Report Run Date: 21-Aug-2017

Data Lock Date: 18-Aug-2017 19:00:04

Earliest Reaction Date: 12-Mar-2011 MedDRA 20.0 MedDRA Version:

Td/IPV Drug Analysis All UK spontaneous cases concerning the Td/IPV vaccine received between 01/09/2012 and 07/08/2017

Report Run Date: 21-Aug-2017, Page 1

Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	1	0
Bleeding tendencies		
Haemorrhagic disorder	1	0
Coagulopathies		
Coagulopathy	2	0
Haematological disorders		
Histiocytosis haematophagic	1	1
Lymphatic system disorders NEC		
Lymphadenitis	1	0
Lymphadenopathy	12	2 0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	1	1
Pancytopenia	1	0
Neutropenias		
Neutropenia	1	0
Thrombocytopenias		
Immune thrombocytopenic purpura	1	0
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	23	3 2

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac signs and symptoms NEC		
Cyanosis	2	0
Palpitations	4	0
Myocardial disorders NEC		
Left ventricular dysfunction	1	0
Pericardial disorders NEC		
Pericardial effusion	1	0
Rate and rhythm disorders NEC		
Tachycardia	5	0
Supraventricular arrhythmias		
Atrial fibrillation	1	0
Supraventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	15	0

Report Run Date: 21-Aug-2017 Data Lock Date: 18-Aug-2017 19:00:04 Earliest Reaction Date: 12-Mar-2011 MedDRA Version: MedDRA 20.0

Reaction Name	Total	Fatal
Congenital disorders		
Congenital disorders NEC		
Congenital cyst	1	0
Musculoskeletal and connective tissue disorders of limbs congenital		
Syndactyly	1	0
Skin and subcutaneous tissue disorders congenital NEC		
Congenital skin dimples	1	0
Congenital disorders SOC TOTAL	3	l o

Report Run Date: 21-Aug-2017, Page 4

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	1	0
Ear pain		0
Hearing losses		
Deafness		0
Deafness unilateral	1	0
Hypoacusis	2	2 0
Hyperacusia		
Hyperacusis		0
Inner ear signs and symptoms		
Tinnitus	3	0
Vertigo	7	0
Vertigo positional	1	0
Tympanic membrane disorders (excl infections)		
Tympanic membrane perforation		0
Ear disorders SOC TOTAL	19	0

Report Run Date: 21-Aug-2017 Data Lock Date: 18-Aug-2017 19:00:04 Earliest Reaction Date: 12-Mar-2011 MedDRA Version: MedDRA 20.0

Reaction Name	Total	Fatal
Endocrine disorders		
Adrenal gland disorders NEC		
Adrenal disorder	1	0
Endocrine disorders SOC TOTAL	1	0

Report Run Date: 21-Aug-2017, Page 6

Reaction Name	Total	Fatal
Eye disorders		
Blindness (excl colour blindness)		
Blindness transient	1	0
Conjunctival infections, irritations and inflammations		
Conjunctivitis allergic	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Eyelid oedema	4	0
Ocular disorders NEC		
Eye pain	5	0
Eye swelling	8	0
Ocular infections, inflammations and associated manifestations		
Ocular hyperaemia	2	0
Ocular nerve and muscle disorders		
Eye movement disorder	7	0
Gaze palsy	1	0
Ocular sensation disorders		
Asthenopia	1	0
Photophobia	16	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Pupil disorders		
Mydriasis	2	0
Pupil fixed	2	0
Retinal, choroid and vitreous infections and inflammations		
Retinal vasculitis	1	0
Visual colour distortions		
Xanthopsia	1	0
Visual disorders NEC		
Photopsia	2	0
Vision blurred	13	0
Visual impairment	6	0
Eve disorders SOC TOTAL	74	l o

