

Drug Analysis Print

**Spontane Influenza virus indberetninger
(uden Pandemrix) indberettet efter 1/9 2004**

	Total	Fatal
Blood disorders		
<i>Coagulopathies</i>		
Disseminated intravascular coagulation	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenitis	1	0
Lymphadenopathy	1	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	4	0
Thrombotic thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	8	0

	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	2	0
<i>Heart failures NEC</i>		
Cardiac failure	1	1
Cardiac failure acute	1	1
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	2	0
<i>Noninfectious pericarditis</i>		
Pericarditis	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Bradycardia	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Ventricular fibrillation	1	0
Cardiac disorders SOC TOTAL	14	2

	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	2	0
Ear swelling	1	0
<i>Hearing losses</i>		
Deafness	1	0
Deafness unilateral	4	0
Hearing impaired	1	0
<i>Hyperacusia</i>		
Hyperacusis	4	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	6	0
Vertigo	2	0
Ear disorders SOC TOTAL	22	0

	Total	Fatal
Eye disorders		
<i>Blindness (excl colour blindness)</i>		
Amaurosis fugax	1	0
<i>Colour blindness (incl acquired)</i>		
Colour blindness acquired	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctivitis allergic	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	1	0
<i>Lacrimation disorders</i>		
Dry eye	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid oedema	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye oedema	1	0
Eye swelling	2	0
Ocular discomfort	1	0
Retinal disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	1	0
Ocular hyperaemia	2	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
<i>Ocular sensation disorders</i>		
Photophobia	2	0
<i>Orbital infections, inflammations and irritations</i>		
Parophthalmia	1	0
<i>Partial vision loss</i>		
Visual acuity reduced	1	0
<i>Refractive and accommodative disorders</i>		
Accommodation disorder	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
Visual impairment	4	0
Eye disorders SOC TOTAL	26	0

	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Colitis ischaemic	1	0
Colitis ulcerative	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	7	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	8	0
Abdominal pain lower	1	0
Abdominal pain upper	3	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	2	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
Dysphagia	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	2	0
<i>Large intestinal stenosis and obstruction</i>		
Large intestinal obstruction	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	20	0
Vomiting	16	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
<i>Oral soft tissue pain and paraesthesia</i>		
Paraesthesia oral	4	0
<i>Oral soft tissue signs and symptoms</i>		
Burning mouth syndrome	1	0
Hypoaesthesia oral	1	0
Oral discomfort	1	0
Oral mucosal blistering	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
Mouth swelling	1	0
<i>Rectal inflammations NEC</i>		
Proctitis haemorrhagic	1	0
Gastrointestinal disorders SOC TOTAL	81	0

	Total	Fatal
General disorders		
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Application and instillation site reactions</i>		
Application site pain	1	0
Application site pruritus	1	0
<i>Asthenic conditions</i>		
Asthenia	7	0
Fatigue	35	0
Malaise	30	0
<i>Death and sudden death</i>		
Death	2	2
Sudden death	5	5
<i>Febrile disorders</i>		
Pyrexia	49	0
<i>Feelings and sensations NEC</i>		
Chills	9	0
Feeling abnormal	2	0
Feeling cold	2	0
Feeling hot	4	0
<i>Gait disturbances</i>		
Abasia	3	0
Gait disturbance	1	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Influenza like illness	31	0
Local reaction	2	0
Local swelling	4	0
Peripheral swelling	13	0
Swelling	4	0
<i>Inflammations</i>		
Papillitis	1	0
<i>Injection site reactions</i>		
Injection site erythema	18	0
Injection site induration	1	0
Injection site inflammation	2	0
Injection site irritation	2	0
Injection site joint movement impairment	1	0
Injection site pain	12	0
Injection site pruritus	6	0
Injection site rash	4	0
Injection site reaction	5	0
Injection site swelling	11	0
Injection site urticaria	2	0
Injection site warmth	4	0
<i>Oedema NEC</i>		
Face oedema	1	0
Localised oedema	1	0
Oedema	3	0
Oedema peripheral	2	0
<i>Pain and discomfort NEC</i>		
Axillary pain	1	0
Chest discomfort	3	0

		Total	Fatal
General disorders	General disorders cont'd		
	Chest pain	2	0
	Discomfort	3	0
	Facial pain	2	0
	Pain	14	0
	Tenderness	5	0
	<i>Vaccination site reactions</i>		
	Vaccination site pain	3	0
	Vaccination site swelling	1	0
General disorders SOC TOTAL		317	7

	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatic steatosis	1	0
Liver injury	2	0
Hepatic disorders SOC TOTAL	6	0

