#### FOI 22/433 - COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

FOI 22/433 - COVID-19 mRNA Pfizer-BioNTech Vaccine Analysis Print: All UK spontaneous reports received between 9/12/20 and 29/06/22 for COVID-19 Vaccine Pfizer/BioNTech in male patients aged between 12-17 years.

 Report Run Date: 08-Jul-2022
 Data Lock Date: 02-Feb-2022 18:31:05

 Earliest Reaction Date: 08-Feb-2008
 MedDRA Version: MedDRA 24.1

 Reaction Name
 Total Fatal

	10101	<u> </u>
Blood disorders		
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	1	0
Bleeding tendencies		
Increased tendency to bruise	1	0
Eosinophilic disorders		
Eosinophilia	1	0
Haemolyses NEC		
Haemolysis	1	0
Leukocytoses NEC		
Leukocytosis	2	0
Neutrophilia	1	0
Lymphatic system disorders NEC		
Lymph node pain	23	0
Lymphadenitis	2	0
Lymphadenopathy	102	0
Thrombocytopenias		
Immune thrombocytopenia	2	0
Thrombocytopenia	4	0
Blood disorders SOC TOTAL	140	0

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Report Run Date: 08-Jul-2022	Data Lock Date: 02-Feb-2022 18:37	1:05	
Earliest Reaction Date: 08-Feb-2008	MedDRA Version: MedDRA 24.1		
Reaction Name		Total	Fatal
Cardiac disorders			
Aortic valvular disorders			
Aortic valve incompetence		1	0
Cardiac conduction disorders			
Atrioventricular block		2	0
Atrioventricular block second degree		1	0
Cardiac signs and symptoms NEC			
Cardiac discomfort		2	0
Palpitations		58	0
Cardiomyopathies			
Cardiomyopathy		2	0
Ischaemic coronary artery disorders			
Angina pectoris		4	0
Arteriospasm coronary		1	0
Myocardial disorders NEC			
Left ventricular dysfunction		1	0
Myocardial oedema		1	0
Noninfectious myocarditis			
Hypersensitivity myocarditis		1	0
Myocarditis		31	0
Noninfectious pericarditis			
Pericarditis		11	0
Pericardial disorders NEC			
Pericardial effusion		1	0
Rate and rhythm disorders NEC			
Arrhythmia		1	0
Cardiac flutter		4	0
Heart alternation		1	0
Postural orthostatic tachycardia syndrome		1	0
Tachycardia		39	0
Supraventricular arrhythmias			
Atrial tachycardia		1	0
Sinus bradycardia		2	0
Sinus tachycardia		2	0
Supraventricular tachycardia		1	0
Tricuspid valvular disorders			
Tricuspid valve incompetence		1	0
Cardiac disorders SOC TOTAL		170	Õ
		170	

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Earliest Reaction Date: 08-Feb-2008	MedDRA Version: MedDRA 24.1		
Reaction Name		Total	Fatal
Congenital disorders			
Cardiac valve disorders congenital			
Bicuspid aortic valve		1	0
Musculoskeletal and connective tissue d	lisorders of spine congenital		
Block vertebra		1	0
Congenital disorders SOC TOTAL		2	0

Report Run Date: 08-Jul-2022 Earliest Reaction Date: 08-Feb-2008

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear pain	4	0
External ear disorders NEC		
Excessive cerumen production	1	0
Hearing losses		
Deafness	1	0
Deafness unilateral	1	0
Hypoacusis	1	0
Inner ear signs and symptoms		
Tinnitus	6	0
Vertigo	4	0
Ear disorders SOC TOTAL	18	0

Report Run Date: 08-Jul-2022	Data Lock Date: 02-Feb-2022 18:3	1:05	
Earliest Reaction Date: 08-Feb-2008	MedDRA Version: MedDRA 24.1		
Reaction Name		Total	Fatal
Endocrine disorders			
Thyroid hyperfunction disorders			
Hyperthyroidism		1	0
Endocrine disorders SOC TOTAL		1	0

