

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
045850	Prophylaxis	Gardasil	.5 ml	Rash Erythema multiforme
046029	Prophylaxis	Gardasil	.5 ml	Muscle rigidity Seizure Hypotonia Eye movement disorder
046374	Prophylaxis	Gardasil	.5 ml	Urticaria Pruritus
046961	Prophylaxis	Gardasil		Injection site erythema Pruritus Hypersensitivity Erythema
046962	Prophylaxis	Gardasil	.5 ml	Ocular hyperaemia Pallor Dizziness Flushing Erythema Feeling hot Hypersensitivity
046982	Prophylaxis	Gardasil	.5 ml	Syncope
046983	Prophylaxis	Gardasil	.5 ml	Dizziness Headache
047014	Prophylaxis	Gardasil	.5 ml	Peripheral coldness Cyanosis
047022	Prophylaxis	Gardasil	.5 ml	Rash Vomiting Periorbital oedema Dizziness
047024	Prophylaxis	Gardasil	.5 ml	Syncope
047025	Prophylaxis	Gardasil	.5 ml	Syncope
047030	Prophylaxis	Gardasil	.5 ml	Tremor Dizziness Nausea
047031	Prophylaxis	Gardasil	.5 ml	Panic attack Hyperventilation
047039	Prophylaxis	Gardasil		Pain in extremity Abdominal discomfort Oropharyngeal pain
047052	Prophylaxis	Gardasil	.5 ml	Urticaria
047067	Prophylaxis	Gardasil	.5 ml	Syncope
047068	Prophylaxis	Gardasil	.5 ml	Syncope
047073	Prophylaxis	Gardasil	.5 ml	Abdominal discomfort Chest discomfort Throat tightness
047074	Prophylaxis	Gardasil	.5 ml	Syncope Bradycardia Hypotension
047075	Prophylaxis	Gardasil		Cyanosis Peripheral coldness Cold sweat
047077	Prophylaxis	Gardasil	.5 ml	Hypoaesthesia Pain in extremity Gait disturbance Chest discomfort Dizziness Myalgia Groin pain
047082	Prophylaxis	Gardasil		Paraesthesia Paresis
047096	Prophylaxis	Gardasil		Chronic fatigue syndrome Viral infection Lethargy Somnolence Dysstasia Blood alkaline phosphatase

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HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Fatigue Dizziness Dizziness Pallor Headache Joint swelling Rash Arthralgia Irritable bowel syndrome
047097	Prophylaxis	Gardasil	.5 ml	Myalgia Lethargy Headache
047101	Prophylaxis	Gardasil	.5 ml	Presyncope Mydriasis Dizziness Fatigue Visual impairment Photopsia
047103	Prophylaxis	Gardasil		Anaphylactic reaction Swollen tongue
047104	Prophylaxis	Gardasil		Hypersensitivity Angioedema
047105	Prophylaxis	Gardasil		Headache Fatigue
047109	Prophylaxis	Gardasil	.5 ml	Hyperventilation Syncope Tetany
047111	Prophylaxis	Gardasil	.5 ml	Anaphylactic reaction Hypotension Rash maculo-papular Tachycardia Erythema
047114	Prophylaxis	Gardasil	.5 ml	Urticaria Hypersensitivity
047118	Prophylaxis	Gardasil		Hypoaesthesia Hyperventilation Paraesthesia Tetany Joint stiffness Muscle twitching Anxiety
047123	Prophylaxis	Gardasil		Hypersensitivity Rash erythematous Flushing Headache
047127		Gardasil	1 Dosage forms	Muscular weakness Chest pain Back pain Dizziness Abdominal pain upper Fatigue Dyspnoea Paraesthesia Paraesthesia Muscle tightness Pain in extremity
047133		Gardasil		Fatigue Lethargy Somnolence
047134	Prophylaxis	Gardasil		Syncope
047146	Prophylaxis	Gardasil		Blood glucose increased Ketonuria Asthenia
047156	Prophylaxis	Gardasil	.5 ml	Vomiting
047157	Prophylaxis	Gardasil	.5 ml	Rash

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HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Headache Asthenia Nausea Syncope Anxiety
047159	Prophylaxis	Gardasil	.5 ml	Polydipsia Thirst
047160	Prophylaxis	Gardasil	.5 ml	Asthenia
047161	Prophylaxis	Gardasil	.5 ml	Clonus Syncope
047162	Prophylaxis	Gardasil	.5 ml	Dizziness
047190	Prophylaxis	Gardasil		Livedo reticularis Throat irritation Asthenia Dizziness Hypersensitivity
047192	Prophylaxis	Gardasil	.5 ml	Dizziness Nausea Gait disturbance
047194	Prophylaxis	Gardasil		Seizure
2010-000002	Prophylaxis	Gardasil		Fatigue Headache Dizziness Dizziness Pallor Somnolence
2010-000020	Prophylaxis	Gardasil	.5 ml	Injection site reaction Contusion Peripheral swelling Nausea Fatigue
2010-000034	Prophylaxis	Gardasil		Urticaria
2010-000035	Prophylaxis	Gardasil	.5 ml	Headache Fatigue Malaise
2010-000052	Prophylaxis	Gardasil		Pruritus Rash erythematous Nausea
2010-000053	Prophylaxis	Gardasil	.5 ml	Dizziness Decreased appetite Feeling cold Chills
2010-000055	Prophylaxis	Gardasil Per Cent		Syncope Nausea Asthenia Fatigue Malaise
2010-000070	Prophylaxis	Gardasil		Dizziness Crying Emotional distress Cough Flushing Stridor Hyperventilation Tetany Malaise
2010-000071	Prophylaxis	Gardasil		Headache Pain in extremity Pain in extremity Rash Photophobia Fatigue Feeling hot Pallor
2010-000073	Prophylaxis	Gardasil		Peripheral swelling

