

## Case Series Drug Analysis Print

### Name: Revaxis, DT IPV Vaccine

Report Run Date: 09-Apr-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 01-May-1983

MedDRA Version: MedDRA 23.1

Revaxis, DT IPV Vaccine: All UK spontaneous adverse drug reaction (ADR) reports for the Revaxis vaccine from 01/01/2011-31/12/2020

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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
<b><i>Lymphatic system disorders NEC</i></b>		
Lymphadenitis	2	0
Lymphadenopathy	25	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Aplastic anaemia	2	1
Pancytopenia	1	0
<b><i>Neutropenias</i></b>		
Neutropenia	1	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenia	1	0
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>37</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	5	0
<i>Myocardial disorders NEC</i>		
Left ventricular dysfunction	1	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	2	0
Tachycardia	10	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Supraventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>21</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i><b>Congenital disorders NEC</b></i>		
Congenital cyst	1	0
<i><b>Musculoskeletal and connective tissue disorders of limbs congenital</b></i>		
Syndactyly	1	0
<i><b>Musculoskeletal and connective tissue disorders of skull congenital</b></i>		
Plagiocephaly	1	0
<i><b>Neurological disorders congenital NEC</b></i>		
Tourette's disorder	1	0
<i><b>Skin and subcutaneous tissue disorders congenital NEC</b></i>		
Congenital skin dimples	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear discomfort	2	0
Ear pain	2	0
Ear swelling	1	0
<i><b>Hearing losses</b></i>		
Deafness	1	0
Deafness unilateral	1	0
Hypoacusis	6	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	1	0
<i><b>Inner ear disorders NEC</b></i>		
Vestibular disorder	1	0
<i><b>Inner ear signs and symptoms</b></i>		
Tinnitus	3	0
Vertigo	8	0
Vertigo positional	1	0
<i><b>Tympanic membrane disorders (excl infections)</b></i>		
Tympanic membrane perforation	1	0
<b>Ear disorders SOC TOTAL</b>	<b>28</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><b>Conjunctival infections, irritations and inflammations</b></i>		
Conjunctivitis allergic	1	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	1	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Erythema of eyelid	1	0
Eyelid oedema	2	0
Swelling of eyelid	5	0
<i><b>Ocular disorders NEC</b></i>		
Eye pain	8	0
Eye swelling	9	0
Periorbital swelling	1	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye irritation	4	0
Eye pruritus	1	0
Ocular hyperaemia	5	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	15	0
Gaze palsy	2	0
<i><b>Ocular sensation disorders</b></i>		
Asthenopia	1	0
Photophobia	23	0
<i><b>Orbital infections, inflammations and irritations</b></i>		
Parophthalmia	1	0
<i><b>Pupil disorders</b></i>		
Mydriasis	3	0
Pupil fixed	2	0
<i><b>Retinal, choroid and vitreous infections and inflammations</b></i>		
Retinal vasculitis	1	0
<i><b>Visual colour distortions</b></i>		
Xanthopsia	1	0
<i><b>Visual disorders NEC</b></i>		
Photopsia	2	0
Vision blurred	20	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness transient	1	0
Visual impairment	11	0
<b>Eye disorders SOC TOTAL</b>	<b>121</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 surface disorders</i>		
Tooth discolouration	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	55	0
Diarrhoea haemorrhagic	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	19	0
Abdominal pain lower	1	0
Abdominal pain upper	31	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastroesophageal 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	11	0
Dysphagia	11	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	2	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	253	0
Retching	2	0
Vomiting	164	0
Vomiting projectile	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	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	3	0
Oral discomfort	1	0
Oral pain	1	0
Oral pruritus	1	0
Paraesthesia oral	11	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	16	0
Mouth swelling	2	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	7	0
Tongue discolouration	1	0



