

Case Series Drug Analysis Print

Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013 - 16Oct2014

Report Run Date: 20-Oct-2014
Data Lock Date: 16-Oct-2014 19:00:06
Earliest Reaction Date: 28-Oct-2009
MedDRA Version: MedDRA 17.0

Vaxigrip, Fluarix,
Inflexal V og
Influenzavaccine
01Sep2013: Alle cases for Vaxigrip, Fluarix, Inflexal V og
Influenzavaccination pr. 01Sep2013 og frem

Case Series Drug Analysis Print

Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013

Report Run Date: 20-Oct-2014

Data Lock Date: 16-Oct-2014 19:00:06

Earliest Reaction Date: 28-Oct-2009

MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	1	0
<i>Thrombocytopenias</i>		
Thrombotic thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	2	0

Case Series Drug Analysis Print

Name: Vaxigrip, Fluarix, Inflexal V og Influenzacvaccine
01Sep2013

Report Run Date: 20-Oct-2014

Data Lock Date: 16-Oct-2014 19:00:06

Earliest Reaction Date: 28-Oct-2009

MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
Cardiac disorders SOC TOTAL	4	0

Case Series Drug Analysis Print

Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013

Report Run Date: 20-Oct-2014

Data Lock Date: 16-Oct-2014 19:00:06

Earliest Reaction Date: 28-Oct-2009

MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear swelling	1	0
<i>Hearing losses</i>		
Hearing impaired	1	0
<i>Hyperacusia</i>		
Hyperacusis	2	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	3	0
Vertigo	1	0
Ear disorders SOC TOTAL	8	0

Case Series Drug Analysis Print

**Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013**

Report Run Date: 20-Oct-2014
Earliest Reaction Date: 28-Oct-2009

Data Lock Date: 16-Oct-2014 19:00:06
MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Eye disorders		
<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 swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	1	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Visual disorders NEC</i>		
Visual impairment	1	0
Eye disorders SOC TOTAL	7	0

Case Series Drug Analysis Print

**Name: Vaxigrip, Fluarix, Inflexal V og Influenzacvaccine
01Sep2013**

Report Run Date: 20-Oct-2014
Earliest Reaction Date: 28-Oct-2009

Data Lock Date: 16-Oct-2014 19:00:06
MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1	0
Abdominal pain upper	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	3	0
Vomiting	1	0
<i>Oral soft tissue pain and paraesthesia</i>		
Paraesthesia oral	1	0
<i>Oral soft tissue signs and symptoms</i>		
Burning mouth syndrome	1	0
Hypoaesthesia oral	1	0
Oral discomfort	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
Oedema mouth	1	0
Gastrointestinal disorders SOC TOTAL	12	0

Case Series Drug Analysis Print

**Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013**

Report Run Date: 20-Oct-2014
Earliest Reaction Date: 28-Oct-2009

Data Lock Date: 16-Oct-2014 19:00:06
MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	2	0
Fatigue	8	0
Malaise	6	0
<i>Death and sudden death</i>		
Death	1	1
<i>Febrile disorders</i>		
Pyrexia	4	0
<i>Feelings and sensations NEC</i>		
Chills	1	0
Feeling abnormal	2	0
Feeling cold	1	0
<i>General signs and symptoms NEC</i>		
Influenza like illness	6	0
Local reaction	1	0
Local swelling	1	0
<i>Injection site reactions</i>		
Injection site erythema	4	0
Injection site joint movement impairment	1	0
Injection site pain	1	0
Injection site swelling	1	0
<i>Oedema NEC</i>		
Oedema	1	0
Oedema peripheral	1	0
<i>Pain and discomfort NEC</i>		
Discomfort	1	0
Pain	2	0
Tenderness	2	0
<i>Vaccination site reactions</i>		
Vaccination site pain	1	0
General disorders SOC TOTAL	48	1

Case Series Drug Analysis Print

Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013

Report Run Date: 20-Oct-2014
Earliest Reaction Date: 28-Oct-2009

Data Lock Date: 16-Oct-2014 19:00:06
MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	2	0
<i>Anaphylactic responses</i>		
Anaphylactic reaction	1	0
Anaphylactic shock	1	0
<i>Immune and associated conditions NEC</i>		
Multiple chemical sensitivity	1	0
Immune system disorders SOC TOTAL	5	0

Case Series Drug Analysis Print

Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013

Report Run Date: 20-Oct-2014
Earliest Reaction Date: 28-Oct-2009

Data Lock Date: 16-Oct-2014 19:00:06
MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Pneumonia bacterial	1	0
<i>Herpes viral infections</i>		
Herpes simplex	2	0
<i>Influenza viral infections</i>		
Influenza	1	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	1	0
<i>Upper respiratory tract infections</i>		
Pharyngitis	1	0
<i>Viral infections NEC</i>		
Post viral fatigue syndrome	1	0
Infections SOC TOTAL	7	0