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HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2010-000189	Prophylaxis	Gardasil		Alopecia Visual impairment Vision blurred Abdominal pain upper Diarrhoea
2010-000531	Prophylaxis	Gardasil		Syncope Headache
2010-000578		Gardasil		Hypersensitivity Urticaria Urticaria Pruritus
2010-000588	Prophylaxis	Gardasil	.5 ml	Asthenia Headache Malaise Somnolence Diarrhoea Headache
2010-000791	Prophylaxis	Gardasil	.5 ml	Anaphylactic reaction Throat tightness Dizziness Urticaria Cough Cyanosis central
2010-000792	Prophylaxis	Gardasil	.5 ml	Migraine Dizziness Depressed level of consciousness Nausea Hypoaesthesia Pulse abnormal Photophobia Dysarthria
2010-000793	Prophylaxis	Gardasil		Syncope Loss of consciousness Asthenia Disorientation Urinary incontinence Abdominal pain upper Nausea Pyrexia Headache Influenza like illness Dizziness Muscular weakness Cyanosis Dyspnoea Back pain Pain in extremity Myalgia
2010-000837	Prophylaxis	Gardasil		Lip swelling Malaise Hypersensitivity
2010-000852	Prophylaxis	Gardasil	.5 ml	Anaphylactic reaction Dizziness Pallor Tachycardia Tachypnoea Anxiety Wheezing Pulse abnormal Stridor
2010-000884	Prophylaxis	Gardasil	.5 ml	Syncope Headache
2010-000927	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-000929	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-000931	Prophylaxis	Gardasil		Paraesthesia

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HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Pyrexia
2010-000940	Prophylaxis	Gardasil		Headache Dizziness Urticaria
2010-000962	Prophylaxis	Gardasil		Headache Flushing
2010-000968	Prophylaxis	Gardasil		Abdominal discomfort
2010-000969	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-000971	Prophylaxis	Gardasil	.5 ml	Pain in extremity
2010-000972	Prophylaxis	Gardasil		Headache Abdominal discomfort
2010-000975	Prophylaxis	Gardasil	.5 ml	Cyanosis Feeling cold
2010-000992	Prophylaxis	Gardasil	.1	Urticaria
2010-001014		Gardasil	.5 ml	Tonsillitis Oropharyngeal pain Dysphagia Dizziness Abdominal pain upper Paraesthesia Headache Myalgia Neck pain Musculoskeletal stiffness Musculoskeletal stiffness
2010-001050	Prophylaxis	Gardasil	.5 ml	Feeling abnormal Thirst
2010-001054	Prophylaxis	Gardasil		Injection site swelling Injection site pain Injection site erythema
2010-001068	Prophylaxis	Gardasil		Visual impairment Headache Eye swelling Malaise Myalgia Muscular weakness Syncope Fatigue
2010-001087	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001088	Prophylaxis	Gardasil	.5 ml	Dizziness Headache
2010-001089	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001090	Prophylaxis	Gardasil		Headache
2010-001091	Prophylaxis	Gardasil	.5 ml	Headache
2010-001092	Prophylaxis	Gardasil	.5 ml	Abdominal pain upper
2010-001093	Prophylaxis	Gardasil	.5 ml	Epigastric discomfort
2010-001094	Prophylaxis	Gardasil	.5 ml	Pain in extremity
2010-001095	Prophylaxis	Gardasil	.5 ml	Headache Asthenia
2010-001097	Prophylaxis	Gardasil	.5 ml	Headache
2010-001100	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001104	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001132		Gardasil		Urticaria Rash pruritic
2010-001133	Prophylaxis	Gardasil	.5 ml	Urticaria
2010-001152	Prophylaxis	Gardasil		Limb discomfort Myalgia Limb discomfort
2010-001195	Prophylaxis	Gardasil	.5 ml	Urticaria Pruritus
2010-001211	Prophylaxis	Gardasil	.5 ml	Dermatitis allergic Urticaria Pruritus
2010-001212	Prophylaxis	Gardasil	.5 ml	Headache
2010-001213	Prophylaxis	Gardasil	.5 ml	Headache

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HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Flushing
2010-001216	Prophylaxis	Gardasil	.5 ml	Malaise
2010-001217	Prophylaxis	Gardasil	.5 ml	Asthenia
2010-001219	Prophylaxis	Gardasil		Lethargy Headache Local reaction
2010-001220	Prophylaxis	Gardasil	.5 ml	Limb discomfort
2010-001304	Prophylaxis	Gardasil		Pyrexia Oropharyngeal pain Lymphadenopathy
2010-001310	Prophylaxis	Gardasil	.5 ml	Epigastric discomfort
2010-001313	Prophylaxis	Gardasil	.5 ml	Injection site pain
2010-001314	Prophylaxis	Gardasil	.5 ml	Injection site swelling
2010-001315	Prophylaxis	Gardasil	.5 ml	Headache
2010-001316	Prophylaxis	Gardasil	.5 ml	Injection site pain
2010-001362	Prophylaxis	Gardasil	.5 ml	Oropharyngeal pain Swollen tongue
2010-001387	Prophylaxis	Gardasil	.5 ml	Deep vein thrombosis Pulmonary embolism
2010-001389	Prophylaxis	Gardasil	.5 ml	Cellulitis Injection site mass Pyrexia
2010-001390	Prophylaxis	Gardasil		Skin reaction Urticaria
2010-001391	Prophylaxis	Gardasil	.5 ml	Local reaction Injection site induration Pain in extremity Rash macular Urticaria
2010-001402	Prophylaxis	Gardasil	.5 ml	Pallor Dizziness Limb discomfort Eye pruritus
2010-001420	Prophylaxis	Gardasil	.5 ml	Urticaria
2010-001421	Prophylaxis	Gardasil	.5 ml	Urticaria
2010-001422	Prophylaxis	Gardasil	.5 ml	Nausea Vomiting Lethargy
2010-001423	Prophylaxis	Gardasil	.5 ml	Nausea
2010-001435	Prophylaxis	Gardasil		Chest pain
2010-001436	Prophylaxis	Gardasil		Dizziness Vision blurred Pallor
2010-001437	Prophylaxis	Gardasil		Headache Hyperhidrosis
2010-001439		Gardasil		Syncope
2010-001440	Prophylaxis	Gardasil		Dizziness Flushing
2010-001441	Prophylaxis	Gardasil		Syncope
2010-001442	Prophylaxis	Gardasil		Feeling hot Dizziness Asthenia
2010-001443	Prophylaxis	Gardasil		Pain in extremity Headache
2010-001444	Prophylaxis	Gardasil		Nausea Malaise
2010-001445	Prophylaxis	Gardasil		Presyncope
2010-001446	Prophylaxis	Gardasil		Nausea
2010-001447	Prophylaxis	Gardasil		Dizziness Pallor
2010-001448	Prophylaxis	Gardasil		Dizziness
2010-001449		Gardasil		Headache
2010-001450	Prophylaxis	Gardasil		Headache Pallor
2010-001451	Prophylaxis	Gardasil		Abdominal pain upper