	ate: 02-Feb-2022 18:31:05 rsion: MedDRA 24.1	
Reaction Name	Total	Fatal
Eye disorders		
Choroid and vitreous haemorrhages and vascular disord	lers	
Vitreous haemorrhage	1	0
Choroid and vitreous structural change, deposit and deg	neneration	
Vitreous floaters	1	0
Eyelid movement disorders		
Blepharospasm	1	0
Lacrimation disorders		
Dry eye	1	0
Lacrimation increased	3	3 0
Lid, lash and lacrimal infections, irritations and inflamma	ntions	
Eyelid irritation	1	-
Swelling of eyelid	2	2 0
Ocular disorders NEC		
Eye pain	11	
Eye swelling	g	
Periorbital swelling	1	0
Ocular infections, inflammations and associated manifes	stations	
Eye allergy	1	0
Eye discharge	1	
Eye pruritus	2	
Ocular hyperaemia	2	2 0
Ocular sensation disorders		
Photophobia	g	0 0
Pupil disorders		
Mydriasis	1	0
Retinal structural change, deposit and degeneration		
Retinal detachment	1	0
Visual disorders NEC		
Diplopia	2	
Metamorphopsia	1	-
Photopsia	1	0
Vision blurred	13	8 0
Visual field disorders		
Visual field defect	1	0
Visual impairment and blindness (excl colour blindness)		
Blindness	1	0
Blindness transient	1	0
Visual acuity reduced	1	0
Visual impairment	4	4 O
Eye disorders SOC TOTAL	73	

Report Run Date: 08-Jul-2022 Data Lock Date: 02-Feb-2022 18:31:05 Earliest Reaction Date: 08-Feb-2008 MedDRA Version: MedDRA 24.1 Total Fatal Reaction Name Gastrointestinal disorders Colitis (excl infective) Colitis ulcerative 0 1 0 Eosinophilic colitis 1 Diarrhoea (excl infective) Diarrhoea 36 0 0 Diarrhoea haemorrhagic 1 Dyspeptic signs and symptoms 0 Dyspepsia Flatulence, bloating and distension Abdominal distension 0 2 0 Flatulence Gastrointestinal and abdominal pains (excl oral and throat) 0 12 Abdominal pain 0 Abdominal pain lower 1 Abdominal pain upper 28 0 Gastrointestinal atonic and hypomotility disorders NEC 0 Constipation 1 Gastrointestinal disorders NEC 0 Functional gastrointestinal disorder 1 Gastrointestinal signs and symptoms NEC 0 Abdominal discomfort 3 0 Odynophagia Intestinal haemorrhages 0 Anal haemorrhage Nausea and vomiting symptoms 0 Nausea 115 102 0 Vomitina 0 Vomiting projectile 2 Non-site specific gastrointestinal haemorrhages Haematemesis 0 Oesophagitis (excl infective) 0 Oesophagitis Oral dryness and saliva altered Dry mouth 2 0 Oral soft tissue signs and symptoms 0 Hypoaesthesia oral 2 Oral pain 2 0 Oral soft tissue swelling and oedema 10 0 Lip swelling Stomatitis and ulceration Aphthous ulcer 0 1 0 Mouth ulceration 2 0 Stomatitis 1 Tongue signs and symptoms Swollen tongue 0 Δ Gastrointestinal disorders SOC TOTAL 336 n

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Report Run Date: 08-Jul-2022	Data Lock Date: 02-Feb-2022 18:31:0	5	
Earliest Reaction Date: 08-Feb-2008	MedDRA Version: MedDRA 24.1		
Reaction Name	-	<u>Fotal</u>	Fatal
General disorders			
Administration site reactions NEC			
Puncture site bruise		1	0
Puncture site pain		1	0
Asthenic conditions			
Asthenia		20	0
Fatigue		157	0
Malaise		50	0
Febrile disorders			
Pyrexia		149	0
Feelings and sensations NEC			
Chills		45	0
Feeling abnormal		10	0
Feeling cold		9	0
Feeling hot		9	0
Feeling jittery		1	0
Feeling of body temperature change		1	0
Thirst		1	0
General signs and symptoms NEC			0
Crying		1	0
Discharge		1	0
General physical health deterioration		1	0
		29	0
Influenza like illness		12	0
Local reaction		1	0
Peripheral swelling		37	0
Swelling		33	-
Swelling face Inflammations		5	0
Inflammation		7	0
Injection site reactions			0
Injected limb mobility decreased		2	0
Injection site erythema		2	0
Injection site pain		28	0
Injection site pruritus		20	0
Injection site rash		3	0
Injection site swelling		3	0
Injection site warmth		1	0
Interactions			Ū
Drug interaction		2	0
Pain and discomfort NEC		_	Ŭ
Axillary pain		34	0
Chest discomfort		12	0
Chest pain		122	0
Discomfort		5	0
Non-cardiac chest pain		1	0
Pain		37	0
Tenderness		1	0
Therapeutic and nontherapeutic respons	es		Ū
Drug ineffective		2	0
Vaccination failure		1	0
Vaccination site reactions			0
Extensive swelling of vaccinated limb		1	0

