Drug Analysis Print
Drug name: FINASTERIDE

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Drug name:	FINASTERIDE	**Report type:**	Spontaneous
Report run date:	29-Apr-2008	**Report origin:**	UNITED KINGDOM
Data lock date:	28-Apr-2008 08:00:20 PM	**Route of admin:**	ALL
Period covered:	01-Jul-1963 to 28-Apr-2008	**Reporter type:**	ALL
Earliest reaction date:	01-Jan-1992	**Reaction:**	ALL
MedDRA version:	MedDRA 11.0	**Age group:**	ALL

Total number of reactions*:	1534	**Total number of ADR reports:**	1022	**Total number of fatal ADR reports:**	28

Products included in this print - Single active constituent products (PBGs):

PROPECIA

PROSCAR

*It is important to note that one report may contain one or more reactions.

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System Organ Class	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Blood disorders	18	1	0	0	18	1
Cardiac disorders	52	7	0	0	52	7
Congenital disorders	2	0	0	0	2	0
Ear disorders	14	0	0	0	14	0
Endocrine disorders	1	0	0	0	1	0
Eye disorders	21	0	0	0	21	0
Gastrointestinal disorders	152	1	0	0	152	1
General disorders	134	4	0	0	134	4
Hepatic disorders	15	0	0	0	15	0
Immune system disorders	2	0	0	0	2	0
Infections	15	0	0	0	15	0
Injuries	17	0	0	0	17	0
Investigations	51	0	0	0	51	0
Metabolic disorders	16	1	0	0	16	1
Muscle & tissue disorders	59	0	0	0	59	0
Neoplasms	25	7	0	0	25	7
Nervous system disorders	175	2	0	0	175	2
Pregnancy conditions	20	1	0	0	20	1
Psychiatric disorders	110	1	0	0	110	1
Renal & urinary disorders	84	0	0	0	84	0
Reproductive & breast disorders	298	0	0	0	298	0
Respiratory disorders	41	2	0	0	41	2
Skin disorders	173	0	0	0	173	0
Social circumstances	1	0	0	0	1	0
Vascular disorders	38	1	0	0	38	1

TOTAL NUMBER OF REACTIONS	**1534**	**28**	**0**	**0**	**1534**	**28**

TOTAL NUMBER OF FATAL ADR REPORTS*		**28**		**0**		**28***
TOTAL NUMBER OF ADR REPORTS*	**1022**		**0**		**1022***	

*This provides the number of individual reports and may be less than the sum of the single-active constituent and multi-active constituent columns. For example, if both a single- and multi-active constituent product are considered by the reporter to have a suspected causal relationship with the suspected reaction, then the same report will appear in both columns.

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Glossary/Abbreviations

ADR - Adverse Drug Reaction

Age group - lists which age groups are included in the Drug Analysis Print – either ALL, Adolescent, Adult, Child, Elderly, Infant or Neonate

Data lock date - shows data on the database at this specified date and time

HLT - High Level Term - see definition of MedDRA

MedDRA - this stands for **Med**ical **D**ictionary for **R**egulatory **A**ctivities, which is the internationally agreed list of terms used for Medicines Regulation. MedDRA groups related adverse drug reaction terms in a hierarchical structure whereby the *'preferred term' (PT)* (e.g. tunnel vision) is grouped under the broader heading the *'high level term' (HLT)* (e.g. visual field disorders). *'High level terms'* are contained within the *'system organ class' (SOC)* (e.g. eye disorders). The *'preferred term'* is the most specific term on the Drug Analysis Print, while the *'system organ class'* is the most general

Multi active constituent products - contain the drug constituent of interest plus one or more other drug constituents (e.g. co-codamol contains paracetamol and codeine)

NEC - appears in MedDRA and stands for Not Elsewhere Classified

NOS - appears in MedDRA and stands for Not Otherwise Specified

PBG - Product Brand Generic – this means drug brand name e.g. Amoxil is a PBG for the drug substance amoxicillin

Products included in this print - this is a list of the products for which at least one suspected Adverse Drug Reaction (ADR) report has been received that specifies that product as a 'suspected drug' (i.e. suspected causal association with the reaction). It does not provide an exhaustive list of the products which contain the named drug substance

PT - Preferred Term - see definition of MedDRA

Reaction - defines which ADRs are included in the Drug Analysis Print – either ALL, Serious or Non-Serious

Reporter type - lists the reporter types which are included in the Drug Analysis Print – either Patient, Health Professional or ALL (i.e. both)

Report run date - the date the Drug Analysis Print was produced

Route of admin - lists the route of administration of the suspect drug for which reports are included in the Drug Analysis Print, e.g. ORAL only includes reports where the suspect drug was specified as having been taken by the oral route, or ALL which includes all routes of administration

Spontaneous - suspected ADR reports sent in to the Yellow Card Scheme are called spontaneous reports

Single active constituent products - contain only the drug substance of interest

System Organ Class (SOC) - this is the highest level in MedDRA which groups together reactions that affect similar systems/organs in the body