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HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Dizziness
2010-001452	Prophylaxis	Gardasil		Dizziness
2010-001453	Prophylaxis	Gardasil		Pain in extremity Back pain
2010-001454	Prophylaxis	Gardasil		Chills
2010-001456	Prophylaxis	Gardasil		Dizziness
2010-001457	Prophylaxis	Gardasil		Abdominal pain upper
2010-001458	Prophylaxis	Gardasil		Nausea
2010-001459	Prophylaxis	Gardasil		Abdominal pain
2010-001460	Prophylaxis	Gardasil		Dizziness
2010-001461	Prophylaxis	Gardasil		Nausea Headache
2010-001464	Prophylaxis	Gardasil		Dizziness
2010-001465	Prophylaxis	Gardasil		Dizziness Asthenia
2010-001470	Prophylaxis	Gardasil		Panic attack Anxiety Chest pain Dizziness Limb discomfort
2010-001475	Prophylaxis	Gardasil		Nausea Vomiting
2010-001476	Prophylaxis	Gardasil		Dizziness Headache
2010-001477	Prophylaxis	Gardasil		Headache Dizziness Asthenia
2010-001478	Prophylaxis	Gardasil		Feeling hot Hyperhidrosis
2010-001479	Prophylaxis	Gardasil		Dizziness
2010-001480	Prophylaxis	Gardasil	.5 ml	Malaise Headache
2010-001483	Prophylaxis	Gardasil		Anxiety Feeling of body temperature
2010-001484	Prophylaxis	Gardasil		Dizziness Abdominal discomfort
2010-001486	Prophylaxis	Gardasil	.5 ml	Urticaria Lethargy Fatigue Rash vesicular Pruritus Hypersensitivity
2010-001487	Prophylaxis	Gardasil		Abdominal discomfort Dizziness
2010-001488	Prophylaxis	Gardasil		Pain in extremity Headache Nausea
2010-001490	Prophylaxis	Gardasil		Headache Nausea
2010-001492	Prophylaxis	Gardasil		Nausea Dizziness
2010-001493	Prophylaxis	Gardasil		Dizziness Asthenia
2010-001494	Prophylaxis	Gardasil		Nausea Dizziness
2010-001495	Prophylaxis	Gardasil		Dizziness Dizziness Pallor
2010-001496	Prophylaxis	Gardasil		Headache Abdominal discomfort
2010-001497	Prophylaxis	Gardasil		Headache Dizziness
2010-001498	Prophylaxis	Gardasil		Dizziness Dizziness Abdominal discomfort

Please also refer to the caveat document enclosed.

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HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2010-001499	Prophylaxis	Gardasil		Dizziness Dizziness
2010-001500	Prophylaxis	Gardasil		Dizziness Nausea
2010-001501	Prophylaxis	Gardasil		Dizziness Pallor
2010-001502	Prophylaxis	Gardasil		Asthenia Dizziness
2010-001503	Prophylaxis	Gardasil		Dizziness Pallor
2010-001504	Prophylaxis	Gardasil		Syncope Dizziness
2010-001505	Prophylaxis	Gardasil		Dizziness Asthenia
2010-001506	Prophylaxis	Gardasil		Dizziness
2010-001507	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001508	Prophylaxis	Gardasil		Asthenia Dizziness Pain in extremity
2010-001509	Prophylaxis	Gardasil		Oropharyngeal pain
2010-001510	Prophylaxis	Gardasil	.5 ml	Dizziness Emotional distress Headache Nausea
2010-001511		Gardasil	.5 ml	Pallor
2010-001512	Prophylaxis	Gardasil	.5 ml	Dizziness Headache
2010-001513	Prophylaxis	Gardasil	.5 ml	Nausea Headache Malaise
2010-001514	Prophylaxis	Gardasil	.5 ml	Syncope
2010-001515	Prophylaxis	Gardasil	.5 ml	Feeling hot Cold sweat
2010-001516	Prophylaxis	Gardasil	.5 ml	Dizziness Nausea
2010-001517	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001518	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001519	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001520	Prophylaxis	Gardasil	.5 ml	Dizziness Nausea
2010-001521	Prophylaxis	Gardasil	.5 ml	Dizziness Dizziness
2010-001522	Prophylaxis	Gardasil	.5 ml	Dizziness Somnolence
2010-001523	Prophylaxis	Gardasil	.5 ml	Dizziness Headache Dizziness Emotional distress
2010-001524	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001525	Prophylaxis	Gardasil	.5 ml	Generalised tonic-clonic seizure
2010-001526	Prophylaxis	Gardasil	.5 ml	Dizziness Pallor
2010-001527	Prophylaxis	Gardasil	.5 ml	Malaise
2010-001528	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001529	Prophylaxis	Gardasil	.5 ml	Dizziness Pallor
2010-001531	Prophylaxis	Gardasil	.5 ml	Headache Nausea
2010-001532	Prophylaxis	Gardasil		Malaise Hypoaesthesia Pyrexia Vomiting Lethargy
2010-001533	Prophylaxis	Gardasil	.5 ml	Malaise
2010-001534	Prophylaxis	Gardasil	.5 ml	Headache

