

## COVID-19 vaccine Moderna analysis print

Report Run Date: 29-Apr-2021  
Data Lock Date: 28-Apr-2021 18:30:09

All UK spontaneous reports received up to and including 28/04/21 for COVID-19  
vaccine Moderna

# Case Series Drug Analysis Print

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Report Run Date: 29-Apr-2021

Data Lock Date: 28-Apr-2021 18:30:09

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	2	0
Lymphadenopathy	23	0
<b>Blood disorders SOC TOTAL</b>	<b>25</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	7	0
<i>Ischaemic coronary artery disorders</i>		
Myocardial infarction	1	0
<i>Rate and rhythm disorders NEC</i>		
Extrasystoles	1	0
Tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	3	0
<i>Hearing losses</i>		
Deafness	1	0
Deafness unilateral	1	0
Hypoacusis	2	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	9	0
Vertigo	4	0
<b>Ear disorders SOC TOTAL</b>	<b>20</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	1	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	1	0
Lacrimation increased	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye pain	5	0
Eye swelling	3	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye allergy	1	0
Eye irritation	1	0
Ocular hyperaemia	2	0
<i><b>Ocular sensation disorders</b></i>		
Photophobia	2	0
<i><b>Visual disorders NEC</b></i>		
Vision blurred	6	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	1	0
Visual impairment	1	0
<b>Eye disorders SOC TOTAL</b>	<b>25</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i><b>Anal and rectal signs and symptoms</b></i>		
Anal pruritus	1	0
<i><b>Colitis (excl infective)</b></i>		
Colitis ulcerative	1	0
Crohn's disease	2	0
<i><b>Dental pulp disorders</b></i>		
Dental pulp disorder	1	0
<i><b>Diarrhoea (excl infective)</b></i>		
Diarrhoea	23	0
<i><b>Dyspeptic signs and symptoms</b></i>		
Dyspepsia	1	0
<i><b>Faecal abnormalities NEC</b></i>		
Faeces discoloured	1	0
<i><b>Gastrointestinal and abdominal pains (excl oral and throat)</b></i>		
Abdominal pain	4	0
Abdominal pain upper	12	0
<i><b>Gastrointestinal atonic and hypomotility disorders NEC</b></i>		
Gastrooesophageal reflux disease	1	0
<i><b>Gastrointestinal signs and symptoms NEC</b></i>		
Abdominal discomfort	2	0
<i><b>Gingival haemorrhages</b></i>		
Gingival bleeding	1	0
<i><b>Nausea and vomiting symptoms</b></i>		
Nausea	47	0
Vomiting	17	0
<i><b>Oral dryness and saliva altered</b></i>		
Dry mouth	3	0
Lip dry	2	0
Saliva altered	1	0
Salivary hypersecretion	1	0
<i><b>Oral soft tissue haemorrhages</b></i>		
Oral blood blister	1	0
<i><b>Oral soft tissue signs and symptoms</b></i>		
Hypoaesthesia oral	3	0
Paraesthesia oral	6	0
<i><b>Oral soft tissue swelling and oedema</b></i>		
Lip swelling	4	0
Mouth swelling	3	0
<i><b>Stomatitis and ulceration</b></i>		
Mouth ulceration	3	0
Stomatitis	1	0
<i><b>Tongue signs and symptoms</b></i>		
Glossodynia	1	0
Swollen tongue	5	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>148</b>	<b>0</b>

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<b>General disorders</b>		
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Application and instillation site reactions</i>		
Application site pruritus	1	0
<i>Asthenic conditions</i>		
Asthenia	5	0
Fatigue	105	0
Malaise	14	0
<i>Death and sudden death</i>		
Death	1	1
<i>Febrile disorders</i>		
Pyrexia	66	0
<i>Feelings and sensations NEC</i>		
Chills	58	0
Feeling abnormal	8	0
Feeling cold	9	0
Feeling drunk	1	0
Feeling hot	6	0
Feeling jittery	1	0
Feeling of body temperature change	3	0
Thirst	5	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crying	2	0
Illness	6	0
Induration	1	0
Influenza like illness	6	0
Peripheral swelling	74	0
Swelling	32	0
Swelling face	6	0
<i>Inflammations</i>		
Inflammation	2	0
<i>Infusion site reactions</i>		
Infusion site urticaria	1	0
Infusion site warmth	1	0
<i>Injection site reactions</i>		
Injection site bruising	1	0
Injection site erythema	6	0
Injection site mass	6	0
Injection site pain	29	0
Injection site pruritus	3	0
Injection site rash	10	0
Injection site swelling	2	0
Injection site urticaria	5	0
Injection site warmth	6	0
<i>Pain and discomfort NEC</i>		
Axillary pain	10	0
Chest discomfort	2	0
Chest pain	5	0
Discomfort	6	0
Pain	41	0
Tenderness	5	0
<i>Therapeutic and nontherapeutic responses</i>		

