

## Case Series Drug Analysis Print

### Name: Revaxis vaccine VAP

Report Run Date: 19-Feb-2024

Data Lock Date: 16-Feb-2024 18:30:04

Earliest Reaction Date: 01-May-1983

MedDRA Version: MedDRA 26.1

Revaxis vaccine VAP: All UK spontaneous reports for Revaxis vaccine up to and including 16/02/2024

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemias NEC</i></b>		
Anaemia	1	0
<b><i>Bleeding tendencies</i></b>		
Haemorrhagic disorder	1	0
<b><i>Coagulopathies</i></b>		
Coagulopathy	2	0
Disseminated intravascular coagulation	1	0
<b><i>Leukocytoses NEC</i></b>		
Leukocytosis	1	0
<b><i>Lymphatic system disorders NEC</i></b>		
Lymphadenitis	2	0
Lymphadenopathy	40	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Aplastic anaemia	2	1
Pancytopenia	1	0
<b><i>Neutropenias</i></b>		
Neutropenia	4	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenia	2	0
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>58</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	7	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
<i>Left ventricular failures</i>		
Left ventricular failure	1	1
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
Left ventricular dysfunction	1	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	2	0
Bradycardia	4	0
Tachycardia	23	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Supraventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>43</b>	<b>1</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Congenital disorders</b>		
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 21	1	0
<i>Congenital disorders NEC</i>		
Congenital cyst	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Syndactyly	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Plagiocephaly	1	0
<i>Neurological disorders congenital NEC</i>		
Tourette's disorder	1	0
<i>Oral cavity disorders congenital NEC</i>		
Tethered oral tissue	1	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Congenital skin dimples	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	3	0
Ear pain	4	0
Ear swelling	1	0
<i>Hearing losses</i>		
Deafness	3	0
Deafness neurosensory	1	0
Deafness unilateral	2	0
Hypoacusis	7	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear disorders NEC</i>		
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	7	0
Vertigo	14	0
Vertigo positional	2	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	1	0
<b>Ear disorders SOC TOTAL</b>	<b>47</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctivitis allergic	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
Eyelid oedema	2	0
Swelling of eyelid	6	0
<i>Ocular disorders NEC</i>		
Eye pain	14	0
Eye swelling	20	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	5	0
Eye pruritus	5	0
Ocular hyperaemia	8	0
<i>Ocular nerve and muscle disorders</i>		
Binocular eye movement disorder	1	0
Eye movement disorder	31	0
Gaze palsy	2	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	3	0
Photophobia	31	0
<i>Orbital infections, inflammations and irritations</i>		
Parophthalmia	1	0
<i>Pupil disorders</i>		
Mydriasis	11	0
Pupil fixed	2	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Retinal vasculitis	1	0
<i>Visual colour distortions</i>		
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	3	0
Photopsia	3	0
Vision blurred	36	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	1	0
Blindness	3	0
Blindness transient	3	0
Visual impairment	15	0
<b>Eye disorders SOC TOTAL</b>	<b>214</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Colitis (excl infective)</i>		
Colitis ulcerative	2	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	1	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	78	0
Diarrhoea haemorrhagic	1	0
<i>Faecal abnormalities NEC</i>		
Faeces pale	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	40	0
Abdominal pain lower	2	0
Abdominal pain upper	50	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	4	0
Gastrooesophageal reflux disease	4	0
Impaired gastric emptying	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	12	0
Anal incontinence	1	0
Dysphagia	13	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
Irritable bowel syndrome	2	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	367	0
Retching	2	0
Vomiting	234	0
Vomiting projectile	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	2	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	0
Salivary hypersecretion	1	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
Oral disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	4	0
Oral discomfort	1	0
Oral pain	3	0



