Case Series Drug Analysis Print Name: FOI 22/671 - 6-in-1 Vaccine Drug Analysis Print

Report Run Date: 18-May-2022

Data Lock Date: 17-May-2022 18:30:04

Earliest Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 25.0

FOI 22/671 - 6-in-1 DTPA HepB HIB IPV (6-in-1) Vaccine

Vaccine Drug Analysis Drug Analysis Print (DAP). All spontaneous UK Print: suspected Adverse Drug Reaction (ADR) reports

associated with the 6-in-1 vaccine.

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Reaction Name	Total	Fatal
Blood disorders		
Leukocytoses NEC		
Lymphocytic infiltration	1	0
Lymphatic system disorders NEC		
Lymphadenopathy	3	0
Marrow depression and hypoplastic anaemias		
Myelosuppression	1	0
Neutropenias		
Neutropenia	1	0
Thrombocytopenias		
Immune thrombocytopenia	2	0
Blood disorders SOC TOTAL	8	l o

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Reaction Name	Total	Fatal
Cardiac disorders		
Rate and rhythm disorders NEC		
Bradycardia		2 0
Tachycardia		3 0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest		1 1
Cardiac arrest neonatal		1 1
Cardio-respiratory arrest		2 1
Ventricular fibrillation		1 0
Cardiac disorders SOC TOTAL	1:	5 3

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear swelling	4	l ol
Ear disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Eye disorders		
Cataract conditions		
Cataract	1	0
Conjunctival and corneal bleeding and vascular disorders		
Conjunctival haemorrhage	1	0
Ocular bleeding and vascular disorders NEC		
Eye haemorrhage	1	0
Ocular disorders NEC		
Dark circles under eyes	1	0
Eye oedema	1	0
Eye swelling	1	0
Ocular discomfort	1	0
Ocular infections, inflammations and associated manifestations		
Ocular hyperaemia	1	0
Ocular nerve and muscle disorders		
Eye movement disorder	3	0
Gaze palsy	3	0
Strabismus	1	0
Ocular sensation disorders		
Photophobia	1	0
Pupil disorders		
Miosis	1	0
Mydriasis	1	0
Visual disorders NEC		
Vision blurred	1	0
Visual impairment and blindness (excl colour blindness)		
Visual impairment	1	0
Eve disorders SOC TOTAL	20	0

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	sion: MedDRA 25.0	
Reaction Name	Total	<u> Fatal</u>
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	46	6 0
Diarrhoea haemorrhagic	1	0
Dyspeptic signs and symptoms		
Dyspepsia	2	2 0
Faecal abnormalities NEC		
Abnormal faeces	4	· 0
Faecaloma	1	0
Faeces discoloured		
Faeces hard	1	0
Faeces pale	1	0
Mucous stools	8	s o
Flatulence, bloating and distension		
Abdominal distension	1	0
Flatulence	7	' 0
Gastrointestinal and abdominal pains (excl oral and throa	at)	
Abdominal pain		0
Abdominal pain upper	13	s o
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	11	0
Gastrooesophageal reflux disease	7	' o
Gastrointestinal disorders NEC		
Gastrointestinal disorder	2	<u> </u>
Gastrointestinal dyskinetic disorders		
Infant dyschezia	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	1	0
Gastrointestinal spastic and hypermotility disorders		
Frequent bowel movements	2	2 0
Gingival disorders, signs and symptoms NEC		
Gingival discolouration	1	0
Nausea and vomiting symptoms		
Nausea	1	0
Retching	1	0
Vomiting	42	2 0
Vomiting projectile	15	i 0
Non-site specific gastrointestinal haemorrhages		
Haematochezia	6	6 0
Oral dryness and saliva altered		
Salivary hypersecretion	1	0
Oral soft tissue swelling and oedema		
Lip swelling	2	<u> </u> 0
Salivary gland enlargements		
Salivary gland enlargement	1	0
Tongue signs and symptoms		
Protrusion tongue	1	0
Gastrointestinal disorders SOC TOTAL	202	