Report Run Date: 08-Jul-2022DataEarliest Reaction Date: 08-Feb-2008MedD

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site bruising	1	0
Vaccination site discomfort	2	0
Vaccination site erythema	3	0
Vaccination site haemorrhage	1	0
Vaccination site joint movement impairment	1	0
Vaccination site mass	2	0
Vaccination site pain	6	0
Vaccination site swelling	1	0
Withdrawal and rebound effects		
Withdrawal syndrome	1	0
General disorders SOC TOTAL	856	0

Report Run Date: 08-Jul-2022Data Lock Date: 02-Feb-2022 18:31:05Earliest Reaction Date: 08-Feb-2008MedDRA Version: MedDRA 24.1

Total	Fatal
	1 0
	1 0
	1 0
	3 0
	Total

Report Run Date: 08-Jul-2022 Data Lock Date: 02-Feb-2022 18:31:05 MedDRA Version: MedDRA 24.1 Earliest Reaction Date: 08-Feb-2008 Fatal Reaction Name <u>Total</u> Immune system disorders Allergic conditions NEC Hypersensitivity 12 0 Allergies to foods, food additives, drugs and other chemicals Allergy to vaccine 1 0 Drug hypersensitivity 2 0 Anaphylactic and anaphylactoid responses 0 Anaphylactic reaction 4 2 0 Anaphylactic shock Atopic disorders Seasonal allergy 0 1 Immune and associated conditions NEC Bacille Calmette-Guerin scar reactivation 0 2 0 Immune system disorder 1 0 Multisystem inflammatory syndrome in children 3 Immune system disorders SOC TOTAL 28 0

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Earliest Reaction Date: 08-Feb-2008	MedDRA Version: MedDRA 24.1		
Reaction Name		Total	Fatal
Infections			
Abdominal and gastrointestinal infections			•
Appendicitis		4	0
Bacterial infections NEC			•
Cellulitis		1	0
Central nervous system and spinal infection	5		•
Brain abscess		1	0
Coronavirus infections			-
Asymptomatic COVID-19		1	0
COVID-19		24	0
Suspected COVID-19		2	0
Ear infections			
Labyrinthitis		1	0
Eye and eyelid infections			
Conjunctivitis		1	0
Fungal infections NEC			
Myocarditis mycotic		1	0
Herpes viral infections			
Herpes zoster		11	0
Oral herpes		1	0
Varicella		2	0
Influenza viral infections			
Influenza		7	0
Lower respiratory tract and lung infections			
Lower respiratory tract infection		1	0
Streptococcal infections			
Pharyngitis streptococcal		1	0
Tinea infections			
Body tinea		1	0
Toxoplasma infections			
Toxoplasmosis		1	0
Upper respiratory tract infections			
Nasopharyngitis		11	0
Tonsillitis		3	0
Vascular infections			
Lymphangitis		3	0
Viral infections NEC			
Sweating fever		1	0
Viral infection		2	0
Viral rash		4	0
Infections SOC TOTAL		85	0

Report Run Date: 08-Jul-2022 Earliest Reaction Date: 08-Feb-2008

Reaction Name	Total	Fatal
Injuries		
Conditions caused by cold		
Chillblains	1	0
Heat injuries (excl thermal burns)		
Heat exhaustion	1	0
Muscle, tendon and ligament injuries		
Muscle injury	1	0
Tendon rupture	1	0
Overdoses NEC		
Overdose	1	0
Product administration errors and issues		
Inappropriate schedule of product administration	1	0
Product administered at inappropriate site	1	0
Skin injuries NEC		
Contusion	5	0
Thermal burns		
Thermal burn	1	0
Injuries SOC TOTAL	13	0