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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Oral pruritus	2	0
Paraesthesia oral	16	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	26	0
Mouth swelling	3	0
<b><i>Salivary gland enlargements</i></b>		
Parotid gland enlargement	1	0
<b><i>Stomatitis and ulceration</i></b>		
Mouth ulceration	1	0
Stomatitis	1	0
<b><i>Tongue disorders</i></b>		
Glossitis	1	0
Tongue disorder	1	0
<b><i>Tongue signs and symptoms</i></b>		
Swollen tongue	11	0
Tongue coated	1	0
Tongue discolouration	1	0
Tongue movement disturbance	1	0
<b><i>Umbilical hernias</i></b>		
Umbilical hernia	2	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>910</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b>Administration site reactions NEC</b>		
Administration site bruise	1	0
<b>Application and instillation site reactions</b>		
Application site erythema	1	0
<b>Asthenic conditions</b>		
Asthenia	52	0
Chronic fatigue syndrome	3	0
Fatigue	152	0
Malaise	370	0
<b>Febrile disorders</b>		
Hyperpyrexia	2	0
Pyrexia	518	0
<b>Feelings and sensations NEC</b>		
Chills	95	0
Feeling abnormal	21	0
Feeling cold	23	0
Feeling hot	85	0
Feeling of body temperature change	21	0
Sensation of foreign body	2	0
Thirst	3	0
Thirst decreased	1	0
<b>Gait disturbances</b>		
Gait disturbance	9	0
Gait inability	5	0
<b>General signs and symptoms NEC</b>		
Condition aggravated	7	0
Crepitations	2	0
Crying	7	0
Developmental delay	1	0
Effusion	1	0
Exercise tolerance decreased	1	0
Illness	48	0
Induration	3	0
Influenza like illness	89	0
Irritability postvaccinal	1	0
Local reaction	24	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	76	0
Screaming	1	0
Swelling	42	0
Swelling face	26	0
<b>Inflammations</b>		
Inflammation	17	0
Systemic inflammatory response syndrome	2	0
<b>Infusion site reactions</b>		
Infusion site discomfort	1	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	3	0
Injection site bruising	3	0
Injection site coldness	1	0
Injection site discolouration	2	0
Injection site discomfort	1	0
Injection site erythema	34	0

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<b>General disorders</b> General disorders cont'd		
Injection site haemorrhage	3	0
Injection site hypersensitivity	1	0
Injection site induration	4	0
Injection site inflammation	8	0
Injection site irritation	1	0
Injection site mass	7	0
Injection site movement impairment	3	0
Injection site necrosis	1	0
Injection site nodule	1	0
Injection site pain	28	0
Injection site paraesthesia	1	0
Injection site pruritus	8	0
Injection site rash	12	0
Injection site reaction	18	0
Injection site swelling	24	0
Injection site urticaria	1	0
Injection site vesicles	1	0
Injection site warmth	5	0
<b>Mass conditions NEC</b>		
Cyst	1	0
Mass	4	0
<b>Oedema NEC</b>		
Face oedema	5	0
<b>Pain and discomfort NEC</b>		
Axillary pain	10	0
Chest discomfort	21	0
Chest pain	26	0
Discomfort	9	0
Facial pain	1	0
Pain	115	0
Tenderness	12	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	4	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	2	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	3	0
Vaccination site discomfort	1	0
Vaccination site eczema	1	0
Vaccination site erythema	24	0
Vaccination site induration	2	0
Vaccination site inflammation	5	0
Vaccination site joint pain	2	0
Vaccination site mass	2	0
Vaccination site movement impairment	3	0
Vaccination site nodule	1	0
Vaccination site pain	41	0
Vaccination site papule	1	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	2	0
Vaccination site rash	3	0
Vaccination site reaction	4	0
Vaccination site scab	1	0