Case Series Drug Analysis Print

Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013

Report Run Date: 20-Oct-2014

Data Lock Date: 16-Oct-2014 19:00:06

Earliest Reaction Date: 28-Oct-2009

MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Investigations		
<i>Heart rate and pulse investigations</i>		
Heart rate increased	1	0
<i>Physical examination procedures and organ system status</i>		
Weight decreased	1	0
Investigations SOC TOTAL	2	0

Case Series Drug Analysis Print

Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013

Report Run Date: 20-Oct-2014

Data Lock Date: 16-Oct-2014 19:00:06

Earliest Reaction Date: 28-Oct-2009

MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Food intolerance	1	0
Metabolic disorders SOC TOTAL	1	0

Case Series Drug Analysis Print

**Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013**

Report Run Date: 20-Oct-2014
Earliest Reaction Date: 28-Oct-2009

Data Lock Date: 16-Oct-2014 19:00:06
MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	2	0
<i>Joint related disorders NEC</i>		
Periarthritis	1	0
Rotator cuff syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	7	0
Joint stiffness	1	0
<i>Muscle pains</i>		
Myalgia	5	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Musculoskeletal pain	2	0
Neck pain	1	0
Pain in extremity	2	0
Muscle & tissue disorders SOC TOTAL	26	0

Case Series Drug Analysis Print

**Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013**

Report Run Date: 20-Oct-2014
Earliest Reaction Date: 28-Oct-2009

Data Lock Date: 16-Oct-2014 19:00:06
MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
Polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	1	0
Movement disorder	1	0
<i>Facial cranial nerve disorders</i>		
Vllth nerve paralysis	1	0
<i>Headaches NEC</i>		
Headache	5	0
<i>Memory loss (excl dementia)</i>		
Memory impairment	3	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	1	0
<i>Migraine headaches</i>		
Migraine	1	0
<i>Mononeuropathies</i>		
Peroneal nerve palsy	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	4	0
Presyncope	1	0
<i>Paraesthesias and dysaesthesias</i>		
Paraesthesia	4	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	1	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	1	0
Neuralgia	2	0
Sensory disturbance	1	0
<i>Tremor (excl congenital)</i>		
Tremor	1	0
Nervous system disorders SOC TOTAL	35	0

Case Series Drug Analysis Print

Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013

Report Run Date: 20-Oct-2014

Data Lock Date: 16-Oct-2014 19:00:06

Earliest Reaction Date: 28-Oct-2009

MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
Psychiatric disorders SOC TOTAL	2	0

Case Series Drug Analysis Print

Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013

Report Run Date: 20-Oct-2014

Data Lock Date: 16-Oct-2014 19:00:06

Earliest Reaction Date: 28-Oct-2009

MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	3	0
<i>Upper respiratory tract signs and symptoms</i>		
Dysphonia	1	0
Respiratory disorders SOC TOTAL	4	0

Case Series Drug Analysis Print

**Name: Vaxigrip, Fluarix, Inflexal V og Influenzacvaccine
01Sep2013**

Report Run Date: 20-Oct-2014
Earliest Reaction Date: 28-Oct-2009

Data Lock Date: 16-Oct-2014 19:00:06
MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Angioedemas</i>		
Angioedema	1	0
Swelling face	1	0
<i>Apocrine and eccrine gland disorders</i>		
Hyperhidrosis	2	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
<i>Erythemas</i>		
Erythema	3	0
Rash erythematous	1	0
<i>Pruritus NEC</i>		
Pruritus	4	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	5	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	1	0
<i>Urticarias</i>		
Urticaria	4	0
Skin disorders SOC TOTAL	24	0

Case Series Drug Analysis Print

Name: Vaxigrip, Fluarix, Inflexal V og Influenzavaccine
01Sep2013

Report Run Date: 20-Oct-2014

Data Lock Date: 16-Oct-2014 19:00:06

Earliest Reaction Date: 28-Oct-2009

MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Walking disability	1	0
Social circumstances SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: Vaxigrip, Fluarix, Inflexal V og Influenzacvaccine
01Sep2013

Report Run Date: 20-Oct-2014

Data Lock Date: 16-Oct-2014 19:00:06

Earliest Reaction Date: 28-Oct-2009

MedDRA Version: MedDRA 17.0

Reaction Name	Total	Fatal
Vascular disorders		
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Orthostatic hypotension	1	0
Vascular disorders SOC TOTAL	3	0
TOTAL REACTIONS FOR DRUG	191	1
TOTAL REPORTS	46	
TOTAL FATAL OUTCOME REPORTS		1