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Blood disorders						
Anaemias NEC						
Anaemia	1	0	0	0	1	0
Lymphatic system disorders NEC						
Hilar lymphadenopathy	1	0	0	0	1	0
Marrow depression and hypoplastic anaemias						
Aplastic anaemia	2	0	0	0	2	0
Neutropenias						
Neutropenia	1	0	0	0	1	0
Thrombocytopenias						
Idiopathic thrombocytopenic purpura	2	0	0	0	2	0
Thrombocytopenia	10	0	0	0	10	0
Thrombocytopenic purpura	1	1	0	0	1	1
Blood disorders SOC TOTAL	**18**	**1**	**0**	**0**	**18**	**1**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Cardiac disorders						
Cardiac disorders NEC						
Cardiac disorder	1	0	0	0	1	0
Cardiac signs and symptoms NEC						
Palpitations	6	0	0	0	6	0
Cardiomyopathies						
Cardiomyopathy	1	0	0	0	1	0
Coronary artery disorders NEC						
Coronary artery insufficiency	1	0	0	0	1	0
Coronary artery thrombosis	3	2	0	0	3	2
Heart failures NEC						
Cardiac failure	4	1	0	0	4	1
Ischaemic coronary artery disorders						
Acute myocardial infarction	2	2	0	0	2	2
Angina pectoris	9	0	0	0	9	0
Angina unstable	2	0	0	0	2	0
Myocardial infarction	10	0	0	0	10	0
Left ventricular failures						
Left ventricular failure	3	2	0	0	3	2
Rate and rhythm disorders NEC						
Tachycardia	2	0	0	0	2	0
Supraventricular arrhythmias						
Atrial fibrillation	4	0	0	0	4	0
Ventricular arrhythmias and cardiac arrest						
Cardiac arrest	2	0	0	0	2	0
Ventricular fibrillation	1	0	0	0	1	0
Ventricular tachycardia	1	0	0	0	1	0
Cardiac disorders SOC TOTAL	**52**	**7**	**0**	**0**	**52**	**7**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Congenital disorders						
Male reproductive tract disorders congenital						
Hydrocele	1	0	0	0	1	0
Musculoskeletal disorders congenital NEC						
Congenital musculoskeletal anomaly	1	0	0	0	1	0
Congenital disorders SOC TOTAL	**2**	**0**	**0**	**0**	**2**	**0**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Ear disorders						
Ear disorders NEC						
Ear pain	1	0	0	0	1	0
Hearing losses						
Conductive deafness	1	0	0	0	1	0
Inner ear disorders NEC						
Vestibular disorder	1	0	0	0	1	0
Inner ear signs and symptoms						
Tinnitus	5	0	0	0	5	0
Vertigo	6	0	0	0	6	0
Ear disorders SOC TOTAL	**14**	**0**	**0**	**0**	**14**	**0**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Endocrine disorders						
Adrenal cortical hypofunctions						
Addison's disease	1	0	0	0	1	0
Endocrine disorders SOC TOTAL	**1**	**0**	**0**	**0**	**1**	**0**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Eye disorders						
Blindness (excl colour blindness)						
Amaurosis fugax	2	0	0	0	2	0
Blindness transient	1	0	0	0	1	0
Conjunctival and corneal bleeding and vascular disorders						
Conjunctival haemorrhage	2	0	0	0	2	0
Corneal structural change, deposit and degeneration						
Corneal opacity	1	0	0	0	1	0
Lid, lash and lacrimal infections, irritations and inflammations						
Eyelid oedema	1	0	0	0	1	0
Ocular infections, inflammations and associated manifestations						
Eye irritation	1	0	0	0	1	0
Ocular sensation disorders						
Photophobia	1	0	0	0	1	0
Partial vision loss						
Visual acuity reduced	3	0	0	0	3	0
Retinal bleeding and vascular disorders (excl retinopathy)						
Retinal haemorrhage	1	0	0	0	1	0
Retinopathies NEC						
Retinopathy	1	0	0	0	1	0
Visual disorders NEC						
Vision blurred	5	0	0	0	5	0
Visual disturbance	2	0	0	0	2	0
Eye disorders SOC TOTAL	**21**	**0**	**0**	**0**	**21**	**0**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Gastrointestinal disorders						
Acute and chronic pancreatitis						
Pancreatitis	1	0	0	0	1	0
Anal and rectal disorders NEC						
Anal fissure	1	0	0	0	1	0
Anorectal disorder	2	0	0	0	2	0
Anal and rectal pains						
Proctalgia	5	0	0	0	5	0
Anal and rectal signs and symptoms						
Anal pruritus	1	0	0	0	1	0
Rectal discharge	1	0	0	0	1	0
Colitis (excl infective)						
Colitis ulcerative	1	0	0	0	1	0
Dental disorders NEC						
Teeth brittle	1	0	0	0	1	0
Dental pain and sensation disorders						
Sensitivity of teeth	1	0	0	0	1	0
Diaphragmatic hernias						
Hiatus hernia	1	0	0	0	1	0
Diarrhoea (excl infective)						
Diarrhoea	25	0	0	0	25	0
Dyspeptic signs and symptoms						
Dyspepsia	14	0	0	0	14	0
Flatulence, bloating and distension						
Abdominal distension	1	0	0	0	1	0
Flatulence	5	0	0	0	5	0
Gastric ulcers and perforation						
Gastric ulcer	2	1	0	0	2	1
Gastric ulcer perforation	1	0	0	0	1	0
Gastritis (excl infective)						
Gastritis	2	0	0	0	2	0
Gastrointestinal and abdominal pains (excl oral and throat)						
Abdominal pain	8	0	0	0	8	0
Abdominal pain lower	9	0	0	0	9	0
Abdominal pain upper	4	0	0	0	4	0
Gastrointestinal atonic and hypomotility disorders NEC						
Constipation	7	0	0	0	7	0
Gastrointestinal dyskinetic disorders						
Change of bowel habit	1	0	0	0	1	0
Gastrointestinal signs and symptoms NEC						
Abdominal discomfort	2	0	0	0	2	0
Dysphagia	2	0	0	0	2	0

