DRUG ANALYSIS PRINT PAGE: 1

DRUG : FINASTERIDE

ROUTE: ALL

SINGLE-CONSTITUENT PRODS : PROPECIA, PROSCAR

MULTI-CONSTITUENT PRODS : NONE

SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME	SING CONS TOT	Т	CONS	Г	SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME	CONS	LE T FTL	CONS	Т
Blood and lymphatic system disorders Marrow depression and hypoplastic anaemias					Musculoskeletal disorders congenital NEC Congenital musculoskeletal anomaly	1	0	0	0
Aplastic anaemia	2	0	0	0	Male reproductive tract disorders congenital				
Thrombocytopenias					Congenital hydrocele	1	0	0	0
Idiopathic thrombocytopenic purpura	2	0	0	0					
Thrombocytopenia	10	0	0	0	SYS ORGAN CLASS TOTAL:	2	0	0	0
Thrombocytopenic purpura	1	1	0	0					
Lymphatic system disorders NEC					Ear and labyrinth disorders				
Hilar lymphadenopathy	1	0	0	0	Ear disorders NEC				
Neutropenias					Ear pain	1	0	0	0
Neutropenia	1	0	0	0	Hearing losses				
-					Conductive deafness	1	0	0	0
SYS ORGAN CLASS TOTAL:	17	1	0	0	Inner ear disorders NEC				
					Vestibular disorder	1	0	0	0
Cardiac disorders					Inner ear signs and symptoms				
Rate and rhythm disorders NEC					Tinnitus	5	0	0	0
Tachycardia	2	0	0	0	Vertigo	6	0	0	0
Supraventricular arrhythmias									
Atrial fibrillation	4	0	0	0	SYS ORGAN CLASS TOTAL:	14	0	0	0
Ventricular arrhythmias and cardiac arrest									
Cardiac arrest	2	0	0	0	Endocrine disorders				
Ventricular fibrillation	1	0	0	0	Adrenal cortical hypofunctions				
Ventricular tachycardia	1	0	0	0	Adrenocortical insufficiency chronic	1	0	0	0
Cardiac disorders NEC									
Cardiac disorder	1	0	0	0	SYS ORGAN CLASS TOTAL:	1	0	0	0
Cardiac signs and symptoms NEC									
Palpitations	6	0	0	0	Eye disorders				
Coronary artery disorders NEC					Corneal structural change, deposit and degene				
Coronary artery insufficiency	1	0	0	0	Corneal opacity	1	•	0	0
Coronary artery thrombosis	3	2	0	0	Conjunctival and corneal bleeding and vascula				
Ischaemic coronary artery disorders					Conjunctival haemorrhage	2		•	0
Acute myocardial infarction	2	2	0	0	Lid, lash and lacrimal infections, irritation				
Angina pectoris	8	0	0	0	Eyelid oedema	_ 1	0	0	0
Angina unstable	2	0	0	0	Ocular infections, inflammations and associat				
Myocardial infarction	10	0	0	0	Eye irritation	1	0	0	0
Heart failures NEC		_	_	_	Ocular sensation disorders	_	_	_	_
Cardiac failure	4	1	0	0	Photophobia	1	0	0	0
Left ventricular failures	_	_	_	_	Retinal bleeding and vascular disorders (excl				_
Left ventricular failure	3	2	0	0	Retinal haemorrhage	1	0	0	0
Cardiomyopathies	_	_	_	_	Retinopathies NEC	_	_	_	_
Cardiomyopathy	1	0	0	0	Retinopathy	1	0	0	0
					Blindness (excl colour blindness)	_			
SYS ORGAN CLASS TOTAL:	51	7	0	0	Amaurosis fugax	2	0	0	0
					Blindness transient	1	0	0	0
Congenital, familial and genetic disorders					Partial vision loss				

SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME	SINGI CONST TOT I	Γ	CONS	Т	SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME	SING CONS TOT	Т	CONS	Т