	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergy to metals	1	0
Hypersensitivity	8	0
<i>Anaphylactic responses</i>		
Anaphylactic reaction	5	0
Anaphylactic shock	3	0
<i>Immune and associated conditions NEC</i>		
Multiple chemical sensitivity	1	0
Immune system disorders SOC TOTAL	18	0

	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Pneumonia bacterial	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	3	1
Encephalomyelitis	1	1
Myelitis	1	0
<i>Chlamydial infections</i>		
Chlamydial infection	1	0
<i>Eye and eyelid infections</i>		
Eye infection	1	0
<i>Herpes viral infections</i>		
Herpes simplex	2	0
Herpes virus infection	2	0
Herpes zoster	3	0
<i>Infections NEC</i>		
Infection	1	0
<i>Influenza viral infections</i>		
Influenza	8	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	1	0
Bronchitis	1	0
Pneumonia	7	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Streptococcal infections</i>		
Erysipelas	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	10	0
Pharyngitis	3	0
<i>Viral infections NEC</i>		
Eye infection viral	1	0
Post viral fatigue syndrome	2	0
Viral infection	1	0
Infections SOC TOTAL	52	2

	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	3	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
Wound	1	0
Injuries SOC TOTAL	6	0

	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Base excess decreased	1	0
Blood lactic acid increased	1	0
Oxygen saturation decreased	1	0
PCO2 increased	1	0
pH body fluid increased	1	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF protein increased	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	2	0
Heart rate irregular	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin M increased	1	0
Monoclonal immunoglobulin present	1	0
<i>Liver function analyses</i>		
Hepatic enzyme increased	2	0
<i>Mineral and electrolyte analyses</i>		
Blood bicarbonate decreased	1	0
Blood potassium increased	1	0
<i>Neurologic diagnostic procedures</i>		
Romberg test positive	1	0
<i>Physical examination procedures and organ system status</i>		
Weight decreased	3	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	4	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
Investigations SOC TOTAL	25	0

	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	2	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Food intolerance	1	0
Metabolic disorders SOC TOTAL	3	0

	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
Arthritis reactive	2	0
<i>Bone related signs and symptoms</i>		
Pain in jaw	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	3	0
<i>Joint related disorders NEC</i>		
Periarthritis	2	0
Rotator cuff syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	35	0
Joint stiffness	2	0
Joint swelling	5	0
<i>Muscle pains</i>		
Myalgia	33	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle disorder	1	0
Muscle fatigue	1	0
Muscle spasms	4	0
Muscle twitching	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	8	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	5	0
Limb discomfort	1	0
Musculoskeletal pain	15	0
Neck pain	6	0
Pain in extremity	21	0
<i>Musculoskeletal and connective tissue signs and symptoms NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	4	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0
Muscle & tissue disorders SOC TOTAL	155	0

	Total	Fatal
Neoplasms		
<i>Lymphoplasmacytoid lymphomas/immunocytomas</i>		
Lymphoplasmacytoid lymphoma/immunocytoma	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	1	0
Neoplasms SOC TOTAL	3	0

	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Hyperreflexia	1	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	6	0
Miller Fisher syndrome	1	0
Polyneuropathy	3	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem thrombosis	1	0
Cerebral haemorrhage	1	0
Cerebral thrombosis	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	4	0
Coordination abnormal	3	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	1	0
Loss of consciousness	2	0
Somnolence	1	0
Syncope	3	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	1	0
Movement disorder	1	0
<i>Encephalitis NEC</i>		
Encephalitis post immunisation	1	0
<i>Facial cranial nerve disorders</i>		
Facial nerve disorder	1	0
Facial paresis	8	0
VIIIth nerve paralysis	4	0
<i>Headaches NEC</i>		
Headache	30	0
<i>Hypoglossal nerve disorders</i>		
Hypoglossal nerve disorder	1	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	6	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Disturbance in attention	5	0
<i>Migraine headaches</i>		
Migraine	1	0
<i>Mononeuropathies</i>		
Peripheral nerve lesion	1	0
Peroneal nerve palsy	3	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	1	0
<i>Muscle tone abnormal</i>		