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name Gastrointestinal disorders cont'd	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Faecal incontinence	1	0	0	0	1	0
Gastrointestinal spastic and hypermotility disorders						
Defaecation urgency	1	0	0	0	1	0
Frequent bowel movements	1	0	0	0	1	0
Gastrointestinal stenosis and obstruction NEC						
Intestinal obstruction	1	0	0	0	1	0
Gingival disorders NEC						
Gingival hypoplasia	1	0	0	0	1	0
Inguinal hernias						
Inguinal hernia	2	0	0	0	2	0
Intestinal haemorrhages						
Rectal haemorrhage	1	0	0	0	1	0
Nausea and vomiting symptoms						
Nausea	15	0	0	0	15	0
Vomiting	6	0	0	0	6	0
Non-site specific gastrointestinal haemorrhages						
Haematemesis	3	0	0	0	3	0
Oesophageal ulcers and perforation						
Oesophageal ulcer	1	0	0	0	1	0
Oral dryness and saliva altered						
Dry mouth	2	0	0	0	2	0
Lip dry	1	0	0	0	1	0
Oral soft tissue disorders NEC						
Chapped lips	1	0	0	0	1	0
Lip oedema	1	0	0	0	1	0
Lip swelling	7	0	0	0	7	0
Oral soft tissue haemorrhages						
Mouth haemorrhage	1	0	0	0	1	0
Oral soft tissue pain and paraesthesia						
Lip pain	1	0	0	0	1	0
Oral soft tissue swelling and oedema						
Oedema mouth	1	0	0	0	1	0
Salivary gland enlargements						
Parotid gland enlargement	2	0	0	0	2	0
Stomatitis and ulceration						
Aphthous stomatitis	1	0	0	0	1	0
Mouth ulceration	1	0	0	0	1	0
Stomatitis	1	0	0	0	1	0
Umbilical hernias						
Umbilical hernia	1	0	0	0	1	0
Gastrointestinal disorders SOC TOTAL	**152**	**1**	**0**	**0**	**152**	**1**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
General disorders						
Asthenic conditions						
Asthenia	9	0	0	0	9	0
Fatigue	11	0	0	0	11	0
Malaise	4	0	0	0	4	0
Body temperature perception						
Chills	1	0	0	0	1	0
Feeling hot	3	0	0	0	3	0
Death and sudden death						
Sudden death	4	4	0	0	4	4
Febrile disorders						
Pyrexia	2	0	0	0	2	0
Gait disturbances						
Gait disturbance	3	0	0	0	3	0
General signs and symptoms NEC						
Chest discomfort	3	0	0	0	3	0
Condition aggravated	4	0	0	0	4	0
Feeling abnormal	5	0	0	0	5	0
Influenza like illness	1	0	0	0	1	0
Irritability	3	0	0	0	3	0
Local swelling	1	0	0	0	1	0
Swelling	1	0	0	0	1	0
Interactions						
Drug interaction	11	0	0	0	11	0
Inhibitory drug interaction	3	0	0	0	3	0
Potentiating drug interaction	4	0	0	0	4	0
Oedema NEC						
Oedema peripheral	13	0	0	0	13	0
Pitting oedema	1	0	0	0	1	0
Pain and discomfort NEC						
Chest pain	8	0	0	0	8	0
Pain	16	0	0	0	16	0
Tenderness	2	0	0	0	2	0
Therapeutic and nontherapeutic responses						
Adverse drug reaction	1	0	0	0	1	0
Adverse event	1	0	0	0	1	0
Drug ineffective	4	0	0	0	4	0
Therapeutic response unexpected	14	0	0	0	14	0
Trophic disorders						
Atrophy	1	0	0	0	1	0
General disorders SOC TOTAL	**134**	**4**	**0**	**0**	**134**	**4**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Hepatic disorders						
Cholestasis and jaundice						
Jaundice	5	0	0	0	5	0
Jaundice cholestatic	3	0	0	0	3	0
Hepatic and hepatobiliary disorders NEC						
Liver disorder	1	0	0	0	1	0
Hepatic failure and associated disorders						
Hepatic failure	3	0	0	0	3	0
Hepatocellular damage and hepatitis NEC						
Hepatitis	3	0	0	0	3	0
Hepatic disorders SOC TOTAL	**15**	**0**	**0**	**0**	**15**	**0**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Immune system disorders						
Allergic conditions NEC						
Hypersensitivity	2	0	0	0	2	0
Immune system disorders SOC TOTAL	**2**	**0**	**0**	**0**	**2**	**0**

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Drug Analysis Print
Drug name: FINASTERIDE

Drug name:	FINASTERIDE	**Report type:**	Spontaneous
Report run date:	29-Apr-2008	**Report origin:**	UNITED KINGDOM
Data lock date:	28-Apr-2008 08:00:20 PM	**Route of admin:**	ALL
Period covered:	01-Jul-1963 to 28-Apr-2008	**Reporter type:**	ALL
Earliest reaction date:	01-Jan-1992	**Reaction:**	ALL
MedDRA version:	MedDRA 11.0	**Age group:**	ALL