Vision blurred	5 3	0	0	0	Abdominal pain upper	3	0	0	0
Visual acuity reduced Visual disorders NEC	3	U	U	U	Gastrointestinal signs and symptoms NEC Abdominal discomfort	2	0	0	0
Visual disturbance	2	Λ	0	0	Dysphagia	2	0	0	0
Visual disturbance					Faecal incontinence	1	0	0	0
SYS ORGAN CLASS TOTAL:			0		Nausea and vomiting symptoms		U	U	U
SIS ORGAN CLASS TOTAL:					Nausea and vomitting symptoms Nausea	15	0	0	0
Gastrointestinal disorders					Vomiting	6	0	0	0
Diaphragmatic hernias					Gastrointestinal stenosis and obstruction NEC	U	U	U	U
Hiatus hernia	1	0	0	0	Intestinal obstruction	1	0	0	0
Inquinal hernias	_	O	O	O	Gastric ulcers and perforation	_	O	O	O
Inquinal hernia	2	0	0	0	Gastric ulcer	2	1	0	0
Anal and rectal disorders NEC	-	Ū	ŭ	Ü	Gastric ulcer perforation	1	0	0	Ö
Anal fissure	1	0	0	0	Oesophageal ulcers and perforation	_		-	-
Anorectal disorder	2	Ō	Ö	Ö	Oesophageal ulcer	1	0	0	0
Anal and rectal pains					Oral soft tissue haemorrhages				
Proctalgia	5	0	0	0	Mouth haemorrhage	1	0	0	0
Anal and rectal signs and symptoms					Oral soft tissue swelling and oedema				
Pruritus ani	1	0	0	0	Oedema mouth	1	0	0	0
Dental disorders NEC					Stomatitis and ulceration				
Teeth brittle	1	0	0	0	Aphthous stomatitis	1	0	0	0
Dental pain and sensation disorders					Mouth ulceration	1	0	0	0
Sensitivity of teeth	1	0	0	0	Stomatitis	1	0	0	0
Gingival disorders NEC					Oral dryness and saliva altered				
Gingival hypoplasia	1	0	0	0	Dry mouth	2	0	0	0
Acute and chronic pancreatitis					Salivary gland enlargements				
Pancreatitis	1	0	0	0	Parotid gland enlargement	1	0	0	0
Intestinal haemorrhages									
Rectal haemorrhage	1	0	0	0	SYS ORGAN CLASS TOTAL:	131			0
Non-site specific gastrointestinal haemorrhage									
Haematemesis	3	0	0	0	General disorders and administration site condi	⊥tions			
Colitis (excl infective)		_	_	_	Body temperature perception			_	_
Colitis ulcerative	1	0	0	0	Chills	1	0	0	0
Gastritis (excl infective)	_	_	_	_	Feeling hot	1	0	0	0
Gastritis	2	0	0	0	Febrile disorders			_	
Diarrhoea (excl infective)	1.0	_	•	•	Pyrexia	2	0	0	0
Diarrhoea	19	0	0	0	Death and sudden death	4	4	0	0
Gastrointestinal atonic and hypomotility disor	aers i	U NEC	0	0	Sudden death	4	4	U	0
Constipation	6	U	0	0	Asthenic conditions	9	0	0	0
Gastrointestinal dyskinetic disorders Change of bowel habit	1	0	0	0	Asthenia	9	0	0	0
Gastrointestinal spastic and hypermotility dis	_	•	U	U	Fatigue Malaise	4	0	0	0
Frequent bowel movements	orders 1		0	0	Gait disturbances	4	U	U	U
Dyspeptic signs and symptoms	1	U	U	U	Gait disturbance	3	0	0	0
Dyspepsia	13	0	0	0	General signs and symptoms NEC	3	U	U	U
Faeces abnormal	13	U	U	U	Chest discomfort	3	0	0	0
Loose stools	4	0	0	0	Condition aggravated	3	0	0	0
Flatulence, bloating and distension	-	U	O	U	Feeling abnormal	5	0	0	0
Abdominal distension	1	0	0	0	Influenza like illness	1	0	0	0