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Reaction Name		<u>Total</u>	Fatal
General disorders			
Asthenic conditions			
Asthenia		7	0
Decreased activity		1	0
Fatigue		4	0
Malaise		12	0
Body temperature altered			
Hyperthermia		1	0
Death and sudden death			
Death		4	4
Sudden death		4	4
Sudden infant death syndrome		4	3
Febrile disorders			
Pyrexia		125	0
Feelings and sensations NEC			
Chills		6	0
Feeling abnormal		1	0
Feeling cold		1	0
Feeling hot		4	0
Thirst decreased		2	0
Gait disturbances		_	ŭ
Gait disturbance		3	0
Gait inability		1	0
General signs and symptoms NEC		·	J
Condition aggravated		2	0
Crying		69	0
Developmental delay		2	0
Developmental regression		1	0
General physical health deterioration		1	0
Glassy eyes		3	0
High-pitched crying		10	0
Illness		3	0
Induration		2	0
Influenza like illness		1	0
Moaning		1	0
Multiple organ dysfunction syndrome		1	0
Peripheral swelling		17	0
Screaming		23	0
Secretion discharge		1	0
Swelling		6	0
Swelling face		4	0
Inflammations			J
Inflammation		8	0
Systemic inflammatory response syndrome		1	0
Injection site reactions			J
Injection site discolouration		1	0
Injection site induration		1	0
Injection site mass		2	0
Injection site pain		2 1	0
Injection site pruritus		1	0
Injection site reaction		1	0
Injection site swelling		2	0
Injection site vesicles		2 1	0
Oedema NEC			

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Oedema	1	0
Oedema peripheral	1	0
Pain and discomfort NEC		
Axillary pain	1	0
Discomfort	5	0
Pain	25	0
Tenderness	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	1	0
Drug ineffective	1	0
Vaccination failure	5	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	2	0
Vaccination site discomfort	1	0
Vaccination site erythema	12	0
Vaccination site haemorrhage	1	0
Vaccination site induration	2	0
Vaccination site inflammation	5	0
Vaccination site mass	11	0
Vaccination site pain	7	0
Vaccination site rash	4	0
Vaccination site swelling	9	0
Vaccination site vesicles	1	0
Vaccination site warmth	1	0
General disorders SOC TOTAL	444	11

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Reaction Name	Total	Fatal
Hepatic disorders		
Cholestasis and jaundice		
Jaundice cholestatic	1	0
Hepatocellular damage and hepatitis NEC		
Hepatitis	1	0
Hepatic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	9	0
Multiple allergies	1	0
Allergies to foods, food additives, drugs and other chemicals		
Allergy to vaccine	1	0
Food allergy	4	0
Milk allergy	3	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	10	0
Anaphylactic shock	1	0
Atopic disorders		
Atopy	1	0
Seasonal allergy	1	0
Immune and associated conditions NEC		
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	1	0
Immunodeficiency disorders NEC		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	34	1

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Reaction Name	MedDRA Version: MedDRA 25.0 Total	Fatal
	IOLAI	<u> гацаі</u>
Infections Bacterial infections NEC		
Cellulitis		
		1
Meningitis bacterial		•
Skin bacterial infection		0
Vaccination site cellulitis		0
Bordetella infections		
Pertussis	2	0
Central nervous system and spinal infections		
Meningitis		0
Meningitis aseptic	2	0
Ear infections		
Ear infection	1	1 0
Enteroviral infections NEC		
Meningitis enteroviral	1	1 0
Haemophilus infections		
Haemophilus infection	4	1
Meningitis haemophilus	1	0
Infections NEC		
Abscess		
Abscess limb	1	1 0
Infection	1	0
Vaccination site abscess	1	ı 0
Vaccination site infection	2	2 0
Lower respiratory tract and lung infections		
Lower respiratory tract infection	1	
Pneumonia	1	1 0
Pneumonia aspiration	1	0
Sepsis, bacteraemia, viraemia and fungaemia	a NEC	
Sepsis	1	0
Skin structures and soft tissue infections		
Eczema infected	1	-
Skin infection		3 0
Staphylococcal infections		
Staphylococcal infection	1	0
Upper respiratory tract infections		
Croup infectious	1	0
Nasopharyngitis	1	ı 0
Tonsillitis	1	ı 0
Urinary tract infections		
Urinary tract infection	2	2 0
Viral infections NEC		
Bronchiolitis		0
Viral rash		0
Infections SOC TOTAL	44	l o