	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Infections						
Bacterial infections NEC						
Gangrene	1	0	0	0	1	0
Breast infections						
Mastitis	3	0	0	0	3	0
Dental and oral soft tissue infections						
Sialoadenitis	1	0	0	0	1	0
Eye and eyelid infections						
Eye infection	1	0	0	0	1	0
Infections NEC						
Infection susceptibility increased	1	0	0	0	1	0
Lower respiratory tract and lung infections						
Lower respiratory tract infection	1	0	0	0	1	0
Male reproductive tract infections						
Orchitis	4	0	0	0	4	0
Skin structures and soft tissue infections						
Eczema infected	1	0	0	0	1	0
Upper respiratory tract infections						
Sinusitis	1	0	0	0	1	0
Urinary tract infections						
Urinary tract infection	1	0	0	0	1	0
Infections SOC TOTAL	**15**	**0**	**0**	**0**	**15**	**0**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Injuries						
Conditions caused by cold						
Chillblains	1	0	0	0	1	0
Eye and ear procedural complications						
Floppy iris syndrome	3	0	0	0	3	0
Maladministrations						
Drug administration error	1	0	0	0	1	0
Medication errors due to accidental exposures						
Accidental exposure	1	0	0	0	1	0
Non-site specific injuries NEC						
Fall	3	0	0	0	3	0
Non-site specific procedural complications						
Post procedural haemorrhage	1	0	0	0	1	0
Pregnancy related accidental exposures and injuries						
Drug exposure during pregnancy	1	0	0	0	1	0
Transmission of drug via semen	2	0	0	0	2	0
Site specific injuries NEC						
Tooth injury	1	0	0	0	1	0
Skin injuries NEC						
Contusion	2	0	0	0	2	0
Spinal fractures and dislocations						
Spinal compression fracture	1	0	0	0	1	0
Injuries SOC TOTAL	**17**	**0**	**0**	**0**	**17**	**0**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Investigations						
Cholesterol analyses						
Blood cholesterol increased	1	0	0	0	1	0
Coagulation and bleeding analyses						
International normalised ratio increased	6	0	0	0	6	0
Prothrombin time shortened	1	0	0	0	1	0
Fertility analyses						
Semen abnormal	3	0	0	0	3	0
Semen viscosity decreased	1	0	0	0	1	0
Semen viscosity increased	1	0	0	0	1	0
Liver function analyses						
Alanine aminotransferase increased	1	0	0	0	1	0
Blood bilirubin increased	1	0	0	0	1	0
Gamma-glutamyltransferase increased	3	0	0	0	3	0
Hepatic enzyme increased	2	0	0	0	2	0
Liver function test abnormal	8	0	0	0	8	0
Mineral and electrolyte analyses						
Blood potassium increased	1	0	0	0	1	0
Blood sodium decreased	1	0	0	0	1	0
Physical examination procedures						
Body temperature decreased	1	0	0	0	1	0
Body temperature increased	1	0	0	0	1	0
Weight decreased	3	0	0	0	3	0
Weight increased	8	0	0	0	8	0
Renal function analyses						
Blood creatinine increased	1	0	0	0	1	0
Reproductive hormone analyses						
Blood testosterone decreased	2	0	0	0	2	0
Blood testosterone increased	1	0	0	0	1	0
Vascular tests NEC (incl blood pressure)						
Blood pressure increased	4	0	0	0	4	0
Investigations SOC TOTAL	**51**	**0**	**0**	**0**	**51**	**0**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Metabolic disorders						
Appetite disorders						
Anorexia	4	0	0	0	4	0
Decreased appetite	2	0	0	0	2	0
Diabetes mellitus (incl subtypes)						
Diabetes mellitus	5	1	0	0	5	1
Type 2 diabetes mellitus	1	0	0	0	1	0
Purine metabolism disorders NEC						
Gout	3	0	0	0	3	0
Sodium imbalance						
Hyponatraemia	1	0	0	0	1	0
Metabolic disorders SOC TOTAL	**16**	**1**	**0**	**0**	**16**	**1**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Muscle & tissue disorders						
Arthropathies NEC						
Arthritis	2	0	0	0	2	0
Bone related signs and symptoms						
Bone pain	1	0	0	0	1	0
Metatarsalgia	1	0	0	0	1	0
Connective tissue disorders (excl LE)						
Polymyalgia rheumatica	3	0	0	0	3	0
Joint related signs and symptoms						
Arthralgia	7	0	0	0	7	0
Joint effusion	1	0	0	0	1	0
Joint stiffness	1	0	0	0	1	0
Joint swelling	1	0	0	0	1	0
Metabolic bone disorders						
Osteoporosis	1	0	0	0	1	0
Muscle pains						
Myalgia	9	0	0	0	9	0
Muscle related signs and symptoms NEC						
Muscle atrophy	1	0	0	0	1	0
Muscle spasms	5	0	0	0	5	0
Muscle weakness conditions						
Muscular weakness	1	0	0	0	1	0
Musculoskeletal and connective tissue signs and symptoms NEC						
Back pain	4	0	0	0	4	0
Musculoskeletal discomfort	1	0	0	0	1	0
Musculoskeletal pain	1	0	0	0	1	0
Musculoskeletal stiffness	2	0	0	0	2	0
Neck pain	1	0	0	0	1	0
Pain in extremity	5	0	0	0	5	0
Sensation of heaviness	1	0	0	0	1	0
Myopathies						
Myopathy	3	0	0	0	3	0
Osteoarthropathies						
Osteoarthritis	1	0	0	0	1	0
Pathological fractures and complications						
Osteoporotic fracture	1	0	0	0	1	0
Rheumatoid arthropathies						
Rheumatoid arthritis	1	0	0	0	1	0
Soft tissue disorders NEC						
Groin pain	3	0	0	0	3	0
Tendon disorders						
Tendonitis	1	0	0	0	1	0