Flatulence	4	0	0	0	Oedema NEC	_	J	J	J
Gastrointestinal and abdominal pains (excl ora					Oedema peripheral	11	0	0	0
Abdominal pain	8	0	0	0	Pitting oedema	1	Ö	Ö	Ö
Abdominal pain lower	9	0	Ō	0	Pain and discomfort NEC				
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SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME	SINGLE MULTI CONST CONST TOT FTL TOT FTL		T	SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME	SING CONST	Т	MULTI CONST TOT FTL		
Chest pain	8	0	0	0					
Pain	10	0	0	0	Injury, poisoning and procedural complications				
Pain exacerbated	2	0	Ö	0	Spinal fractures and dislocations				
Tenderness	2	0	0	0	Spinal compression fracture	1	0	0	0
Interactions	_	-	-	_	Maladministration and accidental exposure	_		-	
Drug interaction	9	0	0	0	Accidental exposure	1	0	0	0
Drug interaction inhibition	3	0	0	0	Medication error	1	0	0	0
Drug interaction potentiation	4	0	0	0	Non-site specific injuries NEC				
Therapeutic and nontherapeutic responses					Contusion	2	0	0	0
Drug ineffective	4	0	0	0	Fall	3	0	0	0
Drug withdrawal syndrome	4	0	0	0	Site specific injuries NEC				
Unexpected therapeutic drug effect	13	0	0	0	Tooth injury	1	0	0	0
					Skin injuries NEC				
SYS ORGAN CLASS TOTAL:	116	4	0	0	Blister	1	0	0	0
					Conditions caused by cold			_	_
Hepatobiliary disorders					Chillblains	1	0	0	0
Cholestasis and jaundice	_	_	_		Non-site specific procedural complications	_			_
Jaundice	5	0	0	0	Post procedural haemorrhage	1	0	0	0
Jaundice cholestatic	3	0	0	0	GVG ODGAN GLAGG HOEAL.	10			
Hepatic and hepatobiliary disorders NEC	1	0	0	0	SYS ORGAN CLASS TOTAL:	12	0	0	0
Liver disorder Hepatic failure and associated disorders	1	0	0	0	Turnations				
Hepatic failure and associated disorders	2	0	0	0	Investigations Vascular tests NEC (incl blood pressure)				
Hepatocellular damage and hepatitis NEC	4	U	U	U	Blood pressure increased	4	0	0	0
Hepatitis	3	0	0	0	Reproductive hormone analyses	4	U	U	U
nepacicis					Blood testosterone decreased	2	0	0	0
SYS ORGAN CLASS TOTAL:	14	0	0	0	Blood testosterone increased	1	0	0	0
SIS ORGIN CHIES TOTTE					Coagulation and bleeding analyses	-	O	Ü	Ü
Immune system disorders					International normalised ratio increased	6	0	0	0
Allergic conditions NEC					Prothrombin time shortened	1	Ō	0	Ö
Hypersensitivity	1	0	0	0	Liver function analyses				
-					Blood bilirubin increased	1	0	0	0
SYS ORGAN CLASS TOTAL:	1	0	0	0	Gamma-glutamyltransferase increased	2	0	0	0
					Hepatic enzyme increased	1	0	0	0
Infections and infestations					Liver function test abnormal	7	0	0	0
Bacterial infections NEC					Cholesterol analyses				
Gangrene	1	0	0	0	Blood cholesterol increased	1	0	0	0
Breast infections					Physical examination procedures				
Mastitis	3	0	0	0	Body temperature increased	1	0	0	0
Dental and oral soft tissue infections	-	•			Weight decreased	2	0	0	0
Sialoadenitis	1	0	0	0	Weight increased	8	0	0	0
Eye and eyelid infections	1	0	0	0	Renal function analyses	-1	0	0	0