Report Run Date: 08-Jul-2022Data LoEarliest Reaction Date: 08-Feb-2008MedDRA

Reaction Name	Total	Fatal
Investigations		
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	2	0
Blood glucose decreased	1	0
Cardiac auscultatory investigations		
Cardiac murmur	1	0
Heart rate and pulse investigations		
Heart rate	3	0
Heart rate decreased	2	0
Heart rate increased	12	0
Heart rate irregular	1	0
Pulse abnormal	2	0
Immunology analyses NEC		
Immunology test	1	0
Physical examination procedures and organ system status		
Body temperature	3	0
Body temperature abnormal	2	0
Body temperature increased	6	0
Grip strength decreased	1	0
Respiratory rate increased	1	0
Platelet analyses		
Platelet count decreased	3	0
Renal function analyses		
Blood creatinine increased	1	0
Respiratory and pulmonary function diagnostic procedures		
Maximal voluntary ventilation	1	0
Urinalysis NEC		
Blood urine present	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	1	0
Virus identification and serology		
Coronavirus test	1	0
SARS-CoV-2 test	1	0
SARS-CoV-2 test positive	2	0
Investigations SOC TOTAL	49	0

Report Run Date: 08-Jul-2022 Data Lock Date: 02-Feb-2022 18:31:05 Earliest Reaction Date: 08-Feb-2008 MedDRA Version: MedDRA 24.1 **Total** Fatal Reaction Name Metabolic disorders Appetite disorders Decreased appetite 12 0 0 Hyperphagia 1 Increased appetite 1 0 General nutritional disorders NEC Abnormal weight gain 1 0 0 Feeding disorder 1 Hypoglycaemic conditions NEC Hypoglycaemia 0 1 Total fluid volume decreased 0 Dehydration 1 Metabolic disorders SOC TOTAL 18 0

Report Run Date: 08-Jul-2022 Data L	_ock Date: 02-Feb-2022 18:31:05	
•	RA Version: MedDRA 24.1	
Reaction Name	Total	Fatal
Muscle & tissue disorders	iotai	
Bone related signs and symptoms		
Bone pain	1	0
Pain in jaw	4	
Spinal pain	2	
Cartilage disorders		Ĭ
Costochondritis	4	0
Joint related signs and symptoms		Ĭ
Arthralgia	28	0
Joint swelling	1	0
Muscle infections and inflammations		ľ
Immune-mediated myositis	1	0
Myositis	3	
Muscle pains		
Myalgia	40	0
Muscle related signs and symptoms NEC		
Muscle spasms	10	0 0
Muscle swelling	1	0
Muscle twitching	5	-
Muscle tone abnormalities		
Muscle rigidity	1	0
Trismus	1	1
Muscle weakness conditions		
Muscular weakness	8	0
Musculoskeletal and connective tissue conditions	NEC	
Mastication disorder	1	0
Mobility decreased	1	0
Musculoskeletal stiffness	4	0
Musculoskeletal and connective tissue pain and di	scomfort	
Back pain	12	0
Limb discomfort	11	0
Musculoskeletal chest pain	3	0
Neck pain	7	0
Pain in extremity	87	0
Myopathies		
Myopathy	1	0
Soft tissue disorders NEC		
Axillary mass	3	0
Groin pain	1	0
Neck mass	1	0
Muscle & tissue disorders SOC TOTAL	242	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Acute polyneuropathies		
Miller Fisher syndrome	1	0
Autonomic nervous system disorders		
Autonomic nervous system imbalance	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebrovascular accident	1	0
Haemorrhagic cerebral infarction	1	0
Central nervous system vascular disorders NEC		
Central nervous system vasculitis	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	1	0
Superior sagittal sinus thrombosis	1	0
Coordination and balance disturbances		
Balance disorder	6	0
Cortical dysfunction NEC		
Aphasia	1	0
Disturbances in consciousness NEC		
Lethargy	12	0
Loss of consciousness	19	0
Somnolence	10	0
Syncope	84	0
Dyskinesias and movement disorders NEC		
Dyskinesia	1	0
Psychomotor hyperactivity	1	0
Facial cranial nerve disorders		
Bell's palsy	2	0
Facial paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	1	0
Headaches NEC		
Cluster headache	1	0
Headache	240	0
Primary headache associated with sexual activity	1	0
Sinus headache	2	0
Tension headache	4	0
Mental impairment (excl dementia and memory loss)		
Disturbance in attention	2	0
Migraine headaches		
Migraine	17	0
Migraine with aura	1	0
Myelitis (incl infective)		
Myelitis transverse	1	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	1	0
Narcolepsy	1	0
Neurologic visual problems NEC		
Tunnel vision	1	0
Neurological signs and symptoms NEC		
Dizziness	112	-
Dizziness exertional	2	0
Dizziness postural	11	0