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<b>General disorders</b> General disorders cont'd		
Vaccination site swelling	28	0
Vaccination site vesicles	1	0
Vaccination site warmth	6	0
<b>General disorders SOC TOTAL</b>	<b>2228</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Cholangitis sclerosing	1	0
<i><b>Cholestasis and jaundice</b></i>		
Jaundice	11	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	2	0
Hypertransaminasaemia	1	0
<i><b>Hepatic failure and associated disorders</b></i>		
Acute hepatic failure	1	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatomegaly	1	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Autoimmune hepatitis	1	0
Hepatitis acute	2	0
Liver injury	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>21</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergy to animal	1	0
Hypersensitivity	32	0
Mite allergy	1	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergic reaction to excipient	1	0
Allergy to vaccine	2	0
Food allergy	1	0
Reaction to excipient	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	57	0
Anaphylactic shock	2	0
Anaphylactoid reaction	1	0
<i><b>Atopic disorders</b></i>		
Seasonal allergy	1	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	2	0
<i><b>Immune and associated conditions NEC</b></i>		
Bacille Calmette-Guerin scar reactivation	1	0
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	1	0
Immune-mediated adverse reaction	1	0
Multisystem inflammatory syndrome in children	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>107</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis perforated	1	0
<b><i>Bacterial infections NEC</i></b>		
Arthritis bacterial	1	0
Cellulitis	10	0
Injection site cellulitis	3	0
Meningitis bacterial	1	0
Tonsillitis bacterial	1	0
<b><i>Bordetella infections</i></b>		
Pertussis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	1	0
Meningitis	1	0
Meningitis aseptic	1	0
Myelitis	1	0
<b><i>Corynebacteria infections</i></b>		
Corynebacterium infection	2	0
Diphtheria	1	0
<b><i>Ear infections</i></b>		
Ear infection	1	0
Labyrinthitis	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	3	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	1	0
<b><i>Flaviviral infections</i></b>		
Yellow fever vaccine-associated viscerotropic disease	1	0
<b><i>Hepatitis virus infections</i></b>		
Hepatitis A	1	0
<b><i>Herpes viral infections</i></b>		
Herpes simplex	1	0
Herpes zoster	1	0
<b><i>Infections NEC</i></b>		
Infection	3	0
Injection site abscess	1	0
Respiratory tract infection	1	0
Vestibulitis	1	0
<b><i>Influenza viral infections</i></b>		
Influenza	8	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	1	0
Lower respiratory tract infection	4	0
<b><i>Mumps viral infections</i></b>		
Mumps	1	0
<b><i>Muscle and soft tissue infections</i></b>		
Soft tissue infection	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Neutropenic sepsis	1	0
Sepsis	4	0
<b><i>Skin structures and soft tissue infections</i></b>		
Skin infection	3	0
<b><i>Staphylococcal infections</i></b>		
Staphylococcal abscess	1	0

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<b>Infections</b>		
Infections cont'd		
<b><i>Streptococcal infections</i></b>		
Pneumococcal sepsis	1	1
Streptococcal infection	1	0
<b><i>Upper respiratory tract infections</i></b>		
Nasopharyngitis	21	0
Pharyngitis	3	0
Rhinitis	2	0
Sinusitis	1	0
Tonsillitis	3	0
<b><i>Urinary tract infections</i></b>		
Urinary tract infection	1	0
<b><i>Vascular infections</i></b>		
Lymphangitis	1	0
<b><i>Viral infections NEC</i></b>		
Encephalitis viral	1	0
Meningitis viral	1	0
Viral diarrhoea	1	0
Viral infection	3	0
Viral pericarditis	1	0
<b>Infections SOC TOTAL</b>	<b>106</b>	<b>1</b>