Eye infection	1	0	0	0	Blood creatinine increased Fertility analyses	1	0	U	0
Infections NEC	1	0	0	0	Semen abnormal	3	0	0	0
Infection in an immunocompromised host Male reproductive tract infections	1	U	U	U	Mineral and electrolyte analyses	3	U	U	U
Orchitis	4	Λ	0	0	Blood potassium increased	1	0	0	0
Upper respiratory tract infections	7	U	O	U	Blood sodium decreased	1	0	0	0
Sinusitis	1	0	0	0	2100a boaram accreabed				
Urinary tract infections	_	J	J	J	SYS ORGAN CLASS TOTAL:	43	0	0	0
Urinary tract infection	1	0	0	0					
•					Metabolism and nutrition disorders				
SYS ORGAN CLASS TOTAL:	13	0	0	0	Appetite disorders				

SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME	SING: CONS' TOT	Т	MULTI CONSI TOT F		SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME	SING CONS TOT	Т	MULT: CONST	Г
Anorexia	4	0	0	0	Breast cancer	5	0	0	0
Decreased appetite	2	0	0	0	Pancreatic neoplasms malignant (excl islet cel	l and	car	cino	id)
Sodium imbalance					Pancreatic carcinoma	2			0
Hyponatraemia	1	0	0	0	Hepatic neoplasms malignant				
Diabetes mellitus (incl subtypes)					Hepatic cancer metastatic	1	1	0	0
Diabetes mellitus	5	1	0	0	Hepatic neoplasm malignant	1	1	0	0
Diabetes mellitus non-insulin-dependent	1	0	0	0	Leukaemias chronic lymphocytic				
Purine metabolism disorders NEC					Chronic lymphocytic leukaemia	1	0	0	0
Gout	3	0	0	0	Lymphomas unspecified NEC				
					Lymphoma	1	0	0	0
SYS ORGAN CLASS TOTAL:			0	0	Metastases to specified sites			_	_
					Metastases to liver	1	0	0	0
Musculoskeletal and connective tissue disorders					Bladder neoplasms malignant	_			
Bone related signs and symptoms	_	_		_	Bladder cancer	1	0	0	0
Bone pain	1	0	0	0	Prostatic neoplasms malignant		•		•
Metabolic bone disorders	_	_		_	Prostate cancer	1	0	0	0
Osteoporosis	1	0	0	0	Reproductive neoplasms male unspecified malign		•		•
Connective tissue disorders (excl LE)	2	_	0	0	Testicular neoplasm	1	0	0	0
Polymyalgia rheumatica	3	0	0	0	Testicular neoplasms malignant	-	0	0	0
Pathological fractures and complications	-1	0	0	0	Testis cancer	1	0	0	0
Osteoporotic fracture	1	0	0	0	Non-small cell neoplasms malignant of the resp	oirato: 1			
Arthropathies NEC	1	0	0	0	Lung adenocarcinoma Respiratory tract and pleural neoplasms malign				0
Arthritis	Τ.	U	U	U		iant e		Cype	unspe 0
Joint related signs and symptoms Arthralgia	7	0	0	0	Lung neoplasm malignant Soft tissue neoplasms benign NEC	۷	U	U	U
Joint effusion	1	0	0	0	Lipoma	1	0	0	0
Joint stiffness	1	0	0	0	птроша				-
Joint swelling	1	0	0	0	SYS ORGAN CLASS TOTAL:			0	
Osteoarthropathies	_	U	U	U	SIS ONGAN CHASS TOTAL:				
Localised osteoarthritis	1	0	0	0	Nervous system disorders				
Rheumatoid arthropathies	_	Ü	Ü	Ü	Central nervous system haemorrhages and cerebi	°OVASC	ular	acc.	idents
Rheumatoid arthritis	1	0	0	0	Cerebral haemorrhage	1	1	0	0
Muscle pains	_	Ū	ŭ	ŭ	Cerebrovascular accident	8	1	Ö	Ö
Myalqia	8	0	0	0	Transient cerebrovascular events	Ü	_	ŭ	Ü