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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Tongue movement disturbance	1	0
<b><i>Umbilical hernias</i></b>		
Umbilical hernia	2	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>619</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site bruise	1	0
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
<i>Asthenic conditions</i>		
Asthenia	34	0
Chronic fatigue syndrome	1	0
Fatigue	111	0
Malaise	272	0
<i>Febrile disorders</i>		
Hyperpyrexia	2	0
Pyrexia	406	0
<i>Feelings and sensations NEC</i>		
Chills	73	0
Feeling abnormal	18	0
Feeling cold	11	0
Feeling hot	50	0
Feeling of body temperature change	15	0
Sensation of foreign body	1	0
Thirst	2	0
<i>Gait disturbances</i>		
Gait disturbance	3	0
Gait inability	3	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	4	0
Crepitations	2	0
Crying	5	0
Developmental delay	1	0
Effusion	1	0
Exercise tolerance decreased	1	0
Illness	38	0
Induration	2	0
Influenza like illness	64	0
Irritability postvaccinal	1	0
Local reaction	6	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	49	0
Screaming	1	0
Swelling	21	0
Swelling face	18	0
<i>Inflammations</i>		
Inflammation	6	0
Systemic inflammatory response syndrome	2	0
<i>Infusion site reactions</i>		
Infusion site discomfort	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	2	0
Injection site bruising	3	0
Injection site coldness	1	0
Injection site discolouration	2	0
Injection site discomfort	1	0
Injection site erythema	14	0
Injection site hypersensitivity	1	0

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<b>General disorders</b> General disorders cont'd		
Injection site induration	2	0
Injection site inflammation	4	0
Injection site irritation	1	0
Injection site mass	7	0
Injection site movement impairment	1	0
Injection site necrosis	1	0
Injection site pain	13	0
Injection site pruritus	6	0
Injection site rash	6	0
Injection site reaction	3	0
Injection site swelling	12	0
Injection site vesicles	1	0
Injection site warmth	4	0
<b>Mass conditions NEC</b>		
Cyst	1	0
Mass	3	0
<b>Oedema NEC</b>		
Face oedema	3	0
<b>Pain and discomfort NEC</b>		
Axillary pain	7	0
Chest discomfort	9	0
Chest pain	15	0
Discomfort	9	0
Facial pain	1	0
Pain	84	0
Tenderness	6	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	1	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	22	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	37	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
Vaccination site swelling	26	0
Vaccination site vesicles	1	0
Vaccination site warmth	5	0
<b>General disorders SOC TOTAL</b>	<b>1576</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Bile duct infections and inflammations</i>		
Cholangitis sclerosing	1	0
<i>Cholestasis and jaundice</i>		
Jaundice	6	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatomegaly	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Liver injury	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>11</b>	<b>0</b>

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<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergy to animal	1	0
Hypersensitivity	19	0
Mite allergy	1	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergic reaction to excipient	1	0
Food allergy	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	38	0
Anaphylactic shock	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>		
Haemophagocytic lymphohistiocytosis	1	1
Immune-mediated adverse reaction	1	0
Immunisation reaction	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>68</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Abdominal and gastrointestinal infections</b></i>		
Appendicitis perforated	1	0
<i><b>Bacterial infections NEC</b></i>		
Arthritis bacterial	1	0
Cellulitis	6	0
Meningitis bacterial	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Encephalitis	1	0
Meningitis	1	0
<i><b>Corynebacteria infections</b></i>		
Corynebacterium infection	1	0
Diphtheria	1	0
<i><b>Ear infections</b></i>		
Ear infection	1	0
Labyrinthitis	1	0
<i><b>Epstein-Barr viral infections</b></i>		
Infectious mononucleosis	1	0
<i><b>Flaviviral infections</b></i>		
Yellow fever vaccine-associated viscerotropic disease	1	0
<i><b>Herpes viral infections</b></i>		
Herpes simplex	1	0
<i><b>Infections NEC</b></i>		
Infection	1	0
Injection site abscess	1	0
Respiratory tract infection	1	0
Vestibulitis	1	0
<i><b>Influenza viral infections</b></i>		
Influenza	7	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Bronchitis	1	0
Lower respiratory tract infection	3	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Neutropenic sepsis	1	0
Sepsis	3	0
<i><b>Skin structures and soft tissue infections</b></i>		
Skin infection	1	0
<i><b>Staphylococcal infections</b></i>		
Staphylococcal abscess	1	0
<i><b>Upper respiratory tract infections</b></i>		
Nasopharyngitis	15	0
Pharyngitis	2	0
Rhinitis	2	0
Sinusitis	1	0
Tonsillitis	3	0
<i><b>Urinary tract infections</b></i>		
Urinary tract infection	1	0
<i><b>Viral infections NEC</b></i>		
Encephalitis viral	1	0
Meningitis viral	1	0
Post viral fatigue syndrome	1	0
Viral infection	2	0
Viral pericarditis	1	0
<b>Infections SOC TOTAL</b>	<b>69</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	9	0
Foetal exposure during pregnancy	6	0
Maternal exposure before pregnancy	2	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Non-site specific injuries NEC</i>		
Fall	3	0
Traumatic haematoma	1	0
<i>Non-site specific procedural complications</i>		
Shunt malfunction	1	0
<i>Off label uses</i>		
Off label use	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Poisoning and toxicity</i>		
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Expired product administered	1	0
Extra dose administered	3	0
Product administered at inappropriate site	1	0
Wrong product administered	3	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	1	0
<i>Reproductive system and breast injuries</i>		
Perineal injury	1	0
<i>Skin injuries NEC</i>		
Contusion	8	0
<i>Vaccination related complications</i>		
Vaccination complication	2	0
<b>Injuries SOC TOTAL</b>	<b>48</b>	<b>0</b>