	Version: MedDRA 20.0	
Reaction Name	Total	Fatal
Gastrointestinal disorders		
Acute and chronic pancreatitis		
Pancreatitis	1	0
Diarrhoea (excl infective)		
Diarrhoea	39	ol ol
Flatulence, bloating and distension		
Abdominal distension	1	0
Gastrointestinal and abdominal pains (excl oral and th	roat)	
Abdominal pain	,	s o
Abdominal pain lower	1	0
Abdominal pain upper	18	
Gastrointestinal atonic and hypomotility disorders NEO		
Constipation	3	0
Gastrooesophageal reflux disease	2	
Impaired gastric emptying	1	
Gastrointestinal disorders NEC		
Gastrointestinal disorder	1 1	0
Gastrointestinal signs and symptoms NEC		Ĭ
Abdominal discomfort	7	0
Dysphagia		
Gastrointestinal spastic and hypermotility disorders		i i
Frequent bowel movements	1	0
Irritable bowel syndrome	2	
Intestinal haemorrhages		
Rectal haemorrhage	1	0
Nausea and vomiting symptoms		
Nausea	171	0
Retching	177	2 0
Vomiting	96	
Vomiting projectile	30	
Oral soft tissue disorders NEC		i
Chapped lips	1	0
Oral disorder	1	
Oral soft tissue pain and paraesthesia		1
Paraesthesia oral	6	0
Oral soft tissue signs and symptoms		i i
Hypoaesthesia oral	3	0
Oral discomfort	1	
Oral pruritus	1	
Oral pruntus Oral soft tissue swelling and oedema		
	12	
Lip swelling	12	1
Mouth swelling	1	0
Tongue signs and symptoms		
Swollen tongue	3	
Gastrointestinal disorders SOC TOTAL	394	H O

	on: MedDRA 20.0	
Reaction Name	Total	<u>Fatal</u>
General disorders		
Administration site reactions NEC		
Administration site bruise	1	0
Application and instillation site reactions		
Application site erythema	1	0
Asthenic conditions		
Asthenia	17	0
Fatigue	56	0
Malaise	191	0
Febrile disorders		
Hyperpyrexia	2	0
Pyrexia	245	0
Feelings and sensations NEC		
Chills	34	0
Feeling abnormal	10	0
Feeling cold	7	0
Feeling hot	26	0
Feeling of body temperature change	7	0
Thirst	1	0
Gait disturbances		
Abasia	1	0
General signs and symptoms NEC		
Condition aggravated	2	0
Crying	3	0
Effusion	1	0
Exercise tolerance decreased	1	0
Induration	1	0
Influenza like illness	42	0
Irritability postvaccinal	1	0
Local reaction	5	0
Local swelling	9	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	30	0
Swelling	2	0
Inflammations		
Inflammation	6	0
Infusion site reactions		
Infusion site discomfort	1	0
Injection site reactions		
Injected limb mobility decreased	2	0
Injection site bruising	2	0
Injection site coldness	1	0
Injection site discolouration	1	0
Injection site erythema	8	0
Injection site hypersensitivity	1	0
Injection site induration	2	0
Injection site inflammation	4	0
Injection site irritation		0
Injection site mass	5	0
Injection site movement impairment	1	0
Injection site necrosis	1	0
Injection site pain	6	0
Injection site pruritus	2	
Injection site rash	2	

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site reaction	3	0
Injection site swelling	7	0
Injection site vesicles	1	0
Injection site warmth	2	0
Mass conditions NEC		
Cyst	1	0
Mass	3	0
Oedema NEC		
Face oedema	2	0
Pain and discomfort NEC		
Axillary pain	4	0
Chest discomfort	4	0
Chest pain	9	0
Discomfort	6	0
Facial pain	1	0
Pain	40	0
Tenderness	3	0
Vaccination site reactions		
Vaccination site bruising	1	0
Vaccination site erythema	9	0
Vaccination site induration	1	0
Vaccination site inflammation	3	0
Vaccination site joint pain	2	0
Vaccination site movement impairment	1	0
Vaccination site pain	16	0
Vaccination site papule	1	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	1	0
Vaccination site swelling	13	0
Vaccination site warmth	2	0
General disorders SOC TOTAL	880	0