Muscle related signs and symptoms NEC	-	-		-	Transient ischaemic attack	2	0	0	0
Muscle cramp	4	0	0	0	Olfactory nerve disorders				
Myopathies					Anosmia	1	0	0	0
Myopathy	3	0	0	0	Parosmia	1	0	0	0
Musculoskeletal and connective tissue signs an	d sym	ptor	ns NEC	1	Trigeminal disorders				
Back pain	3	0	0	0	Trigeminal neuralgia	1	0	0	0
Musculoskeletal stiffness	1	0	0	0	Headaches NEC				
Neck pain	1	0	0	0	Headache	32	0	0	0
Pain in extremity	4	0	0	0	Migraine headaches				
Sensation of heaviness	1	0	0	0	Migraine	3	0	0	0
Soft tissue disorders NEC					Increased intracranial pressure disorders				
Groin pain	2	0	0	0	Benign intracranial hypertension	2	0	0	0
Tendon disorders					Dementia (excl Alzheimer's type)				
Tendonitis	1	0	0	0	Dementia	1	0	0	0
					Memory loss (excl dementia)				
SYS ORGAN CLASS TOTAL:	47	-	0	0	Amnesia	4	0	0	0
					Global amnesia	1	0	0	0
Neoplasms benign, malignant and unspecified (in	cl cy	sts	and p	oTAb	Memory impairment	2	0	0	0
Breast and nipple neoplasms malignant					Mental impairment (excl dementia and memory lo)SS)			

SYSTEM ORGAN CLASS HIGH LEVEL TERM		SINGLE MULTI CONST CONST			SYSTEM ORGAN CLASS HIGH LEVEL TERM	SINGLE CONST		MULTI CONSI		
REACTION NAME		FTL TOT FTL		PT.	REACTION NAME			TOT E		
113113113111111111111111111111111111111	101				_	1.2.1.01.1011 1.11.12				
Disturbance in attention	5	0	(0	0	SYS ORGAN CLASS TOTAL:	160	2	0	0
Dyskinesias and movement disorders NEC										
Psychomotor hyperactivity	1	0	(0	0	Pregnancy, puerperium and perinatal conditions				
Dystonias						Abortion related conditions and complications				
Dystonia	1	0	(0	Ω	Abnormal product of conception	1	0	0	0
Paralysis and paresis (excl congenital and cr					·	Abortions spontaneous	_	Ū	Ū	Ū
Hemiparesis	1		VC)		0	Abortion spontaneous	4	0	0	0
Hemiplegia	1	•	•	0	0	Stillbirth and foetal death	-	U	U	U
Paralysis	1	-		0	0	Stillbirth	1	1	0	0
	1	U		J	U		Т	Т	U	U
Parkinson's disease and parkinsonism	1	0	. ,	^	0	Foetal complications NEC	2	0	0	0
Parkinson's disease	1	0	(0	0	Foetal distress syndrome	2	U	0	0
Tremor (excl congenital)	_	_		_	_	Labour onset and length abnormalities	_	_	_	_
Tremor	5	0	(0	0	Premature labour	1	0	0	0
Cerebellar coordination and balance disturban						Premature rupture of membranes	1	0	0	0
Balance disorder	6	0		0	0	Hypertension associated disorders of pregnancy				
Coordination abnormal	2	0	(0	0	Pre-eclampsia	1	0	0	0
Disturbances in consciousness NEC						Gestational age and weight conditions				
Lethargy	10	0	(0	0	Large for dates baby	1	0	0	0
Sedation	1	0	(0	0	Placental abnormalities (excl neoplasms)				
Somnolence	3	0	(0	0	Chorioamnionitis	1	0	0	0
Syncope	1	0	(0	0	Placental disorder	1	0	0	0
Neurological signs and symptoms NEC						Normal pregnancy, labour and delivery				
Ageusia	2	0		0	0	Pregnancy	1	0	0	0
Dizziness	24	0		0	0	rregianey		-		
Dizziness postural	1	•	,	0	0	SYS ORGAN CLASS TOTAL:	15	1	0	0
Dysgeusia	3	•	•	0	0	SIS ONGAN CHASS ICIAL.				
