIS AGGRAVATED								1
MYOCARDIAL INFARCTION	3							1
Neoplasm								
BLADDER CARCINOMA	1							
HEPATIC NEOPLASM	1							
LEUKAEMIA GRANULOCYTIC								1
LYMPHOMA MALIGNANT	1							