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MedDRA version:	MedDRA 11.0	**Age group:**	ALL

	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name Muscle & tissue disorders cont'd	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Muscle & tissue disorders SOC TOTAL	**59**	**0**	**0**	**0**	**59**	**0**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Neoplasms						
Bladder neoplasms malignant						
Bladder cancer	1	0	0	0	1	0
Breast and nipple neoplasms malignant						
Breast cancer	5	0	0	0	5	0
Gastric neoplasms malignant						
Gastric cancer	1	1	0	0	1	1
Hepatic neoplasms malignant						
Hepatic cancer metastatic	1	1	0	0	1	1
Hepatic neoplasm malignant	1	1	0	0	1	1
Leukaemias chronic lymphocytic						
Chronic lymphocytic leukaemia	1	0	0	0	1	0
Lymphomas unspecified NEC						
Lymphoma	1	0	0	0	1	0
Metastases to specified sites						
Metastases to liver	2	1	0	0	2	1
Non-small cell neoplasms malignant of the respiratory tract cell type specified						
Lung adenocarcinoma	1	1	0	0	1	1
Pancreatic neoplasms malignant (excl islet cell and carcinoid)						
Pancreatic carcinoma	3	2	0	0	3	2
Prostatic neoplasms malignant						
Prostate cancer	3	0	0	0	3	0
Reproductive neoplasms male unspecified malignancy						
Testicular neoplasm	1	0	0	0	1	0
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC						
Lung neoplasm malignant	2	0	0	0	2	0
Soft tissue neoplasms benign NEC						
Lipoma	1	0	0	0	1	0
Testicular neoplasms malignant						
Testis cancer	1	0	0	0	1	0
Neoplasms SOC TOTAL	**25**	**7**	**0**	**0**	**25**	**7**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Nervous system disorders						
Acute polyneuropathies						
Guillain-Barre syndrome	1	0	0	0	1	0
Central nervous system haemorrhages and cerebrovascular accidents						
Cerebral haemorrhage	1	1	0	0	1	1
Cerebrovascular accident	8	1	0	0	8	1
Cerebellar coordination and balance disturbances						
Balance disorder	6	0	0	0	6	0
Coordination abnormal	2	0	0	0	2	0
Cervical spinal cord and nerve root disorders						
Cervical myelopathy	1	0	0	0	1	0
Dementia (excl Alzheimer's type)						
Dementia	1	0	0	0	1	0
Disturbances in consciousness NEC						
Lethargy	10	0	0	0	10	0
Sedation	1	0	0	0	1	0
Somnolence	4	0	0	0	4	0
Syncope	2	0	0	0	2	0
Dyskinesias and movement disorders NEC						
Psychomotor hyperactivity	1	0	0	0	1	0
Dystonias						
Dystonia	1	0	0	0	1	0
Generalised tonic-clonic seizures						
Grand mal convulsion	3	0	0	0	3	0
Headaches NEC						
Headache	34	0	0	0	34	0
Increased intracranial pressure disorders						
Benign intracranial hypertension	2	0	0	0	2	0
Memory loss (excl dementia)						
Amnesia	5	0	0	0	5	0
Global amnesia	1	0	0	0	1	0
Memory impairment	3	0	0	0	3	0
Mental impairment (excl dementia and memory loss)						
Disturbance in attention	6	0	0	0	6	0
Migraine headaches						
Migraine	5	0	0	0	5	0
Muscle tone abnormal						
Hypertonia	1	0	0	0	1	0
Neurologic visual problems NEC						
Visual field defect	1	0	0	0	1	0
Neurological signs and symptoms NEC						
Dizziness	25	0	0	0	25	0

