Report Run Date: 01-Jul-2015

Data Lock Date: 26-Jun-2015 19:00:15

Earliest Reaction Date: 21-Sep-2012 MedDRA Version: MedDRA 18.0

HPV after 31st July

Administration after 09/2012

2012:

Reaction Name	Total	Fatal
Blood disorders		
Lymphatic system disorders NEC		
Lymphadenopathy	1	0
Blood disorders SOC TOTAL	1	0

Reaction Name	Total	Fatal
Cardiac disorders		
Rate and rhythm disorders NEC		
Postural orthostatic tachycardia syndrome	1	0
Cardiac disorders SOC TOTAL	1	l ol

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Reaction Name	Total	Fatal
Eye disorders		
Choroid and vitreous structural change, deposit and degeneration		
Vitreous floaters	1	0
Ocular disorders NEC		
Eye disorder	1	0
Eye pain	1	0
Eye swelling	1	0
Ocular discomfort	1	0
Visual disorders NEC		
Visual impairment	1	0
Eve disorders SOC TOTAL	6	0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	1	0
Abdominal pain upper	2	0
Nausea and vomiting symptoms		
Nausea	12	0
Vomiting	4	0
Oral soft tissue swelling and oedema		
Lip swelling	1	0
Tongue signs and symptoms		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	21	0

Reaction Name	 Total	Fatal
General disorders		
Asthenic conditions		
Chronic fatigue syndrome	1	0
Fatigue	3	0
Malaise	8	0
Febrile disorders		
Pyrexia	19	0
Feelings and sensations NEC		
Chills	2	0
Feeling abnormal	1	0
Feeling hot	1	0
Gait disturbances		
Gait disturbance	1	0
General signs and symptoms NEC		
Peripheral swelling	2	0
Injection site reactions		
Injection site hypoaesthesia	1	0
Injection site pain	1	0
Injection site swelling	2	0
Pain and discomfort NEC		
Chest discomfort	1	0
Chest pain	2	0
Pain	4	0
General disorders SOC TOTAL	49	0

Reaction Name	Total	Fatal
Immune system disorders		
Anaphylactic responses		
Anaphylactic reaction	2	0
Immune system disorders SOC TOTAL	2	l ol

Reaction Name	Total	Fatal
Infections		
Abdominal and gastrointestinal infections		
Appendicitis	1	0
Eye and eyelid infections		
Hordeolum	1	0
Infections SOC TOTAL	2	0

Reaction Name	Total	Fatal
Injuries		
Maladministrations		
Drug administered at inappropriate site	1	0
Injuries SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Investigations		
Physical examination procedures and organ system status		
Body temperature increased	1	0
Reproductive hormone analyses		
Oestradiol decreased	1	0
Investigations SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	1	0
General nutritional disorders NEC		
Abnormal loss of weight	1	0
Feeding disorder	1 1	0
Metabolic disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Joint related signs and symptoms		
Arthralgia	2	0
Joint effusion	1	0
Muscle pains		
Myalgia	2	0
Muscle related signs and symptoms NEC		
Muscle spasms	1	0
Muscle weakness conditions		
Muscular weakness	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	2	0
Limb discomfort	1	0
Pain in extremity	6	0
Muscle & tissue disorders SOC TOTAL	16	0

Reaction Name	Total	Fatal
Nervous system disorders		
Disturbances in consciousness NEC		
Lethargy	1	0
Somnolence	2	0
Syncope	4	0
Dyskinesias and movement disorders NEC		
Hypokinesia	2	0
Facial cranial nerve disorders		
VIIth nerve paralysis	1	0
Headaches NEC		
Headache	12	0
Narcolepsy and hypersomnia		
Narcolepsy	1	0
Neurological signs and symptoms NEC		
Dizziness	7	0
Paraesthesias and dysaesthesias		
Hyperaesthesia	2	0
Hypoaesthesia	2	0
Paraesthesia	2	0
Seizures and seizure disorders NEC		
Seizure	2	0
Sensory abnormalities NEC		
Sensory disturbance	2	0
Sleep disturbances NEC		
Sudden onset of sleep	1	0
Tremor (excl congenital)		
Tremor	1	0
Nervous system disorders SOC TOTAL	42	

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Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	1	0
Anxiety symptoms		
Agitation	1	0
Anxiety	2	0
Behaviour and socialisation disturbances		
Aggression	1	0
Paranoia	1	0
Fear symptoms and phobic disorders (incl social phobia)		
Fear of death	1	0
Mood disorders NEC		
Listless	1	0
Psychotic disorder NEC		
Psychotic disorder	1	0
Sleep disorders NEC		
Sleep disorder	1	0
Psychiatric disorders SOC TOTAL	l 10	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Cervix disorders NEC		
Uterine cervix atrophy	1	0
Menstruation with decreased bleeding		
Amenorrhoea	1	0
Menstruation delayed	1	0
Reproductive & breast disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	3	0
Respiratory distress	1	0
Bronchospasm and obstruction		
Wheezing	1	0
Coughing and associated symptoms		
Cough	1	0
Upper respiratory tract signs and symptoms		
Choking sensation	1	0
Oropharyngeal pain	3	0
Throat irritation	1	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	12	<u>.</u> l o

Reaction Name	Tota	ıЩ	Fatal
Skin disorders			
Alopecias			
Alopecia totalis		1	0
Angioedemas			
Swelling face		2	0
Apocrine and eccrine gland disorders			
Cold sweat		1	0
Hyperhidrosis		_1	0
Bullous conditions			
Erythema multiforme		_1	0
Dermal and epidermal conditions NEC			
Pain of skin		2	0
Skin discolouration		2	0
Dermatitis and eczema			
Dermatitis allergic		1	0
Erythemas			
Erythema		2	0
Photosensitivity and photodermatosis condi	tions		
Photosensitivity reaction		2	0
Pruritus NEC			
Pruritus generalised		1	0
Purpura and related conditions			
Petechiae		1	C
Rashes, eruptions and exanthems NEC			
Rash		4	C
Rash generalised		2	C
Urticarias			
Urticaria		2	C
Skin disorders SOC TOTAL		<u>25</u>	(

Reaction Name	Total	Fatal
Vascular disorders		
Peripheral vascular disorders NEC		
Flushing	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	1	0
Vascular disorders SOC TOTAL	2	0
TOTAL REACTIONS FOR DRUG	198	0
TOTAL REPORTS	61	