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Reaction Name	Total	Fatal
Injuries		
Exposures associated with pregnancy, delivery and lactation		
Maternal exposure during breast feeding	1	0
Medication errors, product use errors and issues NEC		
Medication error	1	0
Wrong technique in product usage process	2	0
Muscle, tendon and ligament injuries		
Muscle injury	2	0
Non-site specific injuries NEC		
Wound secretion	1	0
Product administration errors and issues		
Accidental overdose	1	0
Inappropriate schedule of product administration	1	0
Incorrect dose administered	5	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	2	0
Product preparation errors and issues		
Product preparation issue	5	0
Product prescribing errors and issues		
Product prescribing error	1	0
Product storage errors and issues in the product use system		
Product storage error	1	0
Skin injuries NEC		
Contusion	7	0
Scratch	1	0
Skin injury	1	0
Injuries SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Investigations		
Blood gas and acid base analyses		
Oxygen saturation decreased	2	0
Heart rate and pulse investigations		
Heart rate decreased	1	0
Heart rate increased	1	0
Pulse abnormal	1	0
Hepatobiliary function diagnostic procedures		
Alanine aminotransferase increased	1	0
Immunoglobulin analyses		
Blood immunoglobulin G increased	2	0
Mineral and electrolyte analyses		
Blood magnesium decreased	1	0
Physical examination procedures and organ system status		
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	9	0
Breath sounds abnormal	1	0
Respiratory rate decreased	1	0
Respiratory rate increased	3	0
Protein analyses NEC		
C-reactive protein increased	2	0
Red blood cell analyses		
Haemoglobin decreased	1	0
Urinary tract function analyses NEC		
Urine output decreased	3	0
White blood cell analyses		
Lymphocyte count increased	1	0
Investigations SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Metabolic disorders		1 0.10.1
Appetite disorders		
Appetite disorder	1	0
Decreased appetite	25	0
Food refusal	2	0
Hypophagia	2	0
Increased appetite	1	0
Fluid intake decreased		
Fluid intake reduced	4	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Dairy intolerance	1	0
Food intolerance	2	0
General nutritional disorders NEC		
Feeding disorder	1	0
Food aversion	1	0
Poor feeding infant	20	0
Weight gain poor	1	0
Metabolic acidoses (excl diabetic acidoses)		
Lactic acidosis	1	0
Metabolic acidosis	1	0
Total fluid volume decreased		
Dehydration	1	0
Metabolic disorders SOC TOTAL	64	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Joint related disorders NEC		
Periarthritis	1	0
Joint related signs and symptoms		
Joint swelling	1	0
Muscle related signs and symptoms NEC		
Muscle spasms	4	0
Muscle twitching	3	0
Muscle tone abnormalities		
Floppy infant	17	0
Muscle rigidity	2	0
Muscle weakness conditions		
Muscular weakness	2	0
Musculoskeletal and connective tissue conditions NEC		
Infantile back arching	4	0
Limb mass	1	0
Musculoskeletal stiffness	4	0
Posture abnormal	1	0
Weight bearing difficulty	2	0
Musculoskeletal and connective tissue pain and discomfort		
Flank pain	1	0
Musculoskeletal pain	1	0
Pain in extremity	9	0
Soft tissue disorders NEC		
Groin pain	1	0
Muscle & tissue disorders SOC TOTAL	54	0