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				Dizziness
2010-001535	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001536	Prophylaxis	Gardasil	.5 ml	Nausea
2010-001537	Prophylaxis	Gardasil	.5 ml	Abdominal discomfort Headache Nausea
2010-001538	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001539	Prophylaxis	Gardasil	.5 ml	Abdominal discomfort
2010-001540	Prophylaxis	Gardasil	.5 ml	Abdominal discomfort
2010-001541	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001542	Prophylaxis	Gardasil	.5 ml	Dizziness Abdominal discomfort Headache
2010-001543	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001544	Prophylaxis	Gardasil	.5 ml	Presyncope Pallor Hyperhidrosis
2010-001545	Prophylaxis	Gardasil	.5 ml	Nausea Dizziness
2010-001547	Prophylaxis	Gardasil		Dizziness
2010-001548	Prophylaxis	Gardasil		Dizziness Chills
2010-001549	Prophylaxis	Gardasil	.5 ml	Presyncope Headache
2010-001550	Prophylaxis	Gardasil	.5 ml	Headache
2010-001551	Prophylaxis	Gardasil		Dizziness Nausea
2010-001552	Prophylaxis	Gardasil		Dizziness
2010-001556	Prophylaxis	Gardasil		Dizziness Pallor
2010-001557	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001558	Prophylaxis	Gardasil	.5 ml	Headache Nausea
2010-001559	Prophylaxis	Gardasil		Dizziness Dizziness Headache
2010-001560	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001561	Prophylaxis	Gardasil	.5 ml	Nausea
2010-001562	Prophylaxis	Gardasil	.5 ml	Abdominal pain Dizziness Feeling of body temperature
2010-001563	Prophylaxis	Gardasil		Dizziness Panic attack
2010-001564	Prophylaxis	Gardasil	.5 ml	Dizziness Feeling of body temperature
2010-001565	Prophylaxis	Gardasil		Dizziness Pallor
2010-001566	Prophylaxis	Gardasil	.5 ml	Dizziness Asthenia
2010-001567	Prophylaxis	Gardasil		Headache Pain in extremity
2010-001568	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001569	Prophylaxis	Gardasil		Dizziness Hypoaesthesia
2010-001570	Prophylaxis	Gardasil	.5 ml	Presyncope
2010-001571	Prophylaxis	Gardasil	.5 ml	Dizziness
2010-001572	Prophylaxis	Gardasil	.5 ml	Abdominal pain Headache
2010-001573	Prophylaxis	Gardasil	.5 ml	Presyncope
2010-001574	Prophylaxis	Gardasil	.5 ml	Dizziness Headache
2010-001575	Prophylaxis	Gardasil	.5 ml	Malaise
2010-001576	Prophylaxis	Gardasil	.5 ml	Malaise Fatigue
2010-001577	Prophylaxis	Gardasil	.5 ml	Fatigue

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2010-001578	Prophylaxis	Gardasil	.5 ml	Malaise Dizziness
2010-001579	Prophylaxis	Gardasil	.5 ml	Malaise Headache
2010-001580	Prophylaxis	Gardasil	.5 ml	Headache
2010-001581	Prophylaxis	Gardasil	.5 ml	Abdominal pain
2010-001584		Gardasil	.5 ml	Presyncope Nausea
2010-001590		Gardasil		Cyanosis
2010-001591		Gardasil		Cyanosis
2010-001595		Gardasil		Urticaria
2010-001607	Prophylaxis	Gardasil		Seizure
2010-001608	Prophylaxis	Gardasil	.5 ml	Abdominal discomfort Headache
2010-001610	Prophylaxis	Gardasil	.5 ml	Dermatitis allergic Pruritus Rash erythematous
2010-001616	Prophylaxis	Gardasil		Nausea Vomiting
2010-001617	Prophylaxis	Gardasil	.5 ml	Rash Headache Urticaria
2010-001671	Prophylaxis	Gardasil	.5 ml	Headache
2010-001675	Prophylaxis	Gardasil		Rash pruritic Sleep disorder
2011-001706	Prophylaxis	Gardasil	.5 ml	Headache Dizziness Presyncope Tonsillitis
2011-001712	Prophylaxis	Gardasil	.5 ml	Headache
2011-001714	Prophylaxis	Gardasil	.5 ml	Headache Influenza like illness Asthenia
2011-001729	Prophylaxis	Gardasil		Abdominal pain Vomiting
2011-001754	Prophylaxis	Gardasil	.5 ml	Asthenia
2011-001755	Prophylaxis	Gardasil		Abdominal pain Vomiting
2011-001791	Prophylaxis	Gardasil	.5 ml	Nausea Dizziness Chest discomfort
2011-001792	Prophylaxis	Gardasil		Dizziness Anxiety Dyspnoea
2011-001793	Prophylaxis	Gardasil	.5 ml	Eye irritation Rash Pruritus
2011-001800	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-001801	Prophylaxis	Gardasil	.5 ml	Nausea Dizziness
2011-001802	Prophylaxis	Gardasil	.5 ml	Dizziness Injection site pain
2011-001803	Prophylaxis	Gardasil	.5 ml	Nausea Headache
2011-001804	Prophylaxis	Gardasil	.5 ml	Malaise Headache
2011-001805	Prophylaxis	Gardasil		Headache Dizziness Nausea
2011-001806	Prophylaxis	Gardasil		Abdominal pain upper Feeling hot Dysgeusia Headache Cold sweat
2011-001807	Prophylaxis	Gardasil	.5 ml	Chills