Myoclonus	1			0	0	Psychiatric disorders				
Paraesthesias and dysaesthesias	1	U	,	J	U					
Burning sensation	10	0		0	0	Anxiety symptoms Agitation	1	0	0	0
	10			0	0		3	0	0	0
Burning sensation mucosal				0	0	Anxiety	3	U	U	U
Formication	1				-	Panic symptoms	-1	0	0	0
Hyperaesthesia	1	•	•	0	0	Panic attack	1	0	0	0
Hypoaesthesia	1		,	0	0	Stereotypies and automatisms	-		•	•
Paraesthesia	5	0	(0	0	Bruxism	1	0	0	0
Speech and language abnormalities				_	_	Confusion and disorientation	_	_	_	_
Dysphasia	1	0	(0	0	Confusional state	8	0	0	0
Neurologic visual problems NEC						Disorientation	1	0	0	0
Visual field defect	1	0	(0	0	Depressive disorders				
Muscle tone abnormal						Depression	19	0	0	0
Hypertonia	1	0	(0	0	Mood alterations with depressive symptoms				
Acute polyneuropathies						Decreased interest	1	0	0	0
Guillain-Barre syndrome	1	0	(0	0	Perception disturbances				
Peripheral neuropathies NEC						Derealisation	1	0	0	0
Neuropathy peripheral	2	0	(0	0	Hallucination	1	0	0	0
Generalised tonic-clonic seizures						Hallucination, olfactory	1	0	0	0
Grand mal convulsion	3	0	(0	0	Hallucination, visual	2	0	0	0
Partial complex seizures						Thinking disturbances				
Temporal lobe epilepsy	1	0	(0	0	Thinking abnormal	1	0	0	0
Seizures and seizure disorders NEC	_	_		-	-	Affect alterations NEC	_	-	-	-
Epilepsy	1	0	(0	0	Mood altered	2	0	0	0
Cervical spinal cord and nerve root disorders	_	J	,	~	J	Emotional and mood disturbances NEC	ے	J	J	J
Cervical myelopathy		0	(0	0	Emotional distress	1	0	0	0
cervicar mycropacity						Fluctuating mood symptoms	_	U	U	U
	_				_	riactaating mood symptoms				

SYSTEM ORGAN CLASS HIGH LEVEL TERM	SING		MULT CONS		SYSTEM ORGAN CLASS HIGH LEVEL TERM	SING:		MULT:	
REACTION NAME	TOT	FTL	TOT	FTL	REACTION NAME	TOT 1	FTL	TOT :	FTL
Mood awings	1	0	0	0					
Mood swings Behaviour and socialisation disturbances	1	U	U	U	SYS ORGAN CLASS TOTAL:	70	0	0	0
Irritability	3	0	0	0	SIS ORGAN CHASS TOTAL!				
Abnormal behaviour NEC	3	O	Ŭ	Ü	Reproductive system and breast disorders				
Abnormal behaviour	1	0	0	0	Benign and malignant breast neoplasms				
Psychiatric symptoms NEC					Breast hyperplasia	1	0	0	0
Psychiatric symptom	1	0	0	0	Breast disorders NEC				
Psychotic disorder NEC					Breast mass	1	0	0	0
Psychotic disorder	1	0	0	0	Gynaecomastia	72	0	0	0
Orgasmic disorders and disturbances	_		_	_	Hypertrophy breast	6	0	0	0
Orgasm abnormal	3	0	0	0	Nipple disorder	1	0	0	0
Sexual desire disorders	1.0	0	0	0	Breast signs and symptoms	1	0	^	0
Libido decreased	19 2	0	0	0	Breast engorgement	1 6	0	0	0
Libido increased Loss of libido	10	0	0	0	Breast pain Breast tenderness	8	0	0	0
Disturbances in initiating and maintaining sl		U	U	U	Nipple pain	11	0	0	0
Insomnia	.eep 1	0	0	0	Testicular and epididymal infections and infla		-	U	U
Parasomnias		U	U	U	Epididymitis	1	0115	0	0
Abnormal dreams	3	0	0	0	Penile disorders NEC (excl erection and ejacul	ation)	O	O
Nightmare	5	0	0	0	Penile pain	3	0	0	0
Sleep disorders NEC					Penile size reduced	3	Ō	Ō	Ō
Sleep disorder	1	0	0	0	Penile swelling	1	0	0	0
Suicidal and self-injurious behaviour					Penis disorder	4	0	0	0