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<b>General disorders</b> General disorders cont'd		
Adverse drug reaction	3	0
<b><i>Vaccination site reactions</i></b>		
Vaccination site bruising	1	0
Vaccination site erythema	15	0
Vaccination site induration	2	0
Vaccination site inflammation	1	0
Vaccination site mass	4	0
Vaccination site pain	12	0
Vaccination site pruritus	3	0
Vaccination site rash	7	0
Vaccination site swelling	3	0
Vaccination site warmth	4	0
<b>General disorders SOC TOTAL</b>	<b>608</b>	<b>1</b>



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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Bile duct infections and inflammations</i>		
Biliary colic	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergic oedema	1	0
Hypersensitivity	5	0
Infusion related hypersensitivity reaction	1	0
Type IV hypersensitivity reaction	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	2	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>11</b>	<b>0</b>

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<b>Infections</b>		
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	1	0
<i><b>Candida infections</b></i>		
Vulvovaginal candidiasis	2	0
<i><b>Coronavirus infections</b></i>		
COVID-19	1	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	2	0
<i><b>Fungal infections NEC</b></i>		
Fungal skin infection	1	0
<i><b>Herpes viral infections</b></i>		
Herpes zoster	2	0
Oral herpes	3	0
<i><b>Infections NEC</b></i>		
Infection	4	0
Localised infection	1	0
Vaccination site infection	1	0
Vestibulitis	1	0
<i><b>Infectious transmissions</b></i>		
Secondary transmission	1	0
<i><b>Influenza viral infections</b></i>		
Influenza	4	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Lower respiratory tract infection	1	0
Pneumonia	1	0
<i><b>Skin structures and soft tissue infections</b></i>		
Pustule	2	0
Skin infection	1	0
<i><b>Tinea infections</b></i>		
Body tinea	1	0
<i><b>Upper respiratory tract infections</b></i>		
Nasopharyngitis	5	0
<i><b>Urinary tract infections</b></i>		
Cystitis	1	0
Urinary tract infection	1	0
<i><b>Viral infections NEC</b></i>		
Sweating fever	2	0
<b>Infections SOC TOTAL</b>	<b>39</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Conditions caused by cold</i>		
Chillblains	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	4	0
Maternal exposure during pregnancy	3	0
Paternal exposure during pregnancy	1	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	1	0
Procedural pain	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
<i>Skin injuries NEC</i>		
Contusion	6	0
<i>Thermal burns</i>		
Thermal burn	1	0
<b>Injuries SOC TOTAL</b>	<b>20</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	2	0
<i>Heart rate and pulse investigations</i>		
Heart rate	4	0
Heart rate increased	2	0
Heart rate irregular	1	0
<i>Liver function analyses</i>		
Liver function test abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	2	0
Body temperature increased	2	0
Skin temperature	2	0
<i>Urinary tract function analyses NEC</i>		
Urine output	2	0
<i>Urinary tract imaging procedures</i>		
Bladder scan	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure measurement	1	0
<b>Investigations SOC TOTAL</b>	<b>20</b>	<b>0</b>