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				Fatigue Dizziness
2011-001809	Prophylaxis	Gardasil	.5 ml	Malaise
2011-001818	Prophylaxis	Gardasil		Dizziness Headache
2011-001819	Prophylaxis	Gardasil	.5 ml	Headache
2011-001824	Prophylaxis	Gardasil	.5 ml	Headache Nausea
2011-001826	Prophylaxis	Gardasil	.5 ml	Headache
2011-001827		Gardasil	.5 ml	Dizziness
2011-001828	Prophylaxis	Gardasil	.5 ml	Dizziness Nausea
2011-001829	Prophylaxis	Gardasil	.5 ml	Dizziness Nausea
2011-001830	Prophylaxis	Gardasil		Dizziness Visual impairment Headache
2011-001831	Prophylaxis	Gardasil	.5 ml	Chills Feeling cold Abdominal discomfort
2011-001832	Prophylaxis	Gardasil	.5 ml	Headache Dizziness
2011-001849	Prophylaxis	Gardasil	.5 ml	Feeling hot Dizziness
2011-001854	Prophylaxis	Gardasil		Dizziness Nausea
2011-001856	Prophylaxis	Gardasil		Nausea Headache Dizziness Abdominal pain
2011-001857	Prophylaxis	Gardasil		Dizziness
2011-001859	Prophylaxis	Gardasil		Pain
2011-001863	Prophylaxis	Gardasil		Dizziness
2011-001864	Prophylaxis	Gardasil		Nausea Dizziness
2011-001866	Prophylaxis	Gardasil		Dizziness
2011-001869	Prophylaxis	Gardasil		Asthenia Dizziness Pallor
2011-001870	Prophylaxis	Gardasil		Dizziness Headache
2011-001872	Prophylaxis	Gardasil		Headache
2011-001873	Prophylaxis	Gardasil		Syncope Dizziness
2011-001874	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-001875	Prophylaxis	Gardasil	.5 ml	Dizziness Headache Nausea
2011-001924	Prophylaxis	Gardasil	.5 ml	Vertigo Syncope Emotional distress Pallor Nausea Anxiety Pain in extremity Burning sensation Insomnia Local reaction
2011-001944	Prophylaxis	Gardasil	.5 ml	Pain in extremity
2011-001977	Prophylaxis	Gardasil	.5 ml	Pyrexia Pain in extremity
2011-001982	Prophylaxis	Gardasil	.5 ml	Limb discomfort Erythema
2011-002012	Prophylaxis	Gardasil	.5 ml	Body temperature increased Pain

Please also refer to the caveat document enclosed.

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Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Lymphadenopathy Asthenia Decreased appetite
2011-002013	Prophylaxis	Gardasil	.5 ml	Syncope
2011-002014	Prophylaxis	Gardasil	.5 ml	Asthenia Nausea Pain in extremity
2011-002015	Prophylaxis	Gardasil	.5 ml Milligram	Syncope Muscle twitching Headache Dizziness
2011-002037	Prophylaxis	Gardasil		Arthralgia
2011-002222	Prophylaxis	Gardasil		Dizziness
2011-002370		Gardasil		Trance Memory impairment Anxiety Somnolence Eye movement disorder Fatigue Headache
2011-002757	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-002758	Prophylaxis	Gardasil	.5 ml	Pallor
2011-002759	Prophylaxis	Gardasil	.5 ml	Injection site pain
2011-002761	Prophylaxis	Gardasil	.5 ml	Headache
2011-002763	Prophylaxis	Gardasil	.5 ml	Malaise
2011-002765	Prophylaxis	Gardasil	.5 ml	Dizziness Malaise
2011-002766	Prophylaxis	Gardasil	.5 ml	Headache
2011-002767	Prophylaxis	Gardasil	.5 ml	Asthenia
2011-002768	Prophylaxis	Gardasil	.5 ml	Headache
2011-002769	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-002883	Prophylaxis	Gardasil		Vision blurred Syncope Dermal cyst Fatigue Tremor
2011-002901	Prophylaxis	Gardasil		Pain in extremity Swelling Peripheral coldness Skin discolouration Complex regional pain syndrome
2011-002919	Prophylaxis	Gardasil	.05	Chills Vomiting Decreased appetite
2011-002929	Prophylaxis	Gardasil	.5 ml	Dizziness Nausea
2011-002930	Prophylaxis	Gardasil	.5 ml	Dizziness Tremor
2011-002934	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-002935	Prophylaxis	Gardasil	.5 ml	Dizziness Feeling hot
2011-002936	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-002937	Prophylaxis	Gardasil	.5 ml	Dizziness Headache
2011-002941	Prophylaxis	Gardasil	.5 ml	Headache Dizziness Abdominal discomfort
2011-002942	Prophylaxis	Gardasil	.5 ml	Dizziness Dizziness
2011-002943	Prophylaxis	Gardasil	.5 ml	Dizziness Dizziness
2011-002944	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-002945	Prophylaxis	Gardasil	.5 ml	Feeling abnormal Pallor
2011-002946	Prophylaxis	Gardasil	.5 ml	Feeling of body temperature

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Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Tachycardia
2011-002947	Prophylaxis	Gardasil	.5 ml	Dizziness Headache Tremor Feeling hot
2011-002948	Prophylaxis	Gardasil	.5 ml	Headache
2011-002952	Prophylaxis	Gardasil	.5 ml	Dizziness Abdominal discomfort
2011-002953	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-002954	Prophylaxis	Gardasil	.5 ml	Dizziness Cold sweat
2011-002955	Prophylaxis	Gardasil	.5 ml	Oropharyngeal pain Pain in extremity Headache Cough
2011-002956	Prophylaxis	Gardasil	.5 ml	Abdominal pain Muscle spasms
2011-002957	Prophylaxis	Gardasil	.5 ml	Headache
2011-002958	Prophylaxis	Gardasil	.5 ml	Dizziness Headache
2011-002959	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-002960	Prophylaxis	Gardasil	.5 ml	Dizziness Chest discomfort
2011-002961	Prophylaxis	Gardasil	.5 ml	Dizziness Abdominal pain lower Headache
2011-002962	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-002963	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-002964	Prophylaxis	Gardasil	.5 ml	Nausea
2011-002965	Prophylaxis	Gardasil	.5 ml	Dizziness Headache
2011-002966	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-002967	Prophylaxis	Gardasil	.5 ml	Dizziness Ear discomfort
2011-002968	Prophylaxis	Gardasil	.5 ml	Dizziness Headache Feeling cold
2011-002970	Prophylaxis	Gardasil	.5 ml	Nausea Pain in extremity Rash macular
2011-002971	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-002972	Prophylaxis	Gardasil	.5 ml	Nausea Headache
2011-002973	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-002983	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-002985	Prophylaxis	Gardasil	.5 ml	Dizziness Headache Nausea
2011-002991	Prophylaxis	Gardasil	.5 ml	Pain in extremity Injection site pain
2011-002992	Prophylaxis	Gardasil	.5 ml	Nausea Paraesthesia
2011-003081	Prophylaxis	Gardasil		Lymphadenopathy Oropharyngeal pain Chills
2011-003104	Prophylaxis	Gardasil	.5 ml	Anaphylactoid reaction Hypotension Tachycardia Nausea Asthenia Dyspnoea Throat tightness
2011-003108	Prophylaxis	Gardasil	.5 ml	Dizziness Asthenia Syncope