Reaction Name	Total	Fatal
Hepatic disorders		
Cholestasis and jaundice		
Jaundice	4	0
Hepatic enzymes and function abnormalities		
Hepatic function abnormal	1	0
Hepatic failure and associated disorders		
Acute hepatic failure	1	0
Hepatobiliary signs and symptoms		
Hepatomegaly	1	0
Hepatocellular damage and hepatitis NEC		
Liver injury	1	0
Hepatic disorders SOC TOTAL	8	l o

Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Allergy to animal	1	0
Hypersensitivity	9	0
Mite allergy	1	0
Allergies to foods, food additives, drugs and other chemicals		
Food allergy	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	25	0
Atopic disorders		
Seasonal allergy	1	0
Autoimmune disorders NEC		
Autoimmune disorder	2	0
Immune system disorders SOC TOTAL	40	l o

Earliest Reaction Date: 12-Mar-2011 MedDRA Version: MedD		
Reaction Name	Total	<u>Fatal</u>
Infections		
Abdominal and gastrointestinal infections		
Appendicitis perforated	1	0
Bacterial infections NEC		
Arthritis bacterial	1	0
Cellulitis	5	0
Central nervous system and spinal infections		
Encephalitis	1	C
Meningitis	2	O
Corynebacteria infections		
Diphtheria	1	O
Ear infections		
Ear infection	1	0
Labyrinthitis	1	0
Herpes viral infections		
Herpes simplex	1	0
Infections NEC		
Injection site abscess	1	0
Respiratory tract infection	1	0
Influenza viral infections		
Influenza	3	0
Lower respiratory tract and lung infections		
Bronchitis	1	0
Lower respiratory tract infection	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Neutropenic sepsis	1	0
Sepsis	1	O
Skin structures and soft tissue infections		
Skin infection	1	O
Staphylococcal infections		_
Staphylococcal abscess	1	O
Upper respiratory tract infections		_
Nasopharyngitis	1	0
Pharyngitis	2	0
Rhinitis	1	0
Sinusitis	1	O
Tonsillitis	2	C
Urinary tract infections		
Urinary tract infection	1	C
Viral infections NEC		
Meningitis viral	1	C
Post viral fatigue syndrome	1	(
Viral infection	1	Č
Viral pericarditis	1	
Viral upper respiratory tract infection	10	
Infections SOC TOTAL	47	Č

Reaction Name	Total	Fatal
Injuries		
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	7	0
Foetal exposure during pregnancy	6	0
Maternal exposure before pregnancy	1	0
Medication errors, product use errors and issues NEC		
Medication error	1	0
Muscle, tendon and ligament injuries		
Muscle injury	1	0
Non-site specific injuries NEC		
Fall	3	0
Traumatic haematoma	1	0
Non-site specific procedural complications		
Shunt malfunction	1	0
Poisoning and toxicity		
Toxicity to various agents	1	0
Product administration errors and issues		
Extra dose administered	1	0
Wrong drug administered	3	0
Reproductive system and breast injuries		
Perineal injury	1	0
Skin injuries NEC		
Contusion	6	0
Vaccination related complications		
Vaccination complication	1	0
Injuries SOC TOTAL	34	l o

Earliest Reaction Date: 12-Mar-2011	Medura version: Medura 20.0		
Reaction Name	Tot	<u>al</u> _,	<u>Fatal</u>
Investigations			
Blood gas and acid base analyses			
Oxygen consumption increased		1	0
Carbohydrate tolerance analyses (incl d	liabetes)		
Blood glucose decreased		2	0
Blood glucose increased		_1	0
Chemistry analyses NEC			
Inflammatory marker increased		_1	0
Coagulation and bleeding analyses			
International normalised ratio increase		_1	0
Foetal and neonatal diagnostic procedu	res		
Foetal monitoring abnormal		_1	0
Heart rate and pulse investigations			
Heart rate increased		3	0
Heart rate irregular		3	0
Investigations NEC			
Quality of life decreased		1	0
Liver function analyses			
Alanine aminotransferase increased		1	0
Blood bilirubin increased		2	0
Liver function test abnormal		1	0
Mineral and electrolyte analyses			
Blood iron decreased		1	C
Physical examination procedures and or	rgan system status		
Body temperature abnormal		1	C
Body temperature decreased		_1	C
Body temperature increased		54	C
General physical condition abnormal		_1	C
Respiratory rate increased		1	C
Weight decreased		_1	C
Protein analyses NEC			
C-reactive protein increased		_1	C
Respiratory and pulmonary function diag	gnostic procedures		
Vital capacity decreased	·	_1	C
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased		1	C
Vitamin analyses			
Vitamin D decreased		1	C
Investigations SOC TOTAL		82	0

