Report Run Date: 01-Jul-2015

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

Earliest Reaction Date: 13-Oct-2009 MedDRA Version: MedDRA 18.0

HPV after 31st July Administration before 09/2012

2012:

Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	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	0

Reaction Name	Total	Fatal
Ear disorders		
Hearing losses		
Deafness	1	0
Ear disorders SOC TOTAL	1	0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastric ulcers and perforation		
Gastritis erosive	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain upper	1	0
Nausea and vomiting symptoms		
Vomiting	1	0
Gastrointestinal disorders SOC TOTAL	3	l o

Edition Flores 10 Oct 2000	Model at voicion: Model at 10:0		
Reaction Name		Total	Fatal
General disorders			
Asthenic conditions			
Asthenia		3	0
Fatigue		4	0
Malaise		3	0
Febrile disorders			
Pyrexia		2	0
Feelings and sensations NEC			
Feeling abnormal		1	0
Thirst		1	0
Gait disturbances			
Abasia		1	0
Gait disturbance		1	0
General signs and symptoms NEC			
General physical health deterioration		1	0
Influenza like illness		1	0
Pain and discomfort NEC			
Pain		6	0
General disorders SOC TOTAL		24	0

Reaction Name	Total	Fatal
Hepatic disorders		
Cholestasis and jaundice		
Jaundice	1	0
Hepatocellular damage and hepatitis NEC		
Autoimmune hepatitis	1	0
Hepatic disorders SOC TOTAL	2	0

Reaction Name	Total	Fatal
Infections		
Infections NEC		
Infection susceptibility increased	1	0
Viral infections NEC		
Post viral fatigue syndrome	1	0
Infections SOC TOTAL	2	0

Reaction Name	Total	Fatal
Investigations		
Endocrine analyses and imaging NEC		
Hormone level abnormal	1	0
Physical examination procedures and organ system status		
Weight decreased	2	0
Investigations SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Diabetes mellitus (incl subtypes)		
Type 1 diabetes mellitus	1	0
Metabolic disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Joint related signs and symptoms		
Arthralgia	2	0
Joint stiffness	1	0
Muscle pains		
Myalgia	1	0
Muscle related signs and symptoms NEC		
Muscle spasms	1	0
Muscle twitching	1	0
Musculoskeletal and connective tissue pain and discomfort		
Pain in extremity	2	0
Musculoskeletal and connective tissue signs and symptoms NEC		
Back disorder	1	0
Musculoskeletal stiffness	1	0
Muscle & tissue disorders SOC TOTAL	10	0

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Reaction Name		<u>Total</u>	Fatal
Nervous system disorders			
Coordination and balance disturbances			
Coordination abnormal		1	0
Cortical dysfunction NEC			
Aphasia		1	0
Disturbances in consciousness NEC			
Lethargy		2	0
Somnolence		1	0
Syncope		3	0
Dyskinesias and movement disorders NEC			
Hypokinesia		1	0
Headaches NEC			
Headache		2	0
Nervous system disorders NEC			
Nervous system disorder		1	0
Neurologic visual problems NEC			
Visual field defect		1	0
Neurological signs and symptoms NEC			
Dizziness		1	0
Paraesthesias and dysaesthesias			
Hypoaesthesia		1	0
Paraesthesia		1	0
Seizures and seizure disorders NEC			
Seizure		2	0
Sensory abnormalities NEC			
Complex regional pain syndrome		1	0
Sensory loss		1	0
Speech and language abnormalities			
Aphonia		1	0
Nervous system disorders SOC TOTAL		21	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
Anxiety symptoms		
Anxiety	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	1	0
Emotional and mood disturbances NEC		
Irritability	1	0
Mood alterations with depressive symptoms		
Depressive symptom	1	0
Psychiatric disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Urinary tract signs and symptoms NEC		
Polyuria	1	0
Renal & urinary disorders SOC TOTAL	1	l o

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	1	0
Menstruation irregular		0
Menstruation with decreased bleeding		
Amenorrhoea	2	0
Menstruation delayed	1	0
Menstruation with increased bleeding		
Menorrhagia	1	0
Ovarian and fallopian tube cysts and neoplasms		
Ovarian cyst	1	0
Ovarian and fallopian tube disorders NEC		
Ovarian failure	1	0
Vulvovaginal disorders NEC		
Vaginal ulceration	1	0
Reproductive & breast disorders SOC TOTAL	g	0

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	1	0
Coughing and associated symptoms		
Cough	1	0
Upper respiratory tract signs and symptoms		
Oropharyngeal pain	2	0
Respiratory disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Skin disorders		
Apocrine and eccrine gland disorders		
Hyperhidrosis	1	0
Dermal and epidermal conditions NEC		
Skin discolouration	1	0
Skin disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Social circumstances		
Disability issues		
Bedridden	1	0
Social circumstances SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
Site specific vascular disorders NEC		
Pallor	1	0
Vascular disorders SOC TOTAL	1	0
TOTAL REACTIONS FOR DRUG	91	0
TOTAL REPORTS	15	