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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure during pregnancy	10	0
Foetal exposure during pregnancy	8	0
Foetal exposure timing unspecified	1	0
Maternal exposure before pregnancy	2	0
<i><b>Gastrointestinal and hepatobiliary procedural complications</b></i>		
Procedural nausea	1	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Medication error	1	0
Vaccination error	1	0
Wrong technique in device usage process	1	0
<i><b>Muscle, tendon and ligament injuries</b></i>		
Epicondylitis	1	0
Muscle injury	1	0
<i><b>Nerve injuries NEC</b></i>		
Nerve injury	1	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	5	0
Traumatic haematoma	1	0
<i><b>Non-site specific procedural complications</b></i>		
Shunt malfunction	1	0
<i><b>Off label uses</b></i>		
Off label use	1	0
<i><b>Overdoses NEC</b></i>		
Overdose	2	0
<i><b>Poisoning and toxicity</b></i>		
Toxicity to various agents	1	0
<i><b>Product administration errors and issues</b></i>		
Expired product administered	4	0
Extra dose administered	4	0
Inappropriate schedule of product administration	1	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	2	0
Product dose omission issue	1	0
Wrong product administered	6	0
<i><b>Product preparation errors and issues</b></i>		
Product preparation error	1	0
<i><b>Product storage errors and issues in the product use system</b></i>		
Product storage error	1	0
<i><b>Reproductive system and breast injuries</b></i>		
Perineal injury	1	0
<i><b>Site specific injuries NEC</b></i>		
Head injury	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	10	0
Scratch	1	0
<i><b>Vaccination related complications</b></i>		
Immunisation reaction	4	0
<b>Injuries SOC TOTAL</b>	<b>77</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Blood gas and acid base analyses</i></b>		
Oxygen consumption increased	1	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose decreased	5	0
Blood glucose increased	2	0
<b><i>Cell marker analyses</i></b>		
Carbohydrate antigen 19-9 increased	1	0
<b><i>Chemistry analyses NEC</i></b>		
Inflammatory marker increased	1	0
<b><i>Coagulation and bleeding analyses</i></b>		
International normalised ratio increased	1	0
<b><i>ECG investigations</i></b>		
Electrocardiogram abnormal	1	0
<b><i>Foetal and neonatal diagnostic procedures</i></b>		
Foetal heart rate abnormal	1	0
Foetal monitoring abnormal	1	0
<b><i>Haematological analyses NEC</i></b>		
Red blood cell sedimentation rate increased	1	0
<b><i>Heart rate and pulse investigations</i></b>		
Heart rate decreased	2	0
Heart rate increased	11	0
Heart rate irregular	3	0
Pulse abnormal	18	0
Pulse absent	1	0
<b><i>Hepatobiliary function diagnostic procedures</i></b>		
Alanine aminotransferase increased	4	0
Aspartate aminotransferase increased	1	0
Blood bilirubin increased	3	0
Liver function test abnormal	4	0
Liver function test increased	1	0
Transaminases increased	1	0
<b><i>Investigations NEC</i></b>		
Quality of life decreased	1	0
<b><i>Mineral and electrolyte analyses</i></b>		
Blood iron decreased	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature	1	0
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	80	0
General physical condition abnormal	1	0
Respiratory rate increased	5	0
Weight decreased	3	0
Weight increased	1	0
<b><i>Platelet analyses</i></b>		
Platelet count increased	1	0
Platelet morphology abnormal	1	0
<b><i>Protein analyses NEC</i></b>		
C-reactive protein increased	3	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Vital capacity decreased	1	0
<b><i>Urinalysis NEC</i></b>		

# Case Series Drug Analysis Print

## Name: Revaxis vaccine VAP

Report Run Date: 19-Feb-2024  
 Earliest Reaction Date: 01-May-1983

Data Lock Date: 16-Feb-2024 18:30:04  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Blood urine present	3	0
<b><i>Vascular tests NEC (incl blood pressure)</i></b>		
Blood pressure abnormal	1	0
Blood pressure decreased	5	0
Blood pressure diastolic increased	1	0
Blood pressure increased	6	0
<b><i>Vitamin analyses</i></b>		
Vitamin D decreased	1	0
<b><i>White blood cell analyses</i></b>		
Lymphocyte count increased	1	0
Lymphocyte morphology abnormal	2	0
Neutrophil count abnormal	2	0
Neutrophil toxic granulation present	1	0
<b>Investigations SOC TOTAL</b>	<b>189</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	1	0
Decreased appetite	60	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Dairy intolerance	1	0
Food intolerance	1	0
Milk soy protein intolerance	1	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	2	0
Feeding disorder	2	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Glucose tolerance impaired	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	1	0
<i><b>Mixed acid-base disorders</b></i>		
Acidosis	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>71</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: Revaxis vaccine VAP

Report Run Date: 19-Feb-2024  
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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	3	0
Arthropathy	2	0
<b><i>Bone disorders NEC</i></b>		
Jaw disorder	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	1	0
Pain in jaw	2	0
Spinal pain	2	0
<b><i>Bursal disorders</i></b>		
Bursitis	1	0
<b><i>Connective tissue disorders NEC</i></b>		
Connective tissue disorder	1	0
Morphoea	1	0
Myofascitis	1	0
Polymyalgia rheumatica	1	0
<b><i>Joint related disorders NEC</i></b>		
Periarthritis	2	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	90	0
Joint effusion	1	0
Joint stiffness	7	0
Joint swelling	6	0
<b><i>Metabolic bone disorders</i></b>		
Osteoporosis	1	0
<b><i>Muscle infections and inflammations</i></b>		
Myositis	1	0
<b><i>Muscle pains</i></b>		
Myalgia	100	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle atrophy	2	0
Muscle fatigue	4	0
Muscle spasms	17	0
Muscle swelling	3	0
Muscle twitching	18	0
<b><i>Muscle tone abnormalities</i></b>		
Muscle rigidity	15	0
Trismus	5	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	31	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Growth retardation	1	0
Limb mass	1	0
Mastication disorder	1	0
Mobility decreased	3	0
Musculoskeletal stiffness	47	0
Posture abnormal	2	0
Weight bearing difficulty	1	0
<b><i>Musculoskeletal and connective tissue infections and inflammations NEC</i></b>		
Dactylitis	1	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	63	0
Limb discomfort	21	0