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<b>Investigations</b>		
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen consumption increased	1	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose decreased	3	0
Blood glucose increased	1	0
<i><b>Chemistry analyses NEC</b></i>		
Inflammatory marker increased	1	0
<i><b>Coagulation and bleeding analyses</b></i>		
International normalised ratio increased	1	0
<i><b>ECG investigations</b></i>		
Electrocardiogram abnormal	1	0
<i><b>Foetal and neonatal diagnostic procedures</b></i>		
Foetal monitoring abnormal	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate increased	5	0
Heart rate irregular	3	0
Pulse abnormal	6	0
<i><b>Investigations NEC</b></i>		
Quality of life decreased	1	0
<i><b>Liver function analyses</b></i>		
Alanine aminotransferase increased	1	0
Blood bilirubin increased	2	0
Liver function test abnormal	1	0
<i><b>Mineral and electrolyte analyses</b></i>		
Blood iron decreased	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	64	0
General physical condition abnormal	1	0
Respiratory rate increased	3	0
Weight decreased	2	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	1	0
<i><b>Respiratory and pulmonary function diagnostic procedures</b></i>		
Vital capacity decreased	1	0
<i><b>Urinalysis NEC</b></i>		
Blood urine present	3	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure decreased	2	0
Blood pressure diastolic increased	1	0
<i><b>Vitamin analyses</b></i>		
Vitamin D decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>111</b>	<b>0</b>



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<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	1	0
Decreased appetite	41	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	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>49</b>	<b>0</b>

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<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	1	0
Arthropathy	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	1	0
Spinal pain	2	0
<i><b>Bursal disorders</b></i>		
Bursitis	1	0
<i><b>Connective tissue disorders NEC</b></i>		
Connective tissue disorder	1	0
<i><b>Joint related disorders NEC</b></i>		
Periarthritis	2	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	61	0
Joint stiffness	3	0
Joint swelling	5	0
<i><b>Muscle infections and inflammations</b></i>		
Myositis	1	0
<i><b>Muscle pains</b></i>		
Myalgia	73	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle atrophy	1	0
Muscle fatigue	4	0
Muscle spasms	11	0
Muscle swelling	2	0
Muscle twitching	10	0
<i><b>Muscle tone abnormalities</b></i>		
Muscle rigidity	7	0
Trismus	3	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	19	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Growth retardation	1	0
Limb mass	1	0
Mobility decreased	2	0
Musculoskeletal stiffness	30	0
Posture abnormal	1	0
Weight bearing difficulty	1	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	47	0
Limb discomfort	14	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	4	0
Neck pain	25	0
Pain in extremity	151	0
Rheumatic disorder	1	0
<i><b>Rheumatoid arthropathies</b></i>		
Rheumatoid arthritis	3	0
<i><b>Soft tissue disorders NEC</b></i>		
Axillary mass	2	0
Neck mass	1	0
<i><b>Tendon disorders</b></i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders cont'd		
Muscle & tissue disorders		
Tenosynovitis	1	0
Muscle & tissue disorders SOC TOTAL	496	0