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Reaction Name	Total_	<u>Fatal</u>
Nervous system disorders		
Absence seizures		
Petit mal epilepsy	4	0
Coordination and balance disturbances		
Balance disorder	2	0
Nystagmus	1	0
Cortical dysfunction NEC		
Aphasia	1	0
Disturbances in consciousness NEC		
Depressed level of consciousness	1	0
Lethargy	8	0
Loss of consciousness	2	0
Postictal state	1	0
Somnolence	28	0
Syncope	3	0
Dyskinesias and movement disorders NEC		
Dyskinesia	8	0
Movement disorder	1	0
Psychomotor hyperactivity	1	0
Eye movement disorders		
VIth nerve paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	5	0
Headaches NEC		
Headache	2	0
Intellectual disabilities		
Intellectual disability	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	1	0
Mental impairment	1	0
Muscle tone abnormal		
Hypotonia	10	0
Narcolepsy and hypersomnia		
Hypersomnia	1	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurological signs and symptoms NEC		
Dizziness	1	0
Hyporesponsive to stimuli	3	0
Infant irritability	1	0
Myoclonus	1	0
Unresponsive to stimuli	27	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	16	
Muscle spasticity	1	0
Paralysis and paresis (excl cranial nerve)		
Paralysis	1	0
Seizures and seizure disorders NEC		
Epilepsy	1	0
Epileptic encephalopathy	1	0
Febrile convulsion	11	0
Infantile spasms	3	
Seizure	18	
Status epilepticus	1	0

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Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Sleep disturbances NEC		
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	1	0
Speech disorder	2	0
Tremor (excl congenital)		
Tremor	3	0
Nervous system disorders SOC TOTAL	177	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
Gestational age and weight conditions		
Poor weight gain neonatal	1	0
Pregnancy conditions SOC TOTAL	1	0

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Reaction Name	<u>Total</u>	Fatal
Product quality issues NEC		
Product quality issue	5	i o
null SOC TOTAL	5	l ol

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Earliest Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 25.0		
Reaction Name	<u>Total</u>	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	8	0
Behaviour disorder	1	0
Breath holding	3	0
Staring	4	0
Affect alterations NEC		
Flat affect	1	0
Anxiety disorders NEC		
Separation anxiety disorder	1	0
Anxiety symptoms		
Agitation	5	0
Anxiety	1	0
Nervousness	1	0
Behaviour and socialisation disturbances		
Personality change	1	0
Social avoidant behaviour	2	0
Cognitive and attention disorders and disturbances NEC		
Daydreaming	1	0
Communications disorders		
Communication disorder	1	0
Mutism	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	9	0
Middle insomnia	1	0
Dyssomnias		
Poor quality sleep	6	0
Emotional and mood disturbances NEC		
Anger	2	0
Emotional distress	4	0
Irritability	39	0
Mood altered	1	0
Fear symptoms and phobic disorders (incl social phobia)		
Phonophobia	1	0
Increased physical activity levels		
Restlessness	13	0
Mood alterations with depressive symptoms		
Decreased interest	1	0
Depressed mood	1	0
Mood disorders NEC		
Listless	3	0
Panic attacks and disorders		
Panic reaction	1	0
Parasomnias		
Sleep terror	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	2	0
Psychiatric symptoms NEC		
Decreased eye contact	1	0
Sleep disorders NEC		
Sleep disorder	7	0
Speech articulation and rhythm disturbances		
Dysphemia	1	0
Suicidal and self-injurious behaviour		

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Intentional self-injury	1	0
Tic disorders		
Tic	1	0
Psychiatric disorders SOC TOTAL	127	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal failure and impairment		
Acute kidney injury	1	0
Anuria	1	0
Renal & urinary disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive tract disorders NEC (excl neoplasms)		
Genital blister	1	0
Testicular and epididymal disorders NEC		
Testicular pain	1	0
Testicular swelling	1	0
Reproductive & breast disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Respiratory disorders	Tolai	гаш
Breathing abnormalities		
Apnoea	12	0
Dyspnoea	12	0
Hypopnoea	3	0
Irregular breathing	1	0
Respiration abnormal	3	0
Respiratory arrest	3	0
Respiratory distress	2	0
Tachypnoea	1	0
Bronchospasm and obstruction	1	U
Wheezing	3	0
Conditions associated with abnormal gas exchange	, , , , , , , , , , , , , , , , , , ,	U
Cyanosis central	1	0
Respiratory acidosis	1	0
Coughing and associated symptoms	'	U
Cough	11	0
Haemoptysis	1	0
Productive cough	3	0
Sputum discoloured	1	0
Laryngeal spasm, oedema and obstruction		J
Stridor	1	0
Lower respiratory tract signs and symptoms		
Hiccups	1	0
Nasal disorders NEC		
Epistaxis	2	0
Neonatal hypoxic conditions		
Brief resolved unexplained event	1	0
Infantile apnoea	3	0
Neonatal hypoxia	1	0
Respiratory signs and symptoms NEC		
Use of accessory respiratory muscles	1	0
Upper respiratory tract signs and symptoms		
Choking	1	0
Dysphonia	1	0
Oropharyngeal pain	2	0
Rhinorrhoea	2 4	0
Respiratory disorders SOC TOTAL	76	0