Completed suicide	1	1		0	Peyronie's disease	10	0	0	0
Suicidal ideation	1	•	•	0	Scrotal disorders NEC				
					Scrotal irritation	3	0	0	0
SYS ORGAN CLASS TOTAL:	97		0	0	Scrotal oedema	3	0	0	0
					Scrotal pain	1	0	0	0
Renal and urinary disorders					Prostatic signs, symptoms and disorders NEC	-	0	0	0
Myoneurogenic bladder disorders	1	0	0	0	Prostatic disorder	1 2	0	0	0
Hypertonic bladder Nephritis NEC	Т	U	0	U	Prostatism Gender disorders	2	U	U	U
Nephritis NEC	1	0	0	0	Feminisation acquired	1	0	0	0
Renal failure and impairment		U	U	U	Reproductive tract disorders NEC (excl neoplas		U	U	U
Renal failure	1	0	0	0	Reproductive tract disorder	1	0	0	0
Bladder and urethral symptoms	_	O	O	O	Reproductive tract signs and symptoms NEC	_	O	O	O
Dysuria	16	0	0	0	Perineal pain	5	0	0	0
Enuresis	1	0	Ō	Ö	Erection and ejaculation conditions and disord	lers		_	-
Incontinence	3	0	0	0	Ejaculation disorder	7	0	0	0
Micturition disorder	1	0	0	0	Ejaculation failure	8	0	0	0
Micturition urgency	3	0	0	0	Erectile dysfunction	70	0	0	0
Pollakiuria	13	0	0	0	Painful erection	1	0	0	0
Strangury	1	0	0	0	Priapism	1	0	0	0
Urinary hesitation	5	0	0	0	Sexual function and fertility disorders NEC				
Urinary incontinence	4	0	0	0	Sexual dysfunction	2	0	0	0
Urinary retention	5	0	0	0	Spermatogenesis and semen disorders	_	0	0	0
Urine flow decreased	1	0	0	0	Haematospermia	3	0	0	0
Urinary abnormalities	1	0	0	0	Testicular and epididymal disorders NEC	1	0	0	0
Haematuria	4 1	0	0	0	Epididymal disorder Hydrocele	1 1	0	0	0
Urine abnormality Urinary tract signs and symptoms NEC	1	U	U	U	Testicular pain	11	0	0	0
Nocturia	8	0	0	0	Testicular pain Testicular swelling	5	0	0	0
Polyuria	1	0	0	0	Testicular and epididymal neoplasms	J	U	U	U
1 2 2 2 2 2 2	_	•	•	•					

SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME	CONS	ST	MUL' CON TOT		SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME	SING: CONS' TOT	Т (MULTI CONST FOT F	Г
Epididymal cyst	2	0		0	Dermatitis ascribed to specific agent				_
					Drug eruption	2	0	0	0
SYS ORGAN CLASS TOTAL:	258			0	Erythemas	4	0	0	0
D					Erythema	4	0	0	0
Respiratory, thoracic and mediastinal disorders					Rash erythematous	6	U	0	0
Bronchospasm and obstruction	0	0	0	0	Papulosquamous conditions	0	0	0	0
Asthma	2	0		0	Lichen planus	2 3	0	0	0
Chronic obstructive airways disease exacerbat	1 2	0	-	-	Psoriasis	3	U	U	U
Wheezing		•	-	-	Photosensitivity conditions	4	0	0	0
Lower respiratory tract inflammatory and immun Alveolitis	01091 1	0			Photosensitivity reaction Pruritus NEC	4	U	U	U
Alveolitis fibrosing	1	0		-	Pruritus Pruritus	10	0	0	0
Breathing abnormalities	1	U	U	U		4	0	0	0
Dyspnoea	12	1	0	0	Pruritus generalised Rash pruritic	6	0	0	0
Dysphoea exacerbated	1	0		-	Pustular conditions	O	U	U	U
Dysphoea exacerbated Dysphoea exertional	2	0	•	•	Rash follicular	1	0	0	0
	1	0	-	-	Rashes, eruptions and exanthems NEC		U	U	U
Hyperventilation Coughing and associated symptoms	1	U	U	U	Rash	12	0	0	0
Cought	7	0	0	0	Rash generalised	1	0	0	0
Lower respiratory tract signs and symptoms	,	U	U	U	Rash macular	4	0	0	0
Hiccups	2	0	0	0	Rash maculo-papular	1	0	0	0
Upper respiratory tract signs and symptoms	4	U	U	U	Rash vesicular	1	0	0	0