## Case Series Drug Analysis Print

### Name: Revaxis, DT IPV Vaccine

Report Run Date: 09-Apr-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 01-May-1983

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<b>Neoplasms SOC TOTAL</b>	<b>1</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: Revaxis, DT IPV Vaccine

Report Run Date: 09-Apr-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 01-May-1983

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	3	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coma states</i>		
Coma	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	3	0
Balance disorder	5	0
Cerebellar ataxia	1	0
Cerebellar syndrome	1	0
Coordination abnormal	2	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	3	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Consciousness fluctuating	1	0
Depressed level of consciousness	1	0
Lethargy	48	0
Loss of consciousness	24	0
Somnolence	41	0
Syncope	145	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	22	0
Hypokinesia	4	0
Psychomotor hyperactivity	2	0
<i>Dystonias</i>		
Opisthotonus	2	0
<i>Encephalopathies NEC</i>		
Encephalopathy	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	2	0
Facial paresis	1	0
<i>Headaches NEC</i>		
Headache	389	0
Tension headache	2	0
<i>Intellectual disabilities</i>		
Intellectual disability	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	3	0
Memory impairment	2	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Disturbance in attention	4	0
Judgement impaired	1	0
<i>Migraine headaches</i>		
Migraine	8	0
Migraine with aura	1	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	1	0

# Case Series Drug Analysis Print

## Name: Revaxis, DT IPV Vaccine

Report Run Date: 09-Apr-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 01-May-1983

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Muscle tone abnormal</i></b>		
Hypotonia	5	0
<b><i>Myelitis (incl infective)</i></b>		
Myelitis transverse	1	0
<b><i>Narcolepsy and hypersomnia</i></b>		
Hypersomnia	5	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>		
Dizziness	297	0
Dizziness postural	4	0
Head discomfort	3	0
Hyporesponsive to stimuli	1	0
Myoclonus	3	0
Presyncope	12	0
Unresponsive to stimuli	10	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	3	0
Formication	1	0
Hyperaesthesia	4	0
Hypoaesthesia	31	0
Paraesthesia	42	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Diplegia	1	0
Hemiparesis	1	0
Monoparesis	1	0
Monoplegia	1	0
Paralysis	2	0
Quadriparesis	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuropathy peripheral	3	0
Polyneuropathy	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	3	0
Febrile convulsion	3	0
Seizure	21	0
Seizure like phenomena	4	0
Tonic convulsion	1	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	1	0
Dysgeusia	2	0
Neuralgia	2	0
Sensory disturbance	2	0
Sensory loss	3	0
Taste disorder	1	0
<b><i>Sleep disturbances NEC</i></b>		
Poor quality sleep	1	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	7	0
Speech disorder	3	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		

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Earliest Reaction Date: 01-May-1983

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Radiculitis brachial	2	0
<b><i>Tremor (excl congenital)</i></b>		
Intention tremor	1	0
Tremor	44	0
<b><i>Trigeminal disorders</i></b>		
Trigeminal neuralgia	2	0
<b>Nervous system disorders SOC TOTAL</b>	<b>1270</b>	<b>0</b>

# Case Series Drug Analysis Print

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Earliest Reaction Date: 01-May-1983

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i><b>Abortions spontaneous</b></i>		
Abortion spontaneous	3	0
<i><b>Foetal complications NEC</b></i>		
Foetal distress syndrome	2	0
Foetal hypokinesia	1	0
<i><b>Haemorrhagic complications of pregnancy</b></i>		
Haemorrhage in pregnancy	1	0
<i><b>Labour onset and length abnormalities</b></i>		
Prolonged labour	1	0
<i><b>Maternal complications of pregnancy NEC</b></i>		
Complication of pregnancy	1	0
<i><b>Normal newborn status</b></i>		
Normal newborn	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>10</b>	<b>0</b>



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Earliest Reaction Date: 01-May-1983