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2011-003122	Prophylaxis	Gardasil	.5 ml	Chest pain Dyspnoea
2011-003148	Prophylaxis	Gardasil	.5 ml	Erythema Pain in extremity
2011-003154	Prophylaxis	Gardasil	.5 ml	Headache Dizziness Vomiting
2011-003160	Prophylaxis	Gardasil	.5 ml .5 ml	Headache Abdominal discomfort Asthenia Decreased appetite Weight decreased
2011-003161	Prophylaxis	Gardasil		Malaise Headache Dizziness
2011-003167	Prophylaxis	Gardasil		Fatigue Nausea Headache Vomiting Sleep disorder Chronic fatigue syndrome
2011-003255	Prophylaxis	Gardasil		Urticaria Pruritus
2011-003276	Prophylaxis	Gardasil	.5 ml	Dizziness Pyrexia Chills Nausea Headache Rash generalised
2011-003281	Prophylaxis	Gardasil	.5 ml	Vomiting
2011-003319	Prophylaxis	Gardasil		Injection site swelling Injection site induration Swelling face Erythema
2011-003324	Prophylaxis	Gardasil		Pain in extremity Injection site pain
2011-003347	Prophylaxis	Gardasil		Nausea
2011-003351	Prophylaxis	Gardasil	.5 ml	Epistaxis
2011-003353	Prophylaxis	Gardasil		Dizziness Nausea
2011-003354		Gardasil		Dizziness Dyspnoea
2011-003355	Prophylaxis	Gardasil		Dizziness Dyspnoea
2011-003357	Prophylaxis	Gardasil		Dizziness Pallor
2011-003358	Prophylaxis	Gardasil	.5 ml	Pain in extremity
2011-003360	Prophylaxis	Gardasil		Nausea Dizziness
2011-003362	Prophylaxis	Gardasil		Pallor Dizziness
2011-003384	Prophylaxis	Gardasil	.5 ml	Asthenia Lethargy
2011-003385	Prophylaxis	Gardasil	.5 ml	Asthenia Lethargy
2011-003423	Prophylaxis	Gardasil	.5 ml	Headache Pyrexia Myalgia
2011-003425	Prophylaxis	Gardasil	.5 ml	Headache Pyrexia Myalgia
2011-003448	Prophylaxis	Gardasil	.5 ml	Headache Pyrexia Myalgia Lethargy

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Hypotension Vomiting
2011-003450		Gardasil	.5 ml	Mouth swelling Rash Malaise Pyrexia Chills
2011-003509	Prophylaxis	Gardasil	.5 ml	Influenza like illness
2011-003708	Prophylaxis	Gardasil		Cellulitis
2011-003711	Prophylaxis	Gardasil	.5 ml	Syncope Pulse absent Pallor Anaphylactic reaction
2011-003712	Prophylaxis	Gardasil	.5 ml	Hypoaesthesia Peripheral coldness
2011-003825		Gardasil		Pyrexia Malaise Asthenia
2011-003901	Prophylaxis	Gardasil	.5 ml	Influenza like illness
2011-003902	Prophylaxis	Gardasil	.5 ml	Presyncope
2011-004036	Prophylaxis	Gardasil	.5 ml	Injection site pain
2011-004131	Prophylaxis	Gardasil	.5 ml	Hypersensitivity Swelling face Rash
2011-004196	Prophylaxis	Gardasil		Headache Abdominal pain Alopecia Pollakiuria
2011-004222	Prophylaxis	Gardasil		Lower respiratory tract infection Tonsillitis Herpes zoster Tooth infection Candida infection Fatigue Lethargy
2011-004420	Prophylaxis	Gardasil	.5 ml	Eye swelling Eye pruritus Rash pruritic
2011-004460	Prophylaxis	Gardasil		Fatigue Headache
2011-004480	Prophylaxis	Gardasil	.5 ml .5 ml	Erythema Pain in extremity Injection site pruritus
2011-004491	Prophylaxis	Gardasil	.5 ml .5 ml	Erythema Pruritus Eczema
2011-004591	Prophylaxis	Gardasil		Henoch-Schonlein purpura Joint swelling
2011-004740	Prophylaxis	Gardasil		Exposure during pregnancy No adverse event
2011-005120	Prophylaxis	Gardasil	.5 ml	Dizziness Dizziness Headache
2011-005128	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-005129	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-005130	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-005131	Prophylaxis	Gardasil	.5 ml	Feeling of body temperature Malaise Abdominal discomfort
2011-005132	Prophylaxis	Gardasil	.5 ml	Dizziness Nausea
2011-005133	Prophylaxis	Gardasil	.5 ml	Headache
2011-005134	Prophylaxis	Gardasil	.5 ml	Headache
2011-005135	Prophylaxis	Gardasil	.5 ml	Dizziness Nausea