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name Nervous system disorders cont'd	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Dizziness postural	1	0	0	0	1	0
Myoclonus	1	0	0	0	1	0
Olfactory nerve disorders						
Anosmia	2	0	0	0	2	0
Parosmia	1	0	0	0	1	0
Paraesthesias and dysaesthesias						
Burning sensation	10	0	0	0	10	0
Burning sensation mucosal	1	0	0	0	1	0
Formication	1	0	0	0	1	0
Hyperaesthesia	1	0	0	0	1	0
Paraesthesia	6	0	0	0	6	0
Paralysis and paresis (excl cranial nerve)						
Hemiparesis	1	0	0	0	1	0
Hemiplegia	1	0	0	0	1	0
Paralysis	1	0	0	0	1	0
Parkinson's disease and parkinsonism						
Parkinson's disease	1	0	0	0	1	0
Partial complex seizures						
Temporal lobe epilepsy	1	0	0	0	1	0
Peripheral neuropathies NEC						
Neuropathy peripheral	2	0	0	0	2	0
Seizures and seizure disorders NEC						
Epilepsy	1	0	0	0	1	0
Sensory abnormalities NEC						
Ageusia	2	0	0	0	2	0
Dysgeusia	3	0	0	0	3	0
Hypoaesthesia	2	0	0	0	2	0
Speech and language abnormalities						
Dysphasia	1	0	0	0	1	0
Transient cerebrovascular events						
Transient ischaemic attack	2	0	0	0	2	0
Tremor (excl congenital)						
Tremor	7	0	0	0	7	0
Trigeminal disorders						
Trigeminal neuralgia	1	0	0	0	1	0
Nervous system disorders SOC TOTAL	**175**	**2**	**0**	**0**	**175**	**2**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Pregnancy conditions						
Abortion related conditions and complications						
Abnormal product of conception	1	0	0	0	1	0
Blighted ovum	1	0	0	0	1	0
Abortions spontaneous						
Abortion spontaneous	5	0	0	0	5	0
Foetal complications NEC						
Foetal distress syndrome	2	0	0	0	2	0
Gestational age and weight conditions						
Large for dates baby	1	0	0	0	1	0
Premature baby	1	0	0	0	1	0
Small for dates baby	1	0	0	0	1	0
Hypertension associated disorders of pregnancy						
Pre-eclampsia	1	0	0	0	1	0
Labour onset and length abnormalities						
Premature labour	1	0	0	0	1	0
Premature rupture of membranes	1	0	0	0	1	0
Normal pregnancy, labour and delivery						
Pregnancy	1	0	0	0	1	0
Placental abnormalities (excl neoplasms)						
Chorioamnionitis	1	0	0	0	1	0
Placental disorder	1	0	0	0	1	0
Stillbirth and foetal death						
Stillbirth	1	1	0	0	1	1
Unintended pregnancies						
Unintended pregnancy	1	0	0	0	1	0
Pregnancy conditions SOC TOTAL	**20**	**1**	**0**	**0**	**20**	**1**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Psychiatric disorders						
Abnormal behaviour NEC						
Abnormal behaviour	1	0	0	0	1	0
Anxiety symptoms						
Agitation	1	0	0	0	1	0
Anxiety	6	0	0	0	6	0
Behaviour and socialisation disturbances						
Aggression	1	0	0	0	1	0
Confusion and disorientation						
Confusional state	8	0	0	0	8	0
Disorientation	1	0	0	0	1	0
Depressive disorders						
Depression	20	0	0	0	20	0
Disturbances in initiating and maintaining sleep						
Insomnia	2	0	0	0	2	0
Emotional and mood disturbances NEC						
Dysphoria	1	0	0	0	1	0
Emotional distress	1	0	0	0	1	0
Mood altered	2	0	0	0	2	0
Fluctuating mood symptoms						
Mood swings	1	0	0	0	1	0
Mood alterations with depressive symptoms						
Decreased interest	1	0	0	0	1	0
Depressive symptom	1	0	0	0	1	0
Orgasmic disorders and disturbances						
Orgasm abnormal	3	0	0	0	3	0
Panic attacks and disorders						
Panic attack	2	0	0	0	2	0
Parasomnias						
Abnormal dreams	3	0	0	0	3	0
Nightmare	5	0	0	0	5	0
Perception disturbances						
Derealisation	1	0	0	0	1	0
Hallucination	1	0	0	0	1	0
Hallucination, olfactory	1	0	0	0	1	0
Hallucination, visual	2	0	0	0	2	0
Psychiatric symptoms NEC						
Psychiatric symptom	1	0	0	0	1	0
Psychotic disorder NEC						
Psychotic disorder	1	0	0	0	1	0
Sexual arousal disorders						
Disturbance in sexual arousal	1	0	0	0	1	0

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name Psychiatric disorders cont'd	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Sexual desire disorders						
Libido decreased	22	0	0	0	22	0
Libido increased	1	0	0	0	1	0
Loss of libido	10	0	0	0	10	0
Sleep disorders NEC						
Sleep disorder	1	0	0	0	1	0
Stereotypies and automatisms						
Bruxism	1	0	0	0	1	0
Substance-related disorders						
Withdrawal syndrome	4	0	0	0	4	0
Suicidal and self-injurious behaviour						
Completed suicide	1	1	0	0	1	1
Suicidal ideation	1	0	0	0	1	0
Thinking disturbances						
Thinking abnormal	1	0	0	0	1	0
Psychiatric disorders SOC TOTAL	**110**	**1**	**0**	**0**	**110**	**1**

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Drug Analysis Print
Drug name: FINASTERIDE

Drug name:	FINASTERIDE	**Report type:**	Spontaneous
Report run date:	29-Apr-2008	**Report origin:**	UNITED KINGDOM
Data lock date:	28-Apr-2008 08:00:20 PM	**Route of admin:**	ALL
Period covered:	01-Jul-1963 to 28-Apr-2008	**Reporter type:**	ALL
Earliest reaction date:	01-Jan-1992	**Reaction:**	ALL
MedDRA version:	MedDRA 11.0	**Age group:**	ALL

	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Renal & urinary disorders						
Bladder and urethral symptoms						
Dysuria	18	0	0	0	18	0
Enuresis	1	0	0	0	1	0
Incontinence	3	0	0	0	3	0
Micturition disorder	2	0	0	0	2	0
Micturition urgency	3	0	0	0	3	0
Pollakiuria	16	0	0	0	16	0
Residual urine	1	0	0	0	1	0
Strangury	1	0	0	0	1	0
Urge incontinence	1	0	0	0	1	0
Urinary hesitation	5	0	0	0	5	0
Urinary incontinence	4	0	0	0	4	0
Urinary retention	5	0	0	0	5	0
Urine flow decreased	1	0	0	0	1	0
Genital and urinary tract disorders NEC						
Urinary tract obstruction	1	0	0	0	1	0
Nephritis NEC						
Nephritis	1	0	0	0	1	0
Renal failure and impairment						
Renal failure	1	0	0	0	1	0
Urinary abnormalities						
Haematuria	6	0	0	0	6	0
Urine abnormality	1	0	0	0	1	0
Urine odour abnormal	1	0	0	0	1	0
Urinary tract signs and symptoms NEC						
Nocturia	9	0	0	0	9	0
Polyuria	1	0	0	0	1	0
Renal pain	2	0	0	0	2	0
Renal & urinary disorders SOC TOTAL	**84**	**0**	**0**	**0**	**84**	**0**