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Report Run Date: 19-Feb-2024  
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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	3	0
Neck pain	33	0
Pain in extremity	196	0
Rheumatic disorder	1	0
<b>Rheumatoid arthropathies</b>		
Rheumatoid arthritis	3	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	4	0
Groin pain	1	0
Neck mass	1	0
<b>Spondyloarthropathies</b>		
Ankylosing spondylitis	1	0
<b>Tendon disorders</b>		
Tendonitis	1	0
Tenosynovitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>707</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Histiocytoses</i>		
Histiocytosis	1	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Adenocarcinoma pancreas	1	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<b>Neoplasms SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b>Acute polyneuropathies</b>		
Guillain-Barre syndrome	5	0
<b>Central nervous system haemorrhages and cerebrovascular accidents</b>		
Cerebral haemorrhage	1	1
<b>Cerebrovascular venous and sinus thrombosis</b>		
Cerebral venous sinus thrombosis	1	0
<b>Chronic polyneuropathies</b>		
Chronic inflammatory demyelinating polyradiculoneuropathy	1	0
Demyelinating polyneuropathy	1	0
<b>Coma states</b>		
Coma	1	0
<b>Coordination and balance disturbances</b>		
Ataxia	3	0
Balance disorder	7	0
Cerebellar ataxia	1	0
Cerebellar syndrome	1	0
Coordination abnormal	2	0
Developmental coordination disorder	1	0
Dysstasia	2	0
<b>Cortical dysfunction NEC</b>		
Aphasia	2	0
Sensory processing disorder	1	0
<b>Demyelinating disorders NEC</b>		
Acute disseminated encephalomyelitis	4	0
<b>Disturbances in consciousness NEC</b>		
Altered state of consciousness	1	0
Consciousness fluctuating	1	0
Depressed level of consciousness	3	0
Lethargy	69	0
Loss of consciousness	38	0
Somnolence	55	0
Syncope	233	0
<b>Dyskinesias and movement disorders NEC</b>		
Dyskinesia	34	0
Hypokinesia	7	0
Movement disorder	1	0
Psychomotor hyperactivity	2	0
<b>Dystonias</b>		
Opisthotonus	2	0
<b>Encephalopathies NEC</b>		
Encephalopathy	1	0
<b>Facial cranial nerve disorders</b>		
Bell's palsy	4	0
Facial paralysis	2	0
Facial paresis	1	0
Facial spasm	1	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	3	0
<b>Headaches NEC</b>		
Cluster headache	1	0
Headache	546	0
Primary stabbing headache	1	0
Tension headache	3	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Intellectual disabilities</i></b>		
Intellectual disability	1	0
<b><i>Memory loss (excl dementia)</i></b>		
Amnesia	4	0
Memory impairment	2	0
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	3	0
Disturbance in attention	9	0
Judgement impaired	1	0
<b><i>Migraine headaches</i></b>		
Migraine	11	0
Migraine with aura	1	0
<b><i>Multiple sclerosis acute and progressive</i></b>		
Multiple sclerosis	1	0
<b><i>Muscle tone abnormal</i></b>		
Hypertonia	1	0
Hypotonia	6	0
<b><i>Myelitis (incl infective)</i></b>		
Myelitis transverse	1	0
<b><i>Narcolepsy and hypersomnia</i></b>		
Hypersomnia	7	0
<b><i>Nervous system disorders NEC</i></b>		
Brain stem syndrome	1	0
<b><i>Neurologic visual problems NEC</i></b>		
Tunnel vision	2	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Brain fog	1	0
Dizziness	452	0
Dizziness postural	4	0
Drooling	1	0
Head discomfort	6	0
Hyporesponsive to stimuli	1	0
Myoclonus	4	0
Neurological symptom	1	0
Presyncope	38	0
Unresponsive to stimuli	20	0
<b><i>Neuromuscular disorders NEC</i></b>		
Hypotonic-hyporesponsive episode	1	0
Muscle spasticity	1	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	5	0
Dysaesthesia	1	0
Formication	1	0
Hyperaesthesia	8	0
Hypoaesthesia	55	0
Paraesthesia	80	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Diplegia	2	0
Hemiparesis	2	0
Monoparesis	1	0
Monoplegia	1	0
Paralysis	3	0
Quadriparesis	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Peripheral neuropathies NEC</i></b>		
Neuropathy peripheral	3	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	5	0
Febrile convulsion	3	0
Myoclonic epilepsy	1	0
Seizure	35	0
Seizure like phenomena	4	0
Tonic clonic movements	3	0
Tonic convulsion	1	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	1	0
Dysgeusia	3	0
Electric shock sensation	1	0
Neuralgia	3	0
Sensory disturbance	3	0
Sensory loss	6	0
Taste disorder	1	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	10	0
Incoherent	1	0
Speech disorder	4	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Radiculitis brachial	4	0
<b><i>Tremor (excl congenital)</i></b>		
Intention tremor	1	0
Tremor	71	0
<b><i>Trigeminal disorders</i></b>		
Trigeminal neuralgia	2	0
<b>Nervous system disorders SOC TOTAL</b>	<b>1952</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	1	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	13	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Meconium in amniotic fluid	1	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
Foetal distress syndrome	4	0
Foetal hypokinesia	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
<i>Labour onset and length abnormalities</i>		
Prolonged labour	1	0
<i>Maternal complications of delivery NEC</i>		
Complication of delivery	1	0
<i>Maternal complications of pregnancy NEC</i>		
Complication of pregnancy	1	0
Ectopic pregnancy	1	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>30</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	3	0
<b><i>Adjustment disorders</i></b>		
Adjustment disorder	7	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	7	0
Anxiety	16	0
Nervousness	3	0
Stress	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	3	0
Indifference	1	0
Paranoia	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Mental fatigue	1	0
<b><i>Communications disorders</i></b>		
Communication disorder	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	17	0
Disorientation	19	0
<b><i>Deliria</i></b>		
Delirium	7	0
<b><i>Depressive disorders</i></b>		
Depression	1	0
<b><i>Dissociative states</i></b>		
Dissociation	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	13	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	2	0
<b><i>Eating disorders NEC</i></b>		
Eating disorder	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional disorder	4	0
Emotional distress	3	0
Irritability	3	0
Mood altered	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	1	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	11	0
Hallucination, visual	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	1	0
<b><i>Learning disorders</i></b>		
Learning disability	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	2	0
Tearfulness	2	0
<b><i>Mood disorders NEC</i></b>		
Affective disorder	1	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Listless	3	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	2	0
Panic reaction	3	0
<b><i>Parasomnias</i></b>		
Nightmare	1	0
<b><i>Personality disorders with dramatic behaviour (Cluster B)</i></b>		
Borderline personality disorder	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	1	0
<b><i>Psychiatric elimination disorders</i></b>		
Enuresis	2	0
<b><i>Psychotic disorder NEC</i></b>		
Acute psychosis	1	0
Psychotic disorder	2	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	12	0
<b><i>Somatic symptom disorders</i></b>		
Conversion disorder	1	0
Somatic symptom disorder	1	0
<b><i>Speech articulation and rhythm disturbances</i></b>		
Lack of spontaneous speech	1	0
<b><i>Stereotypies and automatisms</i></b>		
Bruxism	2	0
<b><i>Tic disorders</i></b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>171</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Dysuria	2	0
Incontinence	5	0
Mixed incontinence	1	0
Pollakiuria	1	0
Urinary incontinence	5	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis acute	1	0
Goodpasture's syndrome	1	0
<i><b>Nephritis NEC</b></i>		
Nephritis	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	2	0
Renal failure	1	0
<i><b>Renal failure complications</b></i>		
Azotaemia	1	0
<i><b>Renal obstructive disorders</b></i>		
Hydronephrosis	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	4	0
Haematuria	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>27</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Reproductive &amp; breast disorders</b>		
<i>Breast signs and symptoms</i>		
Breast tenderness	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Menstrual disorder	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	2	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	58	0
Grunting	2	0
Hyperventilation	8	0
Hypopnoea	3	0
Respiration abnormal	1	0
Respiratory arrest	2	0
Tachypnoea	1	0
<i><b>Bronchial conditions NEC</b></i>		
Fibrinous bronchitis	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	8	0
Bronchospasm	1	0
Obstructive airways disorder	1	0
Wheezing	11	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	19	0
Haemoptysis	1	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Vocal cord dysfunction	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	6	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	7	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	1	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Lung consolidation	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal hypoaesthesia	2	0
Pharyngeal inflammation	1	0
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	11	0
Tonsillar erythema	1	0
<i><b>Pleural infections and inflammations</b></i>		
Pleurisy	1	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Painful respiration	2	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	2	0
Choking	1	0
Dry throat	2	0
Dysphonia	4	0
Oropharyngeal discomfort	2	0
Oropharyngeal pain	61	0
Rhinorrhoea	4	0
Throat irritation	8	0
Throat tightness	13	0