	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Hypotonia	1	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	1	0
Narcolepsy	1	0
Neurologic visual problems NEC		
Visual field defect	1	0
Neurological signs and symptoms NEC		
Dizziness	30	0
Head discomfort	1	0
Neurological symptom	1	0
Presyncope	3	0
Olfactory nerve disorders		
Anosmia	2	0
Parosmia	1	0
Optic nerve disorders NEC		
Optic neuritis	1	0
Paraesthesias and dysaesthesias		
Burning sensation	1	0
Dysaesthesia	1	0
Hypoaesthesia	4	0
Paraesthesia	27	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	2	0
Monoparesis	1	0
Monoplegia	1	0
Paralysis	1	0
Paresis	1	0
Peripheral neuropathies NEC		
Neuritis	2	0
Peripheral sensory neuropathy	2	0
Seizures and seizure disorders NEC		
Febrile convulsion	1	0
Status epilepticus	1	0
Sensory abnormalities NEC		
Ageusia	1	0
Dysgeusia	3	0
Neuralgia	4	0
Restless legs syndrome	1	0
Sensory disturbance	2	0
Sensory loss	2	0
Sleep disturbances NEC		
Poor quality sleep	2	0
Speech and language abnormalities		
Aphonia	2	0
Dysarthria	1	0
Speech disorder	1	0
Spinal cord and nerve root disorders NEC		
Myelopathy	1	0
Radiculitis	3	0
Transient cerebrovascular events		
Transient ischaemic attack	1	0

	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
<i>Tremor (excl congenital)</i>		
Tremor	2	0
<i>Trigeminal disorders</i>		
Facial neuralgia	1	0
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	217	0

	Total	Fatal
Pregnancy conditions		
<i>Hypertension associated disorders of pregnancy</i>		
HELLP syndrome	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	1	0
Pregnancy conditions SOC TOTAL	2	0

	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Anxiety	1	0
<i>Confusion and disorientation</i>		
Confusional state	5	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Claustrophobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mental disorders NEC</i>		
Mental status changes	1	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	1	0
Sleep attacks	1	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	1	0
Suicide attempt	1	0
Psychiatric disorders SOC TOTAL	22	0

	Total	Fatal
Renal & urinary disorders		
<i>Bladder disorders NEC</i>		
Bladder disorder	2	0
<i>Renal failure and impairment</i>		
Anuria	1	0
Renal failure	2	0
Renal impairment	1	0
Renal & urinary disorders SOC TOTAL	6	0

	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	1	0
Reproductive & breast disorders SOC TOTAL	2	0

	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	9	0
Respiratory distress	1	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	3	0
Obstructive airways disorder	1	0
<i>Coughing and associated symptoms</i>		
Cough	12	0
Productive cough	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngeal oedema	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal oedema	1	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
Respiratory paralysis	1	1
<i>Respiratory signs and symptoms NEC</i>		
Suffocation feeling	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dysphonia	2	0
Oropharyngeal pain	3	0
Rhinorrhoea	3	0
Sneezing	2	0
Respiratory disorders SOC TOTAL	49	1

	Total	Fatal
Skin disorders		
<i>Alopecias</i>		
Alopecia	1	0
<i>Angioedemas</i>		
Angioedema	3	0
Swelling face	4	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	2	0
Hyperhidrosis	4	0
Night sweats	1	0
<i>Bullous conditions</i>		
Blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Pain of skin	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	5	0
Dermatitis contact	1	0
Eczema	4	0
<i>Dermatitis ascribed to specific agent</i>		
Drug reaction with eosinophilia and systemic symptoms	1	0
<i>Erythemas</i>		
Erythema	12	0
Rash erythematous	1	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
Pityriasis rosea	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	12	0
Pruritus generalised	3	0
Rash pruritic	4	0
<i>Psoriatic conditions</i>		
Psoriasis	1	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	13	0
Rash generalised	9	0
Rash macular	1	0
Rash vesicular	2	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin ulcer	1	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	1	0
<i>Urticarias</i>		
Urticaria	21	0
Skin disorders SOC TOTAL	115	0

	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Walking disability	2	0
Social circumstances SOC TOTAL	2	0

	Total	Fatal
Surgical & medical procedures		
<i>Respiratory tract therapeutic procedures NEC</i>		
Respiratory therapy	1	0
<i>Therapeutic procedures NEC</i>		
Off label use	1	0
Surgical & medical procedures SOC TOTAL	2	0

	Total	Fatal
Vascular disorders		
<i>Arterial inflammations</i>		
Temporal arteritis	1	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
<i>Non-site specific vascular disorders NEC</i>		
Hyperaemia	1	0
<i>Peripheral vascular disorders NEC</i>		
Hot flush	3	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	2	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	3	0
<i>Vascular hypotensive disorders</i>		
Hypotension	3	0
Orthostatic hypotension	1	0
<i>Vasculitides NEC</i>		
Rheumatoid vasculitis	1	1
Vascular disorders SOC TOTAL	17	1
TOTAL REACTIONS FOR DRUG	1170	13
TOTAL REPORTS	384	
TOTAL FATAL OUTCOME REPORTS		13