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MedDRA version:	MedDRA 11.0	**Age group:**	ALL

	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Reproductive & breast disorders						
Benign and malignant breast neoplasms						
Breast hyperplasia	1	0	0	0	1	0
Breast disorders NEC						
Breast enlargement	9	0	0	0	9	0
Breast mass	1	0	0	0	1	0
Gynaecomastia	74	0	0	0	74	0
Nipple disorder	1	0	0	0	1	0
Breast signs and symptoms						
Breast engorgement	1	0	0	0	1	0
Breast pain	6	0	0	0	6	0
Breast tenderness	10	0	0	0	10	0
Nipple pain	11	0	0	0	11	0
Erection and ejaculation conditions and disorders						
Ejaculation disorder	8	0	0	0	8	0
Ejaculation failure	9	0	0	0	9	0
Erectile dysfunction	76	0	0	0	76	0
Painful erection	1	0	0	0	1	0
Priapism	1	0	0	0	1	0
Gender disorders						
Feminisation acquired	1	0	0	0	1	0
Menstruation with increased bleeding						
Menorrhagia	1	0	0	0	1	0
Metrorrhagia	1	0	0	0	1	0
Penile disorders NEC (excl erection and ejaculation)						
Penile pain	3	0	0	0	3	0
Penile size reduced	3	0	0	0	3	0
Penile swelling	1	0	0	0	1	0
Penis disorder	5	0	0	0	5	0
Peyronie's disease	10	0	0	0	10	0
Prostate and seminal vesicles infections and inflammations						
Prostatitis	4	0	0	0	4	0
Prostatic signs, symptoms and disorders NEC						
Prostatic disorder	1	0	0	0	1	0
Prostatism	2	0	0	0	2	0
Reproductive tract disorders NEC (excl neoplasms)						
Reproductive tract disorder	1	0	0	0	1	0
Reproductive tract signs and symptoms NEC						
Pelvic pain	1	0	0	0	1	0
Perineal pain	5	0	0	0	5	0
Scrotal disorders NEC						
Acquired hydrocele	1	0	0	0	1	0

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Earliest reaction date:	01-Jan-1992	**Reaction:**	ALL
MedDRA version:	MedDRA 11.0	**Age group:**	ALL

	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name Reproductive & breast disorders cont'd	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Scrotal irritation	3	0	0	0	3	0
Scrotal oedema	3	0	0	0	3	0
Scrotal pain	1	0	0	0	1	0
Sexual function and fertility disorders NEC						
Infertility	1	0	0	0	1	0
Sexual dysfunction	4	0	0	0	4	0
Spermatogenesis and semen disorders						
Haematospermia	5	0	0	0	5	0
Testicular and epididymal disorders NEC						
Epididymal disorder	1	0	0	0	1	0
Testicular disorder	1	0	0	0	1	0
Testicular mass	1	0	0	0	1	0
Testicular pain	18	0	0	0	18	0
Testicular swelling	8	0	0	0	8	0
Testicular and epididymal infections and inflammations						
Epididymitis	1	0	0	0	1	0
Testicular and epididymal neoplasms						
Epididymal cyst	2	0	0	0	2	0
Reproductive & breast disorders SOC TOTAL	**298**	**0**	**0**	**0**	**298**	**0**

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MedDRA version:	MedDRA 11.0	**Age group:**	ALL

	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Respiratory disorders						
Breathing abnormalities						
Dyspnoea	14	1	0	0	14	1
Dyspnoea exertional	2	0	0	0	2	0
Hyperventilation	1	0	0	0	1	0
Bronchospasm and obstruction						
Asthma	2	0	0	0	2	0
Chronic obstructive pulmonary disease	1	0	0	0	1	0
Wheezing	2	0	0	0	2	0
Coughing and associated symptoms						
Cough	7	0	0	0	7	0
Lower respiratory tract inflammatory and immunologic conditions						
Alveolitis	1	0	0	0	1	0
Alveolitis fibrosing	1	0	0	0	1	0
Lower respiratory tract signs and symptoms						
Hiccups	2	0	0	0	2	0
Nasal disorders NEC						
Epistaxis	2	0	0	0	2	0
Pulmonary thrombotic and embolic conditions						
Pulmonary embolism	1	1	0	0	1	1
Upper respiratory tract signs and symptoms						
Dysphonia	1	0	0	0	1	0
Oropharyngeal blistering	1	0	0	0	1	0
Pharyngolaryngeal pain	1	0	0	0	1	0
Rhinorrhoea	1	0	0	0	1	0
Sneezing	1	0	0	0	1	0
Respiratory disorders SOC TOTAL	**41**	**2**	**0**	**0**	**41**	**2**

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MedDRA version:	MedDRA 11.0	**Age group:**	ALL