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Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2011-005137	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-005138	Prophylaxis	Gardasil	.5 ml	Dizziness
2011-005161	Prophylaxis	Gardasil		Headache Vomiting Lethargy
2011-005169	Prophylaxis	Gardasil Naproxen Valoid Tablets 50 Mg.		Headache Photophobia Vertigo Nausea
2011-005412	Prophylaxis	Gardasil		Abortion spontaneous Exposure during pregnancy
2011-006753	Prophylaxis	Gardasil	.5 ml	Abdominal pain Nausea Hyperhidrosis Hypotension Erythema Heart rate increased Tachycardia
2011-006780	Prophylaxis	Gardasil	.5 ml	Headache Abdominal pain Urticaria
2011-006840	Prophylaxis	Gardasil	.5 ml	Angioedema Eye oedema Nausea Pain Abdominal pain upper
2011-006847	Prophylaxis	Gardasil		Petit mal epilepsy Focal dyscognitive seizures Myoclonic epilepsy Epilepsy
2011-006869	Prophylaxis	Gardasil		Dizziness
2011-006874	Prophylaxis	Gardasil	.5 ml	Headache Dizziness
2011-006876	Prophylaxis	Gardasil	.5 ml	Headache Dizziness
2011-006893	Prophylaxis	Gardasil	.5 ml	Urticaria
2011-006898	Prophylaxis	Gardasil		Syncope Malaise
2011-006916	Prophylaxis	Gardasil	.5 ml	Urticaria Periorbital oedema
2011-006924	Prophylaxis	Gardasil		Cough Throat tightness
2011-006925	Prophylaxis	Gardasil		Cough Throat tightness
2011-006940	Prophylaxis	Gardasil	1	Urticaria
2011-006957	Prophylaxis	Gardasil		Vomiting Dizziness
2011-006982	Prophylaxis	Gardasil		Malaise Pyrexia Vomiting
2011-006985	Prophylaxis	Gardasil	.5 ml	Vomiting
2011-006988	Prophylaxis	Gardasil	.5 ml	Hypopnoea Respiratory rate increased Pain in extremity Muscle spasms Headache Hyperventilation Tetany
2011-006995	Prophylaxis	Gardasil	.5 ml	Headache Nausea
2011-007028	Prophylaxis	Gardasil	.5 ml	Influenza like illness Musculoskeletal stiffness Fatigue Pharyngeal oedema Swollen tongue

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Oedema Headache Limb discomfort
2011-007029	Prophylaxis	Gardasil	.5 ml	Syncope Malaise
2011-007058	Prophylaxis	Gardasil		Post viral fatigue syndrome
2011-007094	Prophylaxis	Gardasil	.5 ml	Syncope
2011-007095	Prophylaxis	Gardasil	.5 ml	Headache Nausea
2011-007096	Prophylaxis	Gardasil	.5 ml	Vomiting
2011-007097	Prophylaxis	Gardasil	.5 ml	Panic attack
2011-007099	Prophylaxis	Gardasil	.5 ml	Urticaria
2011-007123	Prophylaxis	Gardasil		Asthenia
2011-007124	Prophylaxis	Gardasil	.5 ml	Dizziness Flushing Hypotension Tachycardia Cough
2011-007163	Prophylaxis	Gardasil	.5 ml	Rash erythematous Asthenia Headache Nasal congestion Pyrexia
2011-007184	Prophylaxis	Gardasil	.5 ml	Rash
2011-007207	Prophylaxis	Gardasil	.5 ml	Vomiting Dizziness
2011-007210	Prophylaxis	Gardasil	.5 ml	Vomiting Nausea
2011-007211	Prophylaxis	Gardasil		Headache
2011-007212	Prophylaxis	Gardasil	.5 ml	Rash macular Pyrexia
2011-007239	Prophylaxis	Gardasil	.5 ml	Bronchospasm Swollen tongue Erythema Pruritus Cough Chest discomfort Wheezing
2011-007242	Prophylaxis	Gardasil	.5 ml	Medication error
2011-007243	Prophylaxis	Gardasil	.5 ml	Seizure
2011-007274	Prophylaxis	Gardasil	.5 ml	Hypoaesthesia Paraesthesia Sensory loss Headache
2011-007294	Prophylaxis	Gardasil		Syncope
2011-007323	Prophylaxis	Gardasil	.5 ml	Vomiting
2011-007384	Prophylaxis	Gardasil	.5 ml	Exposure during pregnancy No adverse event
2011-007389	Prophylaxis	Gardasil	.5 ml	Syncope
2011-007413	Prophylaxis	Gardasil	.5 ml	Urticaria
2011-007432	Prophylaxis	Gardasil	.5 ml	Urticaria
2011-007474	Prophylaxis	Gardasil	.5 ml	Hypoaesthesia Muscular weakness
2011-007551	Prophylaxis	Gardasil		Pyrexia Chills Fatigue Sinusitis
2011-007676	Prophylaxis	Gardasil	.5 ml	Pain in extremity Joint swelling
2011-008001	Prophylaxis	Gardasil		Headache Rash Oral mucosal eruption
2011-008002	Prophylaxis	Gardasil	.5 ml	Guttate psoriasis
2011-008006	Prophylaxis	Gardasil		Headache
2011-008131	Prophylaxis	Gardasil	.5 ml	Fatigue

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Asthenia
2011-008133	Prophylaxis	Gardasil	.5 ml	Asthenia Vision blurred Headache Cough Cold sweat Flushing Wheezing
2011-008301	Prophylaxis	Gardasil		Urticaria
2011-008390	Prophylaxis	Gardasil	.5 ml	Pain in extremity Paraesthesia
2011-008394	Prophylaxis	Gardasil	.5 ml	Syncope
2011-008409	Prophylaxis	Gardasil	.5 ml	Panic attack
2011-008410	Prophylaxis	Gardasil		Rash
2011-008412	Prophylaxis	Gardasil		Rash
2011-008414	Prophylaxis	Gardasil		Erythema nodosum
2011-008416	Prophylaxis	Gardasil	.5 ml	Headache
2011-008453	Prophylaxis	Gardasil	.5 ml	Rash Headache Abdominal migraine
2011-008455	Prophylaxis	Gardasil	.5 ml	Syncope
2011-008457	Prophylaxis	Gardasil	.5 ml	Pruritus Vomiting Rash
2011-008466	Prophylaxis	Gardasil	.5 ml	Exposure during pregnancy No adverse event
2011-008491	Prophylaxis	Gardasil	.5 ml	Malaise Pain in extremity
2011-008520	Prophylaxis	Gardasil	.5 ml	Malaise Headache
2011-008527	Prophylaxis	Gardasil	.5 ml	Asthenia Headache
2011-008582	Prophylaxis	Gardasil	.5 ml	Urticaria
2011-008583	Prophylaxis	Gardasil	.5 ml	Headache Pyrexia Dizziness Vomiting
2011-008597	Prophylaxis	Gardasil	.5 ml	Syncope Tremor Vision blurred Hypopnoea Chest discomfort Muscular weakness
2011-008601	Prophylaxis	Gardasil	.5 ml	Urticaria Chest discomfort
2011-008614	Prophylaxis	Gardasil	.5 ml	Injection site pain Injection site pain Injection site erythema Injection site oedema
2011-008616	Prophylaxis	Gardasil	.5 ml	Rash maculo-papular Pruritus
2011-008617	Prophylaxis	Gardasil	.5 ml	Headache
2011-008690	Prophylaxis	Gardasil		Urticaria
2011-008692	Prophylaxis	Gardasil	.5 ml	Urticaria
2011-008702	Prophylaxis	Gardasil	.5 ml	Urticaria
2011-008704	Prophylaxis	Gardasil	.5 ml	Abortion spontaneous
2011-008725	Prophylaxis	Gardasil	.5 ml	Fatigue Cough
2011-008812	Prophylaxis	Gardasil	.5 ml	Headache
2011-008833	Prophylaxis	Gardasil	.5 ml	Exposure during pregnancy No adverse event
2011-008836	Prophylaxis	Gardasil		Exposure during pregnancy No adverse event
2011-008837	Prophylaxis	Gardasil	.5 ml	Pain in extremity
2011-008841	Prophylaxis	Gardasil	.5 ml	Vomiting