Report Run Date: 08-Jul-2022 Data Lock Date: 02-Feb-2022 18:31:05 MedDRA Version: MedDRA 24.1 Earliest Reaction Date: 08-Feb-2008 Reaction Name Total Fatal Nervous system disorders us system disorders cont'd 0 Head discomfort 1 16 0 Presyncope Olfactory nerve disorders Anosmia 2 0 Parosmia 4 0 Paraesthesias and dysaesthesias 0 2 **Burning sensation** 0 1 Hyperaesthesia Hypoaesthesia 12 0 0 Paraesthesia 14 Paralysis and paresis (excl cranial nerve) Hemiplegia 2 0 0 Paralysis 1 Seizures and seizure disorders NEC Epilepsy 7 0 Seizure 30 0 0 **Tonic convulsion** 2 Sensory abnormalities NEC 0 Ageusia 3 Dysgeusia 4 0 0 Restless legs syndrome 1 0 Sensory disturbance 1 0 Sensory loss 1 2 0 Taste disorder Speech and language abnormalities 0 Dysarthria 2 Incoherent 1 0 0 Language disorder 1 0 Speech disorder 1 Tremor (excl congenital) 0 Tremor 16 670 0 Nervous system disorders SOC TOTAL

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 Reaction Name
 Total
 Fatal

 Device malfunction events NEC
 1
 0

 Thrombosis in device
 1
 0

 null SOC TOTAL
 1
 0

#### Case Series Drug Analysis Print Name: FOI 22/433 - COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print Data Lock Date: 02-Feb-2022 18:31:05

Analysis Print		
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Earliest Reaction Date: 08-Feb-2008 MedDRA Version: MedDRA 24.1	Total	Fatal
Reaction Name Psychiatric disorders	Total	ralai
Adjustment disorders		
Adjustment disorder	1	0
Adjustment disorder Affect alterations NEC	1	0
	1	0
Affect lability Inappropriate affect	1	0
	1	0
Anxiety symptoms	1	0
Agitation Anxiety	5	0
Nervousness	5 1	0
Behaviour and socialisation disturbances	1	0
	1	0
Aggression Disinhibition	1	0 0
Confusion and disorientation		0
Confusional state	8	0
Disorientation	5	0
Deliria	5	0
Delirium	3	0
Depressive disorders	3	0
Depression	1	0
Dissociative states	1	0
Dissociative states	1	0
Dissociative annesia Disturbances in initiating and maintaining sleep	1	0
Insomnia	9	0
Dyssomnias	3	0
Poor quality sleep	1	0
Emotional and mood disturbances NEC	1	0
Emotional disorder	1	0
Irritability	1	0
Fear symptoms and phobic disorders (incl social phobia)	1	0
Fear	1	0
Hallucinations (excl sleep-related)	1	0
Hallucination	2	0
Increased physical activity levels	2	0
Restlessness	1	0
Mood disorders NEC	1	0
Apathy	1	0
Panic attacks and disorders	1	0
Panic attack	2	0
Parasomnias	2	0
Abnormal dreams	1	0
Parasomnia	2	0
Somnambulism	1	0
Psychiatric symptoms NEC	1	0
Psychiatric symptom	1	0
Sexual arousal disorders		0
Disturbance in sexual arousal	1	0
Speech articulation and rhythm disturbances		0
Dysphemia	1	0
Substance related and addictive disorders		0
Nicotine dependence	1	0
Suicidal and self-injurious behaviour		0
Suicidal ideation	1	0
	1	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Genital and urinary tract disorders NEC		
Genitourinary symptom	1	0
Renal failure and impairment		
Renal impairment	1	0
Urinary abnormalities		
Haematuria	3	0
Urinary tract signs and symptoms NEC		
Polyuria	1	0
Renal pain	2	0
Renal & urinary disorders SOC TOTAL	8	0

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Earliest Reaction Date. 06-Feb-2006 MiedDRA Version. MedDRA 24:1		
Reaction Name	Total	Fatal
Reproductive & breast disorders		
Breast disorders NEC		
Nipple disorder	1	0
Breast infections and inflammations		
Nipple inflammation	1	0
Breast signs and symptoms		
Breast swelling	2	0
Nipple pain	1	0
Menstruation with decreased bleeding		
Menstruation delayed	1	0
Penile disorders NEC (excl erection and ejaculation)		
Penis disorder	1	0
Reproductive tract signs and symptoms NEC		
Genital rash	1	0
Testicular and epididymal disorders NEC		
Testicular pain	3	0
Reproductive & breast disorders SOC TOTAL	11	0