	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Skin disorders						
Acnes						
Acne	3	0	0	0	3	0
Alopecias						
Alopecia	14	0	0	0	14	0
Angioedemas						
Angioedema	1	0	0	0	1	0
Apocrine and eccrine gland disorders						
Dyshidrosis	1	0	0	0	1	0
Hyperhidrosis	5	0	0	0	5	0
Night sweats	4	0	0	0	4	0
Sweat gland disorder	1	0	0	0	1	0
Bullous conditions						
Blister	1	0	0	0	1	0
Dermatitis bullous	2	0	0	0	2	0
Erythema multiforme	1	0	0	0	1	0
Dermal and epidermal conditions NEC						
Dry skin	2	0	0	0	2	0
Pain of skin	1	0	0	0	1	0
Skin burning sensation	1	0	0	0	1	0
Swelling face	5	0	0	0	5	0
Dermatitis and eczema						
Dermatitis	2	0	0	0	2	0
Dermatitis allergic	2	0	0	0	2	0
Eczema	9	0	0	0	9	0
Intertrigo	4	0	0	0	4	0
Seborrhoeic dermatitis	1	0	0	0	1	0
Skin irritation	4	0	0	0	4	0
Dermatitis ascribed to specific agent						
Drug eruption	2	0	0	0	2	0
Erythemas						
Erythema	4	0	0	0	4	0
Rash erythematous	6	0	0	0	6	0
Exfoliative conditions						
Exfoliative rash	1	0	0	0	1	0
Skin exfoliation	2	0	0	0	2	0
Hyperkeratoses						
Lichenoid keratosis	2	0	0	0	2	0
Ichthyoses						
Ichthyosis acquired	1	0	0	0	1	0
Nail and nail bed conditions (excl infections and infestations)						
Nail disorder	2	0	0	0	2	0

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MedDRA version:	MedDRA 11.0	**Age group:**	ALL

	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name Skin disorders cont'd	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Nail growth abnormal	1	0	0	0	1	0
Panniculitides						
Erythema nodosum	1	0	0	0	1	0
Photosensitivity conditions						
Photosensitivity reaction	4	0	0	0	4	0
Pigmentation changes NEC						
Pigmentation disorder	1	0	0	0	1	0
Pilar disorders NEC						
Hair growth abnormal	9	0	0	0	9	0
Pruritus NEC						
Pruritus	13	0	0	0	13	0
Pruritus generalised	4	0	0	0	4	0
Rash pruritic	7	0	0	0	7	0
Psoriatic conditions						
Psoriasis	3	0	0	0	3	0
Purpura and related conditions						
Increased tendency to bruise	1	0	0	0	1	0
Purpura	1	0	0	0	1	0
Pustular conditions						
Rash follicular	1	0	0	0	1	0
Rashes, eruptions and exanthems NEC						
Rash	14	0	0	0	14	0
Rash generalised	1	0	0	0	1	0
Rash macular	4	0	0	0	4	0
Rash maculo-papular	1	0	0	0	1	0
Rash vesicular	1	0	0	0	1	0
Skin and subcutaneous tissue ulcerations						
Skin ulcer	1	0	0	0	1	0
Skin vasculitides						
Cutaneous vasculitis	1	0	0	0	1	0
Leukocytoclastic vasculitis	1	0	0	0	1	0
Vasculitic rash	4	0	0	0	4	0
Skin vasomotor conditions						
Livedo reticularis	1	0	0	0	1	0
Urticarias						
Dermographism	1	0	0	0	1	0
Urticaria	12	0	0	0	12	0
Urticaria papular	1	0	0	0	1	0
Skin disorders SOC TOTAL	**173**	**0**	**0**	**0**	**173**	**0**

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MedDRA version:	MedDRA 11.0	**Age group:**	ALL

	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Social circumstances						
Family and partner issues						
Pregnancy of partner	1	0	0	0	1	0
Social circumstances SOC TOTAL	**1**	**0**	**0**	**0**	**1**	**0**

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	**All**	**Fatal**	**All**	**Fatal**	**All**	**Fatal**
SOC						
HLT						
PT						
Vascular disorders						
Accelerated and malignant hypertension						
Hypertensive crisis	1	0	0	0	1	0
Aortic aneurysms and dissections						
Aortic aneurysm rupture	1	1	0	0	1	1
Arterial inflammations						
Temporal arteritis	2	0	0	0	2	0
Blood pressure disorders NEC						
Blood pressure inadequately controlled	1	0	0	0	1	0
Circulatory collapse and shock						
Circulatory collapse	1	0	0	0	1	0
Non-site specific necrosis and vascular insufficiency NEC						
Arteriosclerosis	1	0	0	0	1	0
Peripheral embolism and thrombosis						
Deep vein thrombosis	10	0	0	0	10	0
Thrombophlebitis	1	0	0	0	1	0
Thrombophlebitis superficial	1	0	0	0	1	0
Venous thrombosis limb	1	0	0	0	1	0
Peripheral vascular disorders NEC						
Flushing	3	0	0	0	3	0
Hot flush	3	0	0	0	3	0
Peripheral vasoconstriction, necrosis and vascular insufficiency						
Poor peripheral circulation	1	0	0	0	1	0
Raynaud's phenomenon	1	0	0	0	1	0
Phlebitis NEC						
Phlebitis superficial	1	0	0	0	1	0
Vascular hypertensive disorders NEC						
Essential hypertension	1	0	0	0	1	0
Hypertension	5	0	0	0	5	0
Vascular hypotensive disorders						
Hypotension	1	0	0	0	1	0
Vasculitides NEC						
Vasculitis	2	0	0	0	2	0
Vascular disorders SOC TOTAL	**38**	**1**	**0**	**0**	**38**	**1**

TOTAL NUMBER OF REACTIONS	**1534**	**28**	**0**	**0**	**1534**	**28**

TOTAL NUMBER OF FATAL ADR REPORTS*		**28**		**0**		**28***
TOTAL NUMBER OF ADR REPORTS*	**1022**		**0**		**1022***	

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