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Reaction Name	Total	Fatal
<del>Respiratory disorders</del> Respiratory disorders cont'd		
<del>Respiratory disorders</del> SOC TOTAL	251	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	1	0
<b><i>Angioedemas</i></b>		
Angioedema	7	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	39	0
Hyperhidrosis	50	0
Night sweats	3	0
<b><i>Bullous conditions</i></b>		
Blister	1	0
Erythema multiforme	3	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	5	0
Macule	1	0
Pain of skin	3	0
Papule	1	0
Sensitive skin	1	0
Skin burning sensation	1	0
Skin discolouration	15	0
Skin discomfort	1	0
Skin induration	1	0
Skin lesion	1	0
Skin reaction	2	0
Skin swelling	1	0
Skin warm	16	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	2	0
Dermatitis allergic	6	0
Eczema	4	0
Skin irritation	2	0
<b><i>Erythemas</i></b>		
Erythema	98	0
<b><i>Exfoliative conditions</i></b>		
Exfoliative rash	1	0
Skin exfoliation	2	0
<b><i>Hyperpigmentation disorders</i></b>		
Solar lentigo	1	0
<b><i>Papulosquamous conditions</i></b>		
Pityriasis rosea	3	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	3	0
<b><i>Pigmentation changes NEC</i></b>		
Pigmentation disorder	1	0
<b><i>Pruritus NEC</i></b>		
Pruritus	56	0
<b><i>Purpura and related conditions</i></b>		
Ecchymosis	1	0
Henoch-Schonlein purpura	3	0
Petechiae	3	0
Purpura	3	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	147	0
Rash erythematous	9	0