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Earliest Reaction Date: 08-Feb-2008 MedDRA Version: MedDRA 24.	1	
Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	74	0
Grunting	1	0
Hyperventilation	1	0
Hypopnoea	1	0
Nocturnal dyspnoea	1	0
Respiration abnormal	2	0
Bronchospasm and obstruction		
Asthma	4	0
Wheezing	8	0
Coughing and associated symptoms		
Cough	13	0
Haemoptysis	2	0
Productive cough	2	0
Lower respiratory tract signs and symptoms		
Hiccups	1	0
Nasal congestion and inflammations		
Nasal congestion	3	0
Nasal disorders NEC		
Epistaxis	24	
Nasal dryness	1	0
Paranasal sinus disorders (excl infections and neoplasms)		
Sinus congestion	2	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal swelling	5	0
Tonsillar hypertrophy	1	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	2	0
Pneumothorax	1	0
Upper respiratory tract signs and symptoms		
Dysphonia	1	0
Nasal discomfort	1	0
Oropharyngeal pain	27	0
Rhinorrhoea	8	
Sneezing	1	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	188	0

Report Run Date: 08-Jul-2022 Data Lock Date: 02-Feb-2022 18:31:05 MedDRA Version: MedDRA 24.1 Earliest Reaction Date: 08-Feb-2008 Reaction Name Total Fatal Skin disorders Acnes Dermatitis acneiform 0 Alopecias Alopecia 0 Angioedemas 6 0 Angioedema Apocrine and eccrine gland disorders Cold sweat 15 0 **Hyperhidrosis** 0 12 Miliaria 0 1 Night sweats 3 0 **Bullous conditions** 0 Blister 9 0 Dermatitis bullous 1 Dermal and epidermal conditions NEC Pain of skin 0 2 Sensitive skin 2 0 0 3 Skin discolouration 0 Skin lesion 1 Skin reaction 0 1 0 Skin swelling 1 0 Skin warm 1 Yellow skin 2 0 Dermatitis and eczema Dermatitis 1 0 2 0 Dermatitis allergic 3 0 Eczema Dermatitis ascribed to specific agent 2 0 **Drug eruption** Erythemas 0 Erythema 7 Papulosquamous conditions 0 3 Pityriasis rosea Pruritus NEC Pruritus 28 0 Psoriatic conditions 0 Guttate psoriasis 1 0 Psoriasis 1 Purpura and related conditions Henoch-Schonlein purpura 0 Petechiae 0 1 Purpura 0 1 Rashes, eruptions and exanthems NEC 74 0 Rash Rash erythematous 18 0 5 0 Rash macular 0 Rash maculo-papular 1 0 Rash morbilliform 1 0 Rash papular 4 6 0 Rash pruritic 0 Rash vesicular 2 Scaly conditions

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Dandruff	1	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	1	0
Skin hypoplasias and atrophies		
Skin atrophy	1	0
Skin vasculitides		
Vasculitic rash	2	0
Urticarias		
Urticaria	34	0
Skin disorders SOC TOTAL	263	0

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Reaction Name		Total	Fatal
Social circumstances			
Dependents			
Sick relative		3	0
Social circumstances SOC TOTAL		3	0

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Large intestine therapeutic procedures Appendicectomy Surgical & medical procedures SOC TOTAL

0

0

1

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Reaction Date:         08-Feb-2008         MedDRA Version:         MedDRA 24.1           Reaction Name	Total	Fatal
Vascular disorders		- atal
Circulatory collapse and shock		
Circulatory collapse	1	0
Neurogenic shock	1	0
Peripheral circulatory failure	1	0
Shock	1	0
Haemorrhages NEC		
Haemorrhage	2	0
Peripheral embolism and thrombosis		
Blue toe syndrome	1	0
Deep vein thrombosis	1	0
Jugular vein thrombosis	1	0
Peripheral vascular disorders NEC		
Cyanosis	2	0
Flushing	7	0
Hot flush	3	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	3	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	1	0
Site specific vascular disorders NEC		
Pallor	24	0
Vascular hypertensive disorders NEC		
Hypertension	1	0
Orthostatic hypertension	1	0
Vascular hypotensive disorders		
Hypotension	7	0
Orthostatic hypotension	1	0
Vascular disorders SOC TOTAL	61	0
TOTAL REACTIONS FOR DRUG	3306	0
TOTAL REPORTS	1253	