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<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	2	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	1	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	1	0
<i><b>General nutritional disorders NEC</b></i>		
Feeding disorder	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	2	0
<b>Metabolic disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	2	0
Pain in jaw	2	0
Spinal pain	1	0
<i><b>Joint related disorders NEC</b></i>		
Rotator cuff syndrome	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	39	0
Joint stiffness	2	0
Joint swelling	2	0
<i><b>Muscle pains</b></i>		
Myalgia	41	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle haemorrhage	1	0
Muscle spasms	7	0
Muscle tightness	2	0
Muscle twitching	2	0
<i><b>Muscle tone abnormalities</b></i>		
Trismus	1	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	1	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Musculoskeletal stiffness	12	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	8	0
Flank pain	1	0
Limb discomfort	12	0
Musculoskeletal discomfort	1	0
Neck pain	6	0
Pain in extremity	100	0
<i><b>Soft tissue disorders NEC</b></i>		
Axillary mass	1	0
Groin pain	1	0
<i><b>Tendon disorders</b></i>		
Trigger finger	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>248</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>1</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b><i>Central nervous system haemorrhages and cerebrovascular accidents</i></b>		
Cerebral haemorrhage	1	1
Subarachnoid haemorrhage	1	0
<b><i>Disturbances in consciousness NEC</i></b>		
Lethargy	9	0
Loss of consciousness	5	0
Somnolence	5	0
Syncope	7	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Movement disorder	1	0
<b><i>Facial cranial nerve disorders</i></b>		
Facial paralysis	1	0
<b><i>Headaches NEC</i></b>		
Cluster headache	1	0
Headache	115	0
Sinus headache	1	0
Tension headache	1	0
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	1	0
Disturbance in attention	1	0
<b><i>Migraine headaches</i></b>		
Migraine	9	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Dizziness	62	0
Dizziness postural	5	0
Head discomfort	1	0
Neurological symptom	2	0
Presyncope	3	0
<b><i>Olfactory nerve disorders</i></b>		
Parosmia	2	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	5	0
Hyperaesthesia	1	0
Hypoaesthesia	18	0
Paraesthesia	25	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Paralysis	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Febrile convulsion	1	0
Seizure	2	0
Status epilepticus	4	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	1	0
Dysgeusia	16	0
Neuralgia	2	0
Post herpetic neuralgia	1	0
Sensory disturbance	1	0
Taste disorder	3	0
<b><i>Sleep disturbances NEC</i></b>		
Poor quality sleep	2	0
Sleep deficit	1	0
<b><i>Speech and language abnormalities</i></b>		
Incoherent	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Slow speech	1	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	7	0
<b>Nervous system disorders SOC TOTAL</b>	<b>327</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Anxiety symptoms</b></i>		
Anxiety	3	0
Nervousness	2	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	1	0
Disorientation	1	0
<i><b>Depressive disorders</b></i>		
Depression	2	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	2	0
Terminal insomnia	2	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Emotional disorder	2	0
Emotional distress	1	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination	3	0
<i><b>Mental disorders NEC</b></i>		
Mental disorder	1	0
<i><b>Mood alterations with depressive symptoms</b></i>		
Depressed mood	1	0
<i><b>Mood disorders NEC</b></i>		
Apathy	1	0
Listless	1	0
<i><b>Panic attacks and disorders</b></i>		
Panic attack	1	0
<i><b>Parasomnias</b></i>		
Abnormal dreams	2	0
Nightmare	1	0
<i><b>Suicidal and self-injurious behaviour</b></i>		
Suicidal ideation	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>28</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Pollakiuria	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	2	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	2	0
Menstrual disorder	1	0
Menstruation irregular	2	0
Metrorrhagia	1	0
<i>Menstruation with decreased bleeding</i>		
Hypomenorrhoea	1	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	4	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal discomfort	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>16</b>	<b>0</b>

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<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	10	0
<i>Bronchospasm and obstruction</i>		
Wheezing	2	0
<i>Coughing and associated symptoms</i>		
Cough	6	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	7	0
Nasal oedema	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	2	0
<i>Upper respiratory tract signs and symptoms</i>		
Nasal discomfort	1	0
Oropharyngeal pain	12	0
Rhinorrhoea	4	0
Sinus pain	2	0
Throat irritation	4	0
Throat tightness	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>57</b>	<b>0</b>

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<b>Skin disorders</b>		
<i><b>Angioedemas</b></i>		
Angioedema	1	0
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	2	0
Hyperhidrosis	6	0
Miliaria	2	0
Night sweats	1	0
<i><b>Bullous conditions</b></i>		
Blister	2	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Dry skin	4	0
Pain of skin	1	0
Papule	2	0
Skin burning sensation	5	0
Skin induration	1	0
Skin reaction	7	0
Skin sensitisation	1	0
Skin warm	5	0
<i><b>Dermatitis and eczema</b></i>		
Dermatitis allergic	6	0
Dermatitis atopic	2	0
Eczema	3	0
<i><b>Erythemas</b></i>		
Erythema	36	0
<i><b>Pruritus NEC</b></i>		
Pruritus	110	0
<i><b>Purpura and related conditions</b></i>		
Petechiae	1	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Butterfly rash	1	0
Rash	74	0
Rash erythematous	41	0
Rash macular	3	0
Rash papular	6	0
Rash pruritic	19	0
<i><b>Rosaceas</b></i>		
Rosacea	1	0
<i><b>Urticarias</b></i>		
Urticaria	14	0
<b>Skin disorders SOC TOTAL</b>	<b>357</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: COVID-19 vaccine Moderna analysis print

Report Run Date: 29-Apr-2021

Data Lock Date: 28-Apr-2021 18:30:09

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 23.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Social circumstances</b>		
<i>Disability issues</i>		
Immobile	1	0
<i>Pregnancy related circumstances</i>		
Breast feeding	1	0
<b>Social circumstances SOC TOTAL</b>	<b>2</b>	<b>0</b>



# Case Series Drug Analysis Print

## Name: COVID-19 vaccine Moderna analysis print

Report Run Date: 29-Apr-2021

Data Lock Date: 28-Apr-2021 18:30:09

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>1</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine Moderna analysis print

Report Run Date: 29-Apr-2021  
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 28-Apr-2021 18:30:09  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Haemorrhages NEC</b></i>		
Bloody discharge	1	0
Haemorrhage	3	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Thrombosis	1	0
<i><b>Peripheral embolism and thrombosis</b></i>		
Blue toe syndrome	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Flushing	1	0
Hot flush	3	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	2	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	1	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	1	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	4	0
<i><b>Vasculitides NEC</b></i>		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>19</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>1996</b>	<b>2</b>
<b>TOTAL REPORTS</b>	<b>683</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>2</b>