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Appetite disorder	1	0
Decreased appetite	24	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Cow's milk intolerance	1	0
Food intolerance	1	0
Milk soy protein intolerance	1	0
General nutritional disorders NEC		
Abnormal loss of weight	1	0
Metabolic disorders SOC TOTAL	29	0

Earliest Reaction Date: 12-Mar-2011	MedDRA Version: MedDRA 20.0	
Reaction Name	Total	<u> Fatal</u>
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	1	I 0
Bone related signs and symptoms		
Bone pain	1	ı 0
Spinal pain	1	ı o
Joint related disorders NEC		
Periarthritis	1	ı o
Joint related signs and symptoms		
Arthralgia	26	6 0
Joint stiffness		
Joint swelling	3	1
Muscle infections and inflammations		
Myositis		ıl o
Muscle pains		
Myalgia	35	0
Muscle related signs and symptoms NEC		
Muscle atrophy	1	ı o
Muscle fatigue	2	
Muscle spasms	6	
Muscle swelling		
Muscle twitching		1
Muscle tone abnormalities		
Muscle rigidity	Ę	5 0
Trismus		
Muscle weakness conditions		
Muscular weakness	13	3 0
Musculoskeletal and connective tissue pain		
Back pain	33	3 0
Limb discomfort		7 0
Musculoskeletal chest pain		ا ا
Musculoskeletal discomfort		i ő
Musculoskeletal pain	3	
Neck pain	15	
Pain in extremity	95	
Musculoskeletal and connective tissue signs		
Limb mass	and symptome N20	0
Mobility decreased	2	1
Musculoskeletal stiffness	18	
Posture abnormal		íl ő
Rheumatoid arthropathies		
Rheumatoid arthritis	3	3 0
Soft tissue disorders NEC		1 "
Axillary mass		
Neck mass		
Muscle & tissue disorders SOC TOTAL	293	-

Reaction Name	Total	Fatal
Neoplasms		
Reproductive neoplasms female benign NEC		
Benign hydatidiform mole	1	0
Neoplasms SOC TOTAL	1	l ol

	MedDRA Version: MedDRA 20.0		
Reaction Name		Total	Fatal
Nervous system disorders			
Acute polyneuropathies			
Guillain-Barre syndrome		2	0
Chronic polyneuropathies			
Demyelinating polyneuropathy		1	0
Coordination and balance disturbances			
Balance disorder		3	0
Coordination abnormal		1	0
Demyelinating disorders NEC			
Acute disseminated encephalomyelitis		2	0
Disturbances in consciousness NEC			
Depressed level of consciousness		1	0
Lethargy		31	0
Loss of consciousness		15	0
Somnolence		20	0
Syncope		89	0
Dyskinesias and movement disorders NEC			
Dyskinesia		14	0
Hypokinesia		1	0
Psychomotor hyperactivity		2	0
Dystonias			
Opisthotonus		2	0
Encephalopathies NEC			
Encephalopathy		1	0
Headaches NEC			
Headache		242	0
Tension headache		2	0
Memory loss (excl dementia)			
Amnesia		2	0
Memory impairment		2	0
Mental impairment (excl dementia and memo	ry loss)		
Cognitive disorder		2	0
Disturbance in attention		4	0
Judgement impaired		1	0
Migraine headaches			
Migraine		5	0
Migraine with aura		1	0
Muscle tone abnormal			
Hypotonia		3	0
Myelitis (incl infective)			
Myelitis transverse		1	0
Narcolepsy and hypersomnia			
Hypersomnia		4	0
Neurologic visual problems NEC			
Tunnel vision		2	0
Neurological signs and symptoms NEC			
Dizziness		192	0
Dizziness postural		1	0
Head discomfort		2	0
Myoclonus		3 6	0
Presyncope			0
Unresponsive to stimuli		3	0
Paraesthesias and dysaesthesias			
Burning sensation		1	0