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	2	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	5	0
Anxiety	11	0
Nervousness	1	0
Stress	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	1	0
Indifference	1	0
Paranoia	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Mental fatigue	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	15	0
Disorientation	15	0
<b><i>Deliria</i></b>		
Delirium	6	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	11	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	9	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	1	0
Tearfulness	1	0
<b><i>Mood disorders NEC</i></b>		
Affective disorder	1	0
Listless	2	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	1	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>Psychiatric elimination disorders</i></b>		

# Case Series Drug Analysis Print

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Report Run Date: 09-Apr-2021

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Earliest Reaction Date: 01-May-1983

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> Psychiatric disorders cont'd		
Enuresis	2	0
<b>Psychotic disorder NEC</b>		
Acute psychosis	1	0
Psychotic disorder	2	0
<b>Sleep disorders NEC</b>		
Sleep disorder	7	0
<b>Somatic symptom disorders</b>		
Somatic symptom disorder	1	0
<b>Stereotypies and automatisms</b>		
Bruxism	2	0
<b>Tic disorders</b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>124</b>	<b>0</b>

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Earliest Reaction Date: 01-May-1983

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Dysuria	2	0
Incontinence	1	0
Pollakiuria	1	0
Urinary incontinence	2	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis acute	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	1	0
Haematuria	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>14</b>	<b>0</b>

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Earliest Reaction Date: 01-May-1983

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<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	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Earliest Reaction Date: 01-May-1983

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	38	0
Grunting	2	0
Hyperventilation	2	0
Respiration abnormal	1	0
Tachypnoea	1	0
<i><b>Bronchial conditions NEC</b></i>		
Fibrinous bronchitis	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	5	0
Wheezing	8	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	15	0
Haemoptysis	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	3	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	5	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	7	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
Dry throat	1	0
Dysphonia	3	0
Oropharyngeal discomfort	2	0
Oropharyngeal pain	45	0
Rhinorrhoea	4	0
Throat irritation	6	0
Throat tightness	9	0
<b>Respiratory disorders SOC TOTAL</b>	<b>171</b>	<b>0</b>

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	1	0
<b><i>Angioedemas</i></b>		
Angioedema	4	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	20	0
Hyperhidrosis	31	0
Night sweats	1	0
<b><i>Bullous conditions</i></b>		
Erythema multiforme	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	5	0
Pain of skin	2	0
Papule	1	0
Sensitive skin	1	0
Skin discolouration	9	0
Skin discomfort	1	0
Skin induration	1	0
Skin lesion	1	0
Skin swelling	1	0
Skin warm	15	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	2	0
Dermatitis allergic	6	0
Eczema	1	0
Skin irritation	1	0
<b><i>Erythemas</i></b>		
Erythema	66	0
<b><i>Exfoliative conditions</i></b>		
Exfoliative rash	1	0
Skin exfoliation	1	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	2	0
<b><i>Pigmentation changes NEC</i></b>		
Pigmentation disorder	1	0
<b><i>Pruritus NEC</i></b>		
Pruritus	31	0
<b><i>Purpura and related conditions</i></b>		
Ecchymosis	1	0
Henoch-Schonlein purpura	2	0
Petechiae	2	0
Purpura	1	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	69	0
Rash erythematous	6	0
Rash macular	12	0
Rash maculo-papular	1	0
Rash papular	6	0
Rash pruritic	5	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Subcutaneous emphysema	2	0
<b><i>Skin hyperplasias and hypertrophies</i></b>		
Skin hypertrophy	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<i><b>Skin vasculitides</b></i>		
Cutaneous vasculitis	1	0
<i><b>Skin vasomotor conditions</b></i>		
Livedo reticularis	6	0
<i><b>Urticarias</b></i>		
Urticaria	36	0
Urticaria chronic	2	0
<b>Skin disorders SOC TOTAL</b>	<b>360</b>	<b>0</b>

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Induced abortions</i>		
Abortion induced	4	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	2	0
Vacuum extractor delivery	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>7</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Blood pressure disorders NEC</i>		
Labile blood pressure	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
Shock	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	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	3	0
Flushing	12	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	11	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	63	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	10	0
Orthostatic hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>112</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>5334</b>	<b>2</b>
<b>TOTAL REPORTS</b>	<b>1487</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>2</b>