

## Case Series Drug Analysis Print

Name: NeisVac-C Vaccine FOI 21/1063

Report Run Date: 07-Oct-2021  
Data Lock Date: 30-Sep-2021 18:30:04  
Earliest Reaction Date: 02-Sep-2000  
MedDRA Version: MedDRA 24.0

NeisVac-C Vaccine  
FOI 21/1063: All UK spontaneous reports received up until 30-Sep-2021 for the NeisVac-C Vaccine analysis print. A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	2	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	2	0
Tachycardia	8	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>13</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Acrodermatitis enteropathica	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Hearing losses</i>		
Deafness unilateral	1	0
Hypoacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Vertigo	1	0
Vertigo positional	1	0
<b>Ear disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Eyelid movement disorders</b></i>		
Eyelid ptosis	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye pain	2	0
Eye swelling	1	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Ocular hyperaemia	1	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	7	0
Strabismus	1	0
<i><b>Ocular sensation disorders</b></i>		
Photophobia	2	0
<i><b>Pupil disorders</b></i>		
Mydriasis	1	0
<i><b>Visual disorders NEC</b></i>		
Photopsia	1	0
Vision blurred	11	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness transient	1	0
Visual impairment	9	0
<b>Eye disorders SOC TOTAL</b>	<b>38</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	12	0
<i>Faecal abnormalities NEC</i>		
Mucous stools	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	14	0
Abdominal pain lower	1	0
Abdominal pain upper	8	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	4	0
Dysphagia	1	0
<i>Nausea and vomiting symptoms</i>		
Infantile spitting up	1	0
Infantile vomiting	2	0
Nausea	83	0
Vomiting	105	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue signs and symptoms</i>		
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	6	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	4	0
Tongue oedema	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>246</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	3	0
Fatigue	8	0
Malaise	67	0
<i><b>Death and sudden death</b></i>		
Death	1	1
Sudden infant death syndrome	1	1
<i><b>Febrile disorders</b></i>		
Pyrexia	53	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	11	0
Feeling abnormal	5	0
Feeling cold	4	0
Feeling hot	27	0
Feeling jittery	1	0
Feeling of body temperature change	2	0
<i><b>General signs and symptoms NEC</b></i>		
Crying	17	0
Developmental delay	1	0
Foaming at mouth	2	0
Glassy eyes	1	0
High-pitched crying	1	0
Illness	3	0
Influenza like illness	3	0
Local reaction	17	0
Peripheral swelling	32	0
Screaming	11	0
Secretion discharge	1	0
Swelling	17	0
Swelling face	6	0
<i><b>Inflammations</b></i>		
Inflammation	9	0
<i><b>Infusion site reactions</b></i>		
Infusion site discomfort	1	0
<i><b>Injection site reactions</b></i>		
Injection site discolouration	1	0
Injection site erythema	5	0
Injection site fibrosis	1	0
Injection site haemorrhage	1	0
Injection site inflammation	12	0
Injection site pain	2	0
Injection site rash	4	0
Injection site reaction	32	0
Injection site swelling	5	0
Injection site warmth	1	0
<i><b>Oedema NEC</b></i>		
Oedema peripheral	6	0
<i><b>Pain and discomfort NEC</b></i>		
Chest discomfort	3	0
Chest pain	2	0
Pain	10	0
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Vaccination failure	14	0