# Case Series Drug Analysis Print

## Name: Revaxis vaccine VAP

Report Run Date: 19-Feb-2024  
 Earliest Reaction Date: 01-May-1983

Data Lock Date: 16-Feb-2024 18:30:04  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash macular	23	0
Rash maculo-papular	2	0
Rash papular	8	0
Rash pruritic	12	0
Rash rubelliform	1	0
<b>Skin and subcutaneous conditions NEC</b>		
Subcutaneous emphysema	2	0
<b>Skin hyperplasias and hypertrophies</b>		
Skin hypertrophy	1	0
<b>Skin vasculitides</b>		
Cutaneous vasculitis	1	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	6	0
<b>Urticarias</b>		
Urticaria	61	0
Urticaria chronic	2	0
<b>Skin disorders SOC TOTAL</b>	<b>617</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: Revaxis vaccine VAP

Report Run Date: 19-Feb-2024  
Earliest Reaction Date: 01-May-1983

Data Lock Date: 16-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Impaired work ability	2	0
Loss of personal independence in daily activities	1	0
<b>Social circumstances SOC TOTAL</b>	<b>3</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: Revaxis vaccine VAP

Report Run Date: 19-Feb-2024  
Earliest Reaction Date: 01-May-1983

Data Lock Date: 16-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Surgical &amp; medical procedures</b>		
<i>Induced abortions</i>		
Abortion induced	4	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	3	0
Vacuum extractor delivery	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>8</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: Revaxis vaccine VAP

Report Run Date: 19-Feb-2024  
Earliest Reaction Date: 01-May-1983

Data Lock Date: 16-Feb-2024 18:30:04  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Blood pressure disorders NEC</i>		
Labile blood pressure	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	6	0
Shock	3	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Peripheral embolism and thrombosis</i>		
Thrombophlebitis	2	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	6	0
Flushing	22	0
Hot flush	4	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	15	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	111	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	3	0
<i>Vascular hypotensive disorders</i>		
Hypotension	23	0
Orthostatic hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>204</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>8060</b>	<b>5</b>
<b>TOTAL REPORTS</b>	<b>2418</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>5</b>