Earliest Reaction Date. 12-Mai-2011	Weddra Version, Weddra 20.0		
Reaction Name		Total	Fatal
Nervous system disorders us system disorders co	ont'd		
Hyperaesthesia		1	0
Hypoaesthesia		17	0
Paraesthesia		27	0
Paralysis and paresis (excl cranial nerve)			
Monoparesis		1	0
Quadriparesis		1	0
Peripheral neuropathies NEC			
Neuropathy peripheral		3	0
Polyneuropathy		1	0
Seizures and seizure disorders NEC			
Epilepsy		2	0
Febrile convulsion		3	0
Seizure		10	0
Seizure like phenomena		4	0
Sensory abnormalities NEC			
Sensory disturbance		2	0
Sensory loss		2	0
Speech and language abnormalities			
Aphonia		1	0
Dysarthria		2	0
Speech disorder		2	0
Spinal cord and nerve root disorders NEC			
Radiculitis brachial		1	0
Tremor (excl congenital)			
Tremor		21	0
Nervous system disorders SOC TOTAL		765	0

Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	2	0
Foetal complications NEC		
Foetal distress syndrome	2	0
Foetal hypokinesia	1	0
Haemorrhagic complications of pregnancy		
Haemorrhage in pregnancy	1	0
Pregnancy conditions SOC TOTAL	6	0

Earliest Reaction Date: 12-Mar-2011	MedDRA Version: MedDRA 20.0		
Reaction Name		Total	Fatal
Psychiatric disorders			
Abnormal behaviour NEC			
Abnormal behaviour		1	0
Anxiety symptoms			
Agitation		3	0
Anxiety		9	0
Stress		1	0
Behaviour and socialisation disturbances			J
Indifference		1	0
Paranoia		1	0
Cognitive and attention disorders and disturba	ances NFC	·	Ŭ
Mental fatigue	11000 1420	1	0
Confusion and disorientation			J
Confusional state		6	0
Disorientation		6	0
Disoriemation Deliria		O	U
		2	0
Delirium Delirium		3	0
Depressive disorders		4	0
Depression		1	0
Dissociative states			
Dissociation		1	0
Disturbances in initiating and maintaining slee	ep	_	_
Insomnia		3	0
Emotional and mood disturbances NEC			
Emotional disorder		3	0
Emotional distress		3	0
Irritability		3	0
Mood altered		1	0
Increased physical activity levels			
Restlessness		1	0
Mood alterations with depressive symptoms			
Tearfulness		1	0
Mood disorders NEC			
Listless		1	0
Panic attacks and disorders			
Panic attack		1	0
Panic reaction		2	0
Parasomnias			
Nightmare		1	0
Perception disturbances			
Hallucination		3	0
Psychotic disorder NEC			_
Acute psychosis		1	0
Psychotic disorder		2	0
Sleep disorders NEC			J
Sleep disorders NEC		4	0
Stereotypies and automatisms		4	U
Bruxism		4	0
		65	0 0
Psychiatric disorders SOC TOTAL		65	U

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Dysuria	2	0
Urinary incontinence	2	0
Glomerulonephritis and nephrotic syndrome		
Glomerulonephritis acute	1	0
Renal failure and impairment		
Acute kidney injury	1	0
Renal failure	1	0
Renal obstructive disorders		
Hydronephrosis	1	0
Urinary abnormalities		
Haematuria	1	0
Renal & urinary disorders SOC TOTAL	9	l o