Dysphonia	1	0	0	0	Scalar conditions	_	U	U	U
Pharyngolaryngeal pain	1	0	-	-	Rash scaly	3	0	0	0
Rhinorrhoea	1	•	-	0	Pigmentation changes NEC	5	O	O	O
Sneezing	1	0	•	•	Pigmentation disorder	1	0	0	0
Nasal disorders NEC	_	U	O	O	Panniculitides	_	O	O	O
Epistaxis	2	0	0	0	Erythema nodosum	1	0	0	0
IPIS canib				-	Skin and subcutaneous tissue ulcerations	_	Ŭ	Ü	J
SYS ORGAN CLASS TOTAL:	38	1			Skin ulcer	1	0	0	0
					Skin and subcutaneous tissue bacterial infecti	_	Ü	Ü	Ü
Skin and subcutaneous tissue disorders					Intertrigo	4	0	0	0
Angioedemas					Acnes	_	-	-	•
Face oedema	1	0	0	0	Acne	2	0	0	0
Urticarias					Alopecias				
Dermographism	1	0	0	0	Alopecia	11	0	0	0
Urticaria	9	0	0	0	Apocrine and eccrine gland disorders				
Urticaria papular	1	0	0	0	Dyshidrosis	1	0	0	0
Ichthyoses					Hyperhidrosis	5	0	0	0
Ichthyosis acquired	1	0	0	0	Night sweats	4	0	0	0
Bullous conditions					Sweat gland disorder	1	0	0	0
Dermatitis bullous	2	0	0	0	Nail and nail bed conditions (excl infections	and i	nfes	tatio	ons)
Erythema multiforme	1	0	0	0	Nail disorder	2	0	0	0
Dermal and epidermal conditions NEC					Pilar disorders NEC				
Dry skin	1	0	0	0	Hair growth abnormal	8	0	0	0
Skin burning sensation	1	0	0	0	Purpura and related conditions				
Swelling face	6	0	0	0	Increased tendency to bruise	1	0	0	0
Dermatitis and eczema					Purpura	1	0	0	0
Dermatitis	2	0	0	0	Skin vasculitides				
Dermatitis allergic	2	0	0	0	Cutaneous vasculitis	1	0	0	0
Eczema	7	0	0	0	Leukocytoclastic vasculitis	1	0	0	0
Seborrhoeic dermatitis	1	0	0	0	Vasculitic rash	4	0	0	0
Skin irritation	2	0	0	0	Skin vasomotor conditions				

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SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME	CON	ST	CONS	TI ST FTL	SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME
Livedo reticularis	1	0	0	0	
SYS ORGAN CLASS TOTAL:	152	0	0	0	
Vascular disorders					
Aortic aneurysms and dissections					
Aortic aneurysm rupture	1	1	0	0	
Non-site specific necrosis and vascular	insufficie	ncy 1	NEC		
Atherosclerosis	1			0	
Peripheral vasoconstriction, necrosis as	nd vascular	insı	affic	ciency	
Poor peripheral circulation	1	0		0	
Raynaud's phenomenon	1	0	0	0	
Blood pressure disorders NEC					
Blood pressure inadequately controlled	1	0	0	0	
Circulatory collapse and shock					
Circulatory collapse	1	0	0	0	
Vascular hypotensive disorders					
Hypotension	1	0	0	0	
Peripheral embolism and thrombosis		_	_	_	
Deep vein thrombosis	10		0	0	
Thrombophlebitis	1		0	0	
Thrombophlebitis superficial	1	0	0	0	
Peripheral vascular disorders NEC	_	_	_	_	
Flushing	2		0	0	
Hot flush	3	0	0	0	
Accelerated and malignant hypertension	-	0	0	0	
Hypertensive crisis	1	0	0	0	
Vascular hypertensive disorders NEC	1	0	0	0	
Essential hypertension Hypertension	1 5	0	0	0	
Arterial inflammations	5	U	U	U	
Temporal arteritis	2	0	0	0	
Phlebitis NEC	2	U	U	U	
Phlebitis superficial	1	0	0	0	
Vasculitides NEC	_	O	O	O	
Vasculitis	2	0	0	0	
Vaboatioib					
SYS ORGAN CLASS TOTAL:	36	1	0	0	
TOTAL REACTIONS FOR DRUG:	134		5 (===		

TOTAL REPORTS: 916 TOTAL FATAL OUTCOME: 25

*** END OF REPORT ***