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2011-008845	Prophylaxis	Gardasil	.5 ml	Panic attack Stress Dyspnoea
2011-008848	Prophylaxis	Gardasil	.5 ml	Pruritus
2011-008895	Prophylaxis	Gardasil	.5 ml	Urticaria
2011-008899	Prophylaxis	Gardasil	.5 ml	Urticaria
2011-008929	Prophylaxis	Gardasil		Abdominal pain lower
2011-008957	Prophylaxis	Gardasil	.5 ml	Urticaria
2012-009098	Prophylaxis	Gardasil	.5 ml	Nausea Abdominal pain Headache
2012-009278	Prophylaxis	Gardasil		Abdominal pain Nausea Vomiting
2012-009481	Prophylaxis	Gardasil	.5 ml	Rash macular Pruritus Rash erythematous
2012-009697	Prophylaxis	Gardasil		Migraine
2012-009945	Prophylaxis	Gardasil		Listless Syncope Restlessness
2012-010136	Prophylaxis	Gardasil		Rash erythematous Pruritus Paraesthesia oral Angioedema Throat tightness Anaphylactic reaction
2012-010296	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Urticaria Malaise Pyrexia Dizziness Abdominal pain
2012-010407	Prophylaxis	Gardasil	.5 ml	Fatigue Lip blister Headache
2012-010427	Prophylaxis	Gardasil		Fatigue Lymphadenopathy Malaise
2012-010428	Prophylaxis	Gardasil	.5 ml .5 ml	Exposure during pregnancy No adverse event
2012-010434	Prophylaxis	Gardasil	.5 ml	Rash macular Fatigue Swelling Dermatitis allergic
2012-010461	Prophylaxis	Gardasil	.5 ml	Arthralgia
2012-010467	Prophylaxis	Gardasil		Exposure during pregnancy No adverse event
2012-010527	Prophylaxis	Gardasil	.5 ml	Headache Vomiting
2012-010617	Prophylaxis	Gardasil	.5 ml	Nausea Lethargy Weight decreased Amnesia Chest pain Headache Syncope
2012-010694	Prophylaxis	Gardasil	.5 ml	Vomiting Rash
2012-010695	Prophylaxis	Gardasil	.5 ml .5 ml	Pyrexia Nausea Injection site pain Pallor
2012-010735	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Asthenia Pallor Pyrexia

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Nausea Decreased appetite
2012-010745	Prophylaxis	Gardasil	.5 ml	Exposure during pregnancy No adverse event
2012-010746	Prophylaxis	Gardasil	.5 ml	Nausea Headache Malaise Cough Wheezing Lower respiratory tract infection
2012-010747	Prophylaxis	Gardasil	.5 ml .5 ml	Erythema Pruritus
2012-010748	Prophylaxis	Gardasil		Migraine Epilepsy
2012-010749	Prophylaxis	Gardasil	.5 ml	Malaise Headache Vomiting Pyrexia
2012-010792	Prophylaxis	Gardasil	.5 ml	Pain in extremity
2012-010793	Prophylaxis	Gardasil	.5 ml	Pruritus Erythema
2012-010796	Prophylaxis	Gardasil	.5 ml	Rash pruritic Injection site rash Rash erythematous
2012-010798	Prophylaxis	Gardasil	.5 ml	Hypoaesthesia Injection site pain
2012-010835	Prophylaxis	Gardasil	.5 ml .5 ml	Paraesthesia Muscular weakness
2012-010840	Prophylaxis	Gardasil	.5 ml	Paraesthesia
2012-010878	Prophylaxis	Gardasil		Facial paralysis
2012-011007	Prophylaxis	Gardasil	.5 ml Milligram	Malaise Nausea Dizziness Feeling of body temperature Headache Oropharyngeal pain Neck pain Pyrexia Lymphadenopathy Lethargy Tonsillitis bacterial Abdominal pain
2012-011130	Prophylaxis	Gardasil	.5 ml	Ovarian abscess
2012-011131	Prophylaxis	Gardasil	.5 ml	Injection site rash
2012-011170	Prophylaxis	Gardasil	.5 ml	Hyperthyroidism
2012-011233	Prophylaxis	Gardasil	.5 ml	Abortion spontaneous
2012-011329	Prophylaxis	Gardasil		Syncope
2012-011335	Prophylaxis	Gardasil	.5 ml	Post viral fatigue syndrome Lymphadenopathy Dizziness Muscular weakness
2012-011346	Prophylaxis	Gardasil	.5 ml	Seizure Fatigue Dyspnoea
2012-011353	Prophylaxis	Gardasil	.5 ml	Diplopia Dizziness
2012-011383	Prophylaxis	Gardasil	.5 ml	Exposure during pregnancy No adverse event
2012-011384	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Psychogenic seizure Epilepsy Loss of consciousness Syncope Drop attacks Head injury Fall

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Eye movement disorder Headache Dizziness Nausea Malaise Body temperature increased Chills Pallor Fatigue Somnolence Fatigue Headache Injection site reaction
2012-011458	Prophylaxis	Gardasil	.5 ml	Pityriasis rosea Oropharyngeal pain