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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
<b><i>Vaccination site reactions</i></b>		
Vaccination site bruising	1	0
Vaccination site erythema	2	0
Vaccination site granuloma	1	0
Vaccination site mass	1	0
Vaccination site scar	1	0
Vaccination site swelling	3	0
<b>General disorders SOC TOTAL</b>	<b>413</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	5	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	15	0
Anaphylactic shock	2	0
Anaphylactoid reaction	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>25</b>	<b>0</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>		
Cellulitis	2	0
Meningitis bacterial	1	0
Pneumonia bacterial	1	0
Vaccination site cellulitis	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Meningitis	1	1
<i><b>Ear infections</b></i>		
Labyrinthitis	1	0
Otitis media	1	0
<i><b>Herpes viral infections</b></i>		
Eczema herpeticum	1	0
<i><b>Infections NEC</b></i>		
Abscess	2	0
Injection site abscess	1	0
<i><b>Neisseria infections</b></i>		
Meningitis meningococcal	11	0
Meningococcal infection	1	0
<i><b>Skin structures and soft tissue infections</b></i>		
Eczema infected	1	0
<i><b>Tuberculous infections</b></i>		
Erythema induratum	1	0
<i><b>Upper respiratory tract infections</b></i>		
Nasopharyngitis	6	0
<i><b>Viral infections NEC</b></i>		
Bronchiolitis	1	0
Viral infection	2	0
<b>Infections SOC TOTAL</b>	<b>36</b>	<b>1</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Injuries</b>		
<i>Medication errors, product use errors and issues NEC</i>		
Product use issue	1	0
<i>Non-site specific injuries NEC</i>		
Fall	4	0
<i>Off label uses</i>		
Off label use	1	0
<i>Product administration errors and issues</i>		
Incorrect route of product administration	1	0
Product administered to patient of inappropriate age	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
<b>Injuries SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Cerebrospinal fluid tests (excl microbiology)</b></i>		
CSF white blood cell count increased	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate decreased	2	0
Heart rate increased	3	0
Heart rate irregular	1	0
Pulse abnormal	9	0
Pulse absent	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	1	0
Body temperature increased	9	0
Breath sounds abnormal	1	0
Respiratory rate increased	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>30</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	6	0
<i>General nutritional disorders NEC</i>		
Poor feeding infant	5	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
<i>Zinc disorders</i>		
Zinc deficiency	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>13</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	3	0
Joint stiffness	2	0
<i><b>Muscle pains</b></i>		
Myalgia	3	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle disorder	3	0
Muscle spasms	5	0
Muscle tightness	2	0
Muscle twitching	21	0
<i><b>Muscle tone abnormalities</b></i>		
Floppy infant	6	0
Muscle rigidity	21	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	3	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Mobility decreased	1	0
Musculoskeletal stiffness	10	0
Posture abnormal	2	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	2	0
Neck pain	3	0
Pain in extremity	19	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>107</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	1	0
<i><b>Coordination and balance disturbances</b></i>		
Ataxia	1	0
Balance disorder	1	0
Nystagmus	1	0
<i><b>Disturbances in consciousness NEC</b></i>		
Depressed level of consciousness	4	0
Lethargy	11	0
Loss of consciousness	16	0
Somnolence	21	0
Syncope	183	0
<i><b>Dyskinesias and movement disorders NEC</b></i>		
Dyskinesia	7	0
<i><b>Dystonias</b></i>		
Opisthotonus	1	0
<i><b>Encephalopathies NEC</b></i>		
Encephalopathy	1	0
<i><b>Facial cranial nerve disorders</b></i>		
Bell's palsy	1	0
Facial paresis	1	0
<i><b>Generalised tonic-clonic seizures</b></i>		
Generalised tonic-clonic seizure	3	0
<i><b>Headaches NEC</b></i>		
Headache	100	0
<i><b>Increased intracranial pressure disorders</b></i>		
Intracranial pressure increased	1	0
<i><b>Mental impairment (excl dementia and memory loss)</b></i>		
Disturbance in attention	1	0
<i><b>Migraine headaches</b></i>		
Migraine	2	0
<i><b>Muscle tone abnormal</b></i>		
Hypotonia	12	0
<i><b>Narcolepsy and hypersomnia</b></i>		
Hypersomnia	1	0
<i><b>Neurological signs and symptoms NEC</b></i>		
Clonus	1	0
Dizziness	156	0
Drooling	2	0
Presyncope	8	0
Unresponsive to stimuli	10	0
<i><b>Neuromuscular disorders NEC</b></i>		
Hypotonic-hyporesponsive episode	1	0
<i><b>Paraesthesias and dysaesthesias</b></i>		
Hypoaesthesia	5	0
Paraesthesia	8	0
<i><b>Seizures and seizure disorders NEC</b></i>		
Epilepsy	4	0
Seizure	12	0
<i><b>Sensory abnormalities NEC</b></i>		
Complex regional pain syndrome	1	0
<i><b>Speech and language abnormalities</b></i>		
Speech disorder	2	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Tremor (excl congenital)</i></b>		
Tremor	13	0
<b>Nervous system disorders SOC TOTAL</b>	<b>593</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	2	0
Breath holding	2	0
Staring	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	1	0
Anxiety	1	0
Nervousness	5	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Disturbance in social behaviour	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	2	0
Disorientation	3	0
<b><i>Decreased physical activity levels</i></b>		
Catatonia	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional distress	2	0
Irritability	10	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination, visual	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	2	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	1	0
Tearfulness	2	0
<b><i>Mood disorders NEC</i></b>		
Listless	1	0
<b><i>Parasomnias</i></b>		
Sleep terror	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	1	0
<b><i>Psychiatric symptoms NEC</i></b>		
Decreased eye contact	2	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	2	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>44</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Urinary incontinence	7	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	3	0
Dyspnoea	11	0
Grunting	2	0
Hyperventilation	2	0
Hypopnoea	1	0
Respiratory arrest	3	0
<i><b>Bronchospasm and obstruction</b></i>		
Wheezing	1	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	1	1
<i><b>Coughing and associated symptoms</b></i>		
Cough	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	1	0
<i><b>Neonatal hypoxic conditions</b></i>		
Neonatal hypoxia	1	0
<i><b>Newborn respiratory disorders NEC</b></i>		
Respiratory disorder neonatal	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal swelling	2	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Dry throat	1	0
Oropharyngeal pain	4	0
Rhinorrhoea	1	0
Throat tightness	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>38</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Angioedemas</i>		
Angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	48	0
Hyperhidrosis	38	0
<i>Bullous conditions</i>		
Blister	2	0
Erythema multiforme	2	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Papule	1	0
Scab	1	0
Skin discolouration	5	0
Skin disorder	1	0
Skin lesion	1	0
Skin reaction	4	0
Skin warm	2	0
<i>Dermatitis and eczema</i>		
Dermatitis atopic	1	0
Eczema	5	0
Seborrhoeic dermatitis	1	0
Skin irritation	1	0
<i>Erythemas</i>		
Erythema	45	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Pruritus NEC</i>		
Pruritus	9	0
<i>Purpura and related conditions</i>		
Petechiae	9	0
Purpura	4	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	50	0
Rash erythematous	8	0
Rash macular	13	0
Rash maculo-papular	2	0
Rash papular	1	0
Rash pruritic	3	0
<i>Skin vasculitides</i>		
Vasculitic rash	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	3	0
<i>Urticarias</i>		
Urticaria	17	0
<b>Skin disorders SOC TOTAL</b>	<b>283</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Immobile	2	0
<b>Social circumstances SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	5	0
<i>Haemorrhages NEC</i>		
Haematoma	2	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	12	0
Flushing	12	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	3	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	139	0
<i>Vascular hypotensive disorders</i>		
Hypotension	6	0
Orthostatic hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>182</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>2088</b>	<b>4</b>
<b>TOTAL REPORTS</b>	<b>895</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>4</b>