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Breast signs and symptoms		
Breast tenderness	1	0
Menstruation and uterine bleeding NEC		
Menstrual disorder	1	0
Scrotal disorders NEC		
Scrotal pain	1	0
Reproductive & breast disorders SOC TOTAL	3	0

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	23	0
Grunting	2	0
Hyperventilation	1	0
Respiration abnormal	1	0
Bronchospasm and obstruction		
Asthma	2	0
Wheezing	5	0
Conditions associated with abnormal gas exchange		
Hypoxia	1	0
Coughing and associated symptoms		
Cough	11	0
Nasal congestion and inflammations		
Nasal congestion	1	0
Nasal disorders NEC		
Epistaxis	3	0
Paranasal sinus disorders (excl infections and neoplasms)		
Sinus congestion	1	0
Parenchymal lung disorders NEC		
Lung consolidation	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal hypoaesthesia	1	0
Pharyngeal oedema	5	0
Pleural infections and inflammations		
Pleurisy	1	0
Respiratory signs and symptoms NEC		
Painful respiration	2	0
Upper respiratory tract signs and symptoms		
Dry throat	1	0
Dysphonia	1	0
Oropharyngeal discomfort	2	0
Oropharyngeal pain	27	0
Rhinorrhoea	2	0
Throat irritation	4	0
Throat tightness	8	0
Respiratory disorders SOC TOTAL	106	l o

Earliest Reaction Date: 12-Mar-2011 MedDRA Version: MedDRA Ver	edDRA 20.0	
Reaction Name	Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	4	0
Swelling face	10	0
Apocrine and eccrine gland disorders		
Cold sweat	10	0
Hyperhidrosis	22	0
Night sweats	1	0
Dermal and epidermal conditions NEC		
Dry skin	4	0
Pain of skin	1	0
Papule	1	0
Skin discolouration	6	0
Skin discomfort	1	0
Skin induration	1	0
Skin lesion	1	0
Skin swelling	1	0
Skin warm	11	0
Dermatitis and eczema		
Dermatitis	1	0
Dermatitis allergic	4	0
Eczema	1	0
Skin irritation	1	0
Erythemas		
Erythema	42	0
Exfoliative conditions		
Exfoliative rash	1	0
Skin exfoliation	1	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	2	0
Pruritus NEC		
Pruritus	16	0
Pruritus generalised	1	0
Rash pruritic	2	0
Purpura and related conditions		
Ecchymosis	1	0
Henoch-Schonlein purpura	1	0
Petechiae	1	0
Purpura	1	0
Rashes, eruptions and exanthems NEC		
Rash	33	0
Rash erythematous	1	0
Rash generalised	5	0
Rash macular	5	0
Rash maculo-papular	1	0
Rash papular	4	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Skin vasculitides		
Cutaneous vasculitis	1	0
Urticarias		
Urticaria	18	0
Urticaria chronic	2	0
Skin disorders SOC TOTAL	221	0

Reaction Name	Total	Fatal
Surgical & medical procedures		
Induced abortions		
Abortion induced	3	0
Obstetric therapeutic procedures		
Caesarean section	1	0
Vacuum extractor delivery	1	0
Surgical & medical procedures SOC TOTAL	5	0

Desetion Name	Total	Eatal
Reaction Name	Total	Fatal
Vascular disorders		
Circulatory collapse and shock		_
Circulatory collapse	1	0
Lymphoedemas		
Lymphoedema	1	0
Non-site specific embolism and thrombosis		
Thrombosis	1	0
Peripheral embolism and thrombosis		
Thrombophlebitis	1	0
Peripheral vascular disorders NEC		
Flushing	7	0
Hot flush	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	8	0
Site specific vascular disorders NEC		
Pallor	39	0
Vascular hypertensive disorders NEC		
Hypertension	1	0
Vascular hypotensive disorders		
Hypotension	9	0
Vascular disorders SOC TOTAL	69	0
TOTAL REACTIONS FOR DRUG	3192	2
	3.02	_
TOTAL REPORTS	897	
TOTAL FATAL OUTCOME REPORTS	097	2