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	edDRA Version: MedDRA 25.0		
Reaction Name	<u>Tc</u>	<u>tal</u>	<u>Fatal</u>
Skin disorders			
Apocrine and eccrine gland disorders			
Cold sweat		2	0
Hyperhidrosis		3	0
Bullous conditions			
Blister		4	0
Dermatitis bullous		1	0
Pemphigoid		1	0
Dermal and epidermal conditions NEC			
Dry skin		4	0
Papule		3	0
Skin burning sensation		1	0
Skin discolouration		13	0
Skin disorder		1	0
Skin induration		1	0
Skin lesion		1	0
Skin plaque		1	0
Skin reaction		1	0
Skin warm		6	0
Skin weeping		1	0
Dermatitis and eczema			
Dermatitis		1	0
Dermatitis allergic		4	0
Dermatitis atopic		2	0
Dermatitis diaper		1	0
Eczema		12	0
Eczema infantile		1	0
Dermatitis ascribed to specific agent			
Palmar-plantar erythrodysaesthesia syndrome	e e	1	0
Erythemas		·	Ū
Erythema		34	0
Exfoliative conditions			·
Skin exfoliation		1	0
Pruritus NEC		·	·
Pruritus		7	0
Purpura and related conditions			·
Petechiae		13	0
Purpura		3	0
Rashes, eruptions and exanthems NEC		Ŭ	J
Rash		48	0
Rash erythematous		11	0
Rash macular		14	0
Rash papular		7	0
Rash pruritic		3	0
Rash vesicular		5	0
Skin and subcutaneous conditions NEC		J	O
Skin mass		1	0
Skin and subcutaneous tissue ulcerations			U
Skin erosion		1	0
Skin vasomotor conditions		'	U
Livedo reticularis		11	0
Lividity		1	0
Urticarias		ı	U
Urticaria		21	0
UTUCATIA		<u> </u>	U

Name: FOI 22/671 - 6-in-1 Vaccine Drug Analysis Print
In Date: 18-May-2022 Data Lock Date: 17-May-2022 18:30:04
Reaction Date: 27-Jan-2015 MedDRA Version: MedDRA 25.0 Report Run Date: 18-May-2022 Earliest Reaction Date: 27-Jan-2015

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Urticaria chronic	1	0
Urticaria pressure	1	0
Skin disorders SOC TOTAL	249	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Therapeutic procedures NEC		
Injection	1	0
Surgical & medical procedures SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
Arterial infections and inflammations		
Kawasaki's disease	1	1
Circulatory collapse and shock		
Circulatory collapse	2	0
Haemorrhages NEC		
Haemorrhage	1	0
Non-site specific necrosis and vascular insufficiency NEC		
Fibromuscular dysplasia	1	1
Peripheral vascular disorders NEC		
Cyanosis	11	0
Flushing	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	5	0
Poor peripheral circulation	1	0
Site specific vascular disorders NEC		
Pallor	41	0
Vascular hypertensive disorders NEC		
Hypertension	1	0
Vascular disorders SOC TOTAL	65	2
TOTAL REACTIONS FOR DRUG	1663	17
TOTAL REPORTS	585	
TOTAL FATAL OUTCOME REPORTS		17