

Drug Analysis Print
Drug name: LIOTHYRONINE

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Drug name:	LIOTHYRONINE	Report type:	Spontaneous
Report run date:	11-May-2014	Report origin:	UNITED KINGDOM
Data lock date:	09-May-2014 23:08:31	Route of admin:	ALL
Period covered:	01-Jul-1963 to 09-May-2014	Reporter type:	ALL
Earliest reaction date:	16-Nov-1967	Reaction:	ALL
MedDRA version:	MedDRA 17.0	Age group:	ALL

Total number of reactions*:	532	Total number of ADR reports:	107	Total number of fatal ADR reports:	0
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Products included in this print - Single active constituent products (PBGs):	
MERCURY PHARMS LIOTHYRONINE	TERTROXIN
Products included in this print - Multi active constituent products (PBGs):	
ARMOUR THYROID	

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System Organ Class	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Blood disorders	2	0	0	0	2	0
Cardiac disorders	15	0	0	0	15	0
Ear disorders	8	0	0	0	8	0
Endocrine disorders	7	0	0	0	7	0
Eye disorders	11	0	0	0	11	0
Gastrointestinal disorders	22	0	0	0	22	0
General disorders	187	0	1	0	188	0
Hepatic disorders	1	0	0	0	1	0
Immune system disorders	5	0	0	0	5	0
Infections	3	0	0	0	3	0
Injuries	3	0	0	0	3	0
Investigations	34	0	0	0	34	0
Metabolic disorders	3	0	0	0	3	0
Muscle & tissue disorders	36	0	0	0	36	0
Nervous system disorders	67	0	0	0	67	0
Pregnancy conditions	1	0	0	0	1	0
Psychiatric disorders	47	0	0	0	47	0
Renal & urinary disorders	3	0	0	0	3	0
Reproductive & breast disorders	8	0	0	0	8	0
Respiratory disorders	16	0	0	0	16	0
Skin disorders	45	0	0	0	45	0
Social circumstances	4	0	0	0	4	0
Surgical & medical procedures	1	0	0	0	1	0
Vascular disorders	2	0	0	0	2	0

TOTAL NUMBER OF REACTIONS	531	0	1	0	532	0
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TOTAL NUMBER OF FATAL ADR REPORTS*		0		0		0*
TOTAL NUMBER OF ADR REPORTS*	106		1		107*	

*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 **Medical Dictionary for Regulatory Activities**, 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 Group – 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

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

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

Substance - is an active ingredient in a product

Substance Variant - is a more specific substance term. A substance may have zero, one or many linked variants. For example LITHIUM is linked to the variant LITHIUM CARBONATE and LITHIUM CITRATE.

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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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Blood disorders						
<i>Lymphatic system disorders NEC</i>						
Lymphadenopathy	2	0	0	0	2	0
Blood disorders SOC TOTAL	2	0	0	0	2	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	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	8	0	0	0	8	0
Ischaemic coronary artery disorders						
Angina pectoris	2	0	0	0	2	0
Rate and rhythm disorders NEC						
Tachycardia	2	0	0	0	2	0
Ventricular arrhythmias and cardiac arrest						
Cardiac arrest	1	0	0	0	1	0
Ventricular fibrillation	1	0	0	0	1	0
Cardiac disorders SOC TOTAL	15	0	0	0	15	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Ear disorders						
<i>Ear disorders NEC</i>						
Ear pain	1	0	0	0	1	0
<i>Hearing losses</i>						
Deafness	1	0	0	0	1	0
Hearing impaired	1	0	0	0	1	0
<i>Inner ear signs and symptoms</i>						
Motion sickness	1	0	0	0	1	0
Tinnitus	4	0	0	0	4	0
Ear disorders SOC TOTAL	8	0	0	0	8	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Endocrine disorders						
<i>Acute and chronic thyroiditis</i>						
Autoimmune thyroiditis	1	0	0	0	1	0
<i>Thyroid disorders NEC</i>						
Goitre	1	0	0	0	1	0
<i>Thyroid hyperfunction disorders</i>						
Hyperthyroidism	1	0	0	0	1	0
<i>Thyroid hypofunction disorders</i>						
Hypothyroidism	3	0	0	0	3	0
Myxoedema	1	0	0	0	1	0
Endocrine disorders SOC TOTAL	7	0	0	0	7	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Eye disorders						
<i>Lacrimation disorders</i>						
Dry eye	2	0	0	0	2	0
<i>Ocular disorders NEC</i>						
Dark circles under eyes	1	0	0	0	1	0
Eye pain	2	0	0	0	2	0
<i>Ocular infections, inflammations and associated manifestations</i>						
Ocular hyperaemia	1	0	0	0	1	0
<i>Ocular sensation disorders</i>						
Asthenopia	1	0	0	0	1	0
<i>Partial vision loss</i>						
Visual acuity reduced	1	0	0	0	1	0
<i>Visual disorders NEC</i>						
Visual impairment	3	0	0	0	3	0
Eye disorders SOC TOTAL	11	0	0	0	11	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Gastrointestinal disorders						
<i>Dental pain and sensation disorders</i>						
Toothache	1	0	0	0	1	0
<i>Dyspeptic signs and symptoms</i>						
Dyspepsia	2	0	0	0	2	0
<i>Flatulence, bloating and distension</i>						
Abdominal distension	5	0	0	0	5	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>						
Constipation	6	0	0	0	6	0
<i>Gastrointestinal signs and symptoms NEC</i>						
Dysphagia	2	0	0	0	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>						
Irritable bowel syndrome	3	0	0	0	3	0
<i>Nausea and vomiting symptoms</i>						
Nausea	2	0	0	0	2	0
<i>Tongue signs and symptoms</i>						
Swollen tongue	1	0	0	0	1	0
Gastrointestinal disorders SOC TOTAL	22	0	0	0	22	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
General disorders						
Asthenic conditions						
Asthenia	9	0	0	0	9	0
Fatigue	40	0	0	0	40	0
Malaise	14	0	0	0	14	0
Sluggishness	1	0	0	0	1	0
Body temperature altered						
Hypothermia	1	0	0	0	1	0
Feelings and sensations NEC						
Feeling abnormal	5	0	0	0	5	0
Feeling cold	3	0	0	0	3	0
Feeling hot	1	0	0	0	1	0
Thirst	2	0	0	0	2	0
General signs and symptoms NEC						
Condition aggravated	7	0	0	0	7	0
Crying	2	0	0	0	2	0
Fat tissue increased	1	0	0	0	1	0
Influenza like illness	2	0	0	0	2	0
Local swelling	1	0	0	0	1	0
Nonspecific reaction	1	0	0	0	1	0
Swelling	3	0	0	0	3	0
Inflammations						
Inflammation	1	0	0	0	1	0
Interactions						
Inhibitory drug interaction	1	0	0	0	1	0
Oedema NEC						
Oedema	1	0	0	0	1	0
Oedema peripheral	1	0	0	0	1	0
Pain and discomfort NEC						
Chest discomfort	2	0	0	0	2	0
Chest pain	1	0	0	0	1	0
Pain	8	0	0	0	8	0
Product quality issues NEC						
Product quality issue	28	0	0	0	28	0
Product substitution issue	4	0	0	0	4	0
Therapeutic and nontherapeutic responses						
Drug effect decreased	2	0	0	0	2	0
Drug ineffective	44	0	1	0	45	0
Therapeutic response decreased	1	0	0	0	1	0
General disorders SOC TOTAL	187	0	1	0	188	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Hepatic disorders						
<i>Hepatic and hepatobiliary disorders NEC</i>						
Liver disorder	1	0	0	0	1	0
Hepatic disorders SOC TOTAL	1	0	0	0	1	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Immune system disorders						
<i>Allergic conditions NEC</i>						
Hypersensitivity	2	0	0	0	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>						
Drug hypersensitivity	1	0	0	0	1	0
Reaction to drug excipients	1	0	0	0	1	0
<i>Anaphylactic responses</i>						
Anaphylactic reaction	1	0	0	0	1	0
Immune system disorders SOC TOTAL	5	0	0	0	5	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Infections						
<i>Abdominal and gastrointestinal infections</i>						
Diverticulitis	1	0	0	0	1	0
<i>Influenza viral infections</i>						
Influenza	1	0	0	0	1	0
<i>Viral infections NEC</i>						
Viral infection	1	0	0	0	1	0
Infections SOC TOTAL	3	0	0	0	3	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Injuries						
<i>Exposures associated with pregnancy, delivery and lactation</i>						
Exposure during pregnancy	1	0	0	0	1	0
<i>Maladministrations</i>						
Wrong technique in drug usage process	1	0	0	0	1	0
<i>Overdoses</i>						
Overdose	1	0	0	0	1	0
Injuries SOC TOTAL	3	0	0	0	3	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Investigations						
<i>Carbohydrate tolerance analyses (incl diabetes)</i>						
Blood glucose increased	1	0	0	0	1	0
<i>Heart rate and pulse investigations</i>						
Heart rate decreased	1	0	0	0	1	0
Heart rate increased	1	0	0	0	1	0
Heart rate irregular	2	0	0	0	2	0
<i>Physical examination procedures and organ system status</i>						
Body temperature decreased	3	0	0	0	3	0
Weight increased	17	0	0	0	17	0
<i>Pituitary analyses anterior</i>						
Blood thyroid stimulating hormone abnormal	2	0	0	0	2	0
Blood thyroid stimulating hormone decreased	1	0	0	0	1	0
Blood thyroid stimulating hormone increased	1	0	0	0	1	0
<i>Thyroid analyses</i>						
Anti-thyroid antibody positive	1	0	0	0	1	0
Tri-iodothyronine increased	1	0	0	0	1	0
<i>Vascular tests NEC (incl blood pressure)</i>						
Blood pressure increased	3	0	0	0	3	0
Investigations SOC TOTAL	34	0	0	0	34	0

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	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Metabolic disorders						
<i>Appetite disorders</i>						
Hyperphagia	1	0	0	0	1	0
Increased appetite	1	0	0	0	1	0
<i>Total fluid volume increased</i>						
Fluid retention	1	0	0	0	1	0
Metabolic disorders SOC TOTAL	3	0	0	0	3	0

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SOC						
HLT						
PT						
Muscle & tissue disorders						
Bone related signs and symptoms						
Bone pain	1	0	0	0	1	0
Joint related signs and symptoms						
Arthralgia	9	0	0	0	9	0
Muscle pains						
Myalgia	4	0	0	0	4	0
Muscle related signs and symptoms NEC						
Muscle spasms	3	0	0	0	3	0
Muscle weakness conditions						
Muscular weakness	3	0	0	0	3	0
Musculoskeletal and connective tissue infections and inflammations NEC						
Plantar fasciitis	1	0	0	0	1	0
Musculoskeletal and connective tissue pain and discomfort						
Back pain	4	0	0	0	4	0
Musculoskeletal pain	2	0	0	0	2	0
Neck pain	2	0	0	0	2	0
Pain in extremity	2	0	0	0	2	0
Musculoskeletal and connective tissue signs and symptoms NEC						
Musculoskeletal stiffness	4	0	0	0	4	0
Osteoarthropathies						
Osteoarthritis	1	0	0	0	1	0
Muscle & tissue disorders SOC TOTAL	36	0	0	0	36	0

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Drug Analysis Print
Drug name: LIOTHYRONINE

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Period covered:	01-Jul-1963 to 09-May-2014	Reporter type:	ALL
Earliest reaction date:	16-Nov-1967	Reaction:	ALL
MedDRA version:	MedDRA 17.0	Age group:	ALL

Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Nervous system disorders						
<i>Alzheimer's disease (incl subtypes)</i>						
Dementia Alzheimer's type	1	0	0	0	1	0
<i>Cortical dysfunction NEC</i>						
Aphasia	1	0	0	0	1	0
<i>Disturbances in consciousness NEC</i>						
Lethargy	5	0	0	0	5	0
Somnolence	4	0	0	0	4	0
Syncope	1	0	0	0	1	0
<i>Dyskinesias and movement disorders NEC</i>						
Psychomotor hyperactivity	1	0	0	0	1	0
<i>Headaches NEC</i>						
Headache	19	0	0	0	19	0
<i>Memory loss (excl dementia)</i>						
Amnesia	1	0	0	0	1	0
Memory impairment	4	0	0	0	4	0
<i>Mental impairment (excl dementia and memory loss)</i>						
Cognitive disorder	1	0	0	0	1	0
Disturbance in attention	6	0	0	0	6	0
Mental impairment	2	0	0	0	2	0
<i>Migraine headaches</i>						
Migraine	2	0	0	0	2	0
<i>Mononeuropathies</i>						
Carpal tunnel syndrome	2	0	0	0	2	0
<i>Neurological signs and symptoms NEC</i>						
Dizziness	7	0	0	0	7	0
<i>Paraesthesias and dysaesthesias</i>						
Burning sensation	2	0	0	0	2	0
Paraesthesia	2	0	0	0	2	0
<i>Paralysis and paresis (excl cranial nerve)</i>						
Monoplegia	1	0	0	0	1	0
<i>Sensory abnormalities NEC</i>						
Neuralgia	1	0	0	0	1	0
<i>Speech and language abnormalities</i>						
Speech disorder	1	0	0	0	1	0
<i>Tremor (excl congenital)</i>						
Tremor	3	0	0	0	3	0
Nervous system disorders SOC TOTAL	67	0	0	0	67	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Pregnancy conditions						
<i>Normal pregnancy, labour and delivery</i>						
Live birth	1	0	0	0	1	0
Pregnancy conditions SOC TOTAL	1	0	0	0	1	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Psychiatric disorders						
Anxiety symptoms						
Agitation	2	0	0	0	2	0
Anxiety	3	0	0	0	3	0
Nervousness	1	0	0	0	1	0
Tension	1	0	0	0	1	0
Confusion and disorientation						
Confusional state	3	0	0	0	3	0
Disorientation	1	0	0	0	1	0
Depressive disorders						
Depression	6	0	0	0	6	0
Disturbances in initiating and maintaining sleep						
Insomnia	5	0	0	0	5	0
Emotional and mood disturbances NEC						
Emotional disorder	1	0	0	0	1	0
Irritability	5	0	0	0	5	0
Mood altered	1	0	0	0	1	0
Fluctuating mood symptoms						
Mood swings	2	0	0	0	2	0
Mood alterations with depressive symptoms						
Depressed mood	4	0	0	0	4	0
Tearfulness	2	0	0	0	2	0
Mood disorders NEC						
Apathy	1	0	0	0	1	0
Psychiatric symptoms NEC						
Abulia	1	0	0	0	1	0
Sexual desire disorders						
Loss of libido	2	0	0	0	2	0
Sleep disorders NEC						
Sleep disorder	1	0	0	0	1	0
Stress disorders						
Burnout syndrome	1	0	0	0	1	0
Suicidal and self-injurious behaviour						
Suicidal ideation	2	0	0	0	2	0
Thinking disturbances						
Tachyphrenia	1	0	0	0	1	0
Tic disorders						
Tic	1	0	0	0	1	0
Psychiatric disorders SOC TOTAL	47	0	0	0	47	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Renal & urinary disorders						
Bladder and urethral symptoms						
Pollakiuria	1	0	0	0	1	0
Bladder disorders NEC						
Bladder disorder	1	0	0	0	1	0
Urinary tract signs and symptoms NEC						
Renal pain	1	0	0	0	1	0
Renal & urinary disorders SOC TOTAL	3	0	0	0	3	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Reproductive & breast disorders						
<i>Breast disorders NEC</i>						
Breast enlargement	1	0	0	0	1	0
<i>Breast signs and symptoms</i>						
Breast tenderness	1	0	0	0	1	0
<i>Erection and ejaculation conditions and disorders</i>						
Erectile dysfunction	1	0	0	0	1	0
<i>Menopausal effects NEC</i>						
Menopausal symptoms	1	0	0	0	1	0
<i>Menstruation and uterine bleeding NEC</i>						
Menstrual disorder	1	0	0	0	1	0
<i>Menstruation with increased bleeding</i>						
Menorrhagia	2	0	0	0	2	0
Polymenorrhoea	1	0	0	0	1	0
Reproductive & breast disorders SOC TOTAL	8	0	0	0	8	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Respiratory disorders						
<i>Breathing abnormalities</i>						
Dyspnoea	2	0	0	0	2	0
<i>Bronchospasm and obstruction</i>						
Asthma	3	0	0	0	3	0
<i>Coughing and associated symptoms</i>						
Cough	1	0	0	0	1	0
<i>Nasal disorders NEC</i>						
Epistaxis	1	0	0	0	1	0
<i>Upper respiratory tract signs and symptoms</i>						
Dysphonia	2	0	0	0	2	0
Oropharyngeal pain	7	0	0	0	7	0
Respiratory disorders SOC TOTAL	16	0	0	0	16	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Skin disorders						
Acnes						
Acne	4	0	0	0	4	0
Alopecias						
Alopecia	9	0	0	0	9	0
Angioedemas						
Swelling face	1	0	0	0	1	0
Apocrine and eccrine gland disorders						
Hyperhidrosis	5	0	0	0	5	0
Miliaria	1	0	0	0	1	0
Night sweats	1	0	0	0	1	0
Dermal and epidermal conditions NEC						
Dry skin	4	0	0	0	4	0
Dermatitis and eczema						
Eczema	1	0	0	0	1	0
Erythemas						
Erythema	2	0	0	0	2	0
Exfoliative conditions						
Skin exfoliation	1	0	0	0	1	0
Nail and nail bed conditions (excl infections and infestations)						
Onychoclasia	1	0	0	0	1	0
Panniculitides						
Erythema nodosum	1	0	0	0	1	0
Pilar disorders NEC						
Hair texture abnormal	1	0	0	0	1	0
Pruritus NEC						
Pruritus	5	0	0	0	5	0
Rashes, eruptions and exanthems NEC						
Rash	5	0	0	0	5	0
Scaly conditions						
Dandruff	1	0	0	0	1	0
Urticarias						
Urticaria	2	0	0	0	2	0
Skin disorders SOC TOTAL	45	0	0	0	45	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Social circumstances						
<i>Disability issues</i>						
Activities of daily living impaired	3	0	0	0	3	0
Bedridden	1	0	0	0	1	0
Social circumstances SOC TOTAL	4	0	0	0	4	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Surgical & medical procedures						
<i>Therapeutic procedures NEC</i>						
Off label use	1	0	0	0	1	0
Surgical & medical procedures SOC TOTAL	1	0	0	0	1	0

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Reaction Name	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
SOC						
<i>HLT</i>						
PT						
Vascular disorders						
<i>Peripheral vascular disorders NEC</i>						
Flushing	1	0	0	0	1	0
Hot flush	1	0	0	0	1	0
Vascular disorders SOC TOTAL	2	0	0	0	2	0

TOTAL NUMBER OF REACTIONS	531	0	1	0	532	0
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TOTAL NUMBER OF FATAL ADR REPORTS*		0		0		0*
TOTAL NUMBER OF ADR REPORTS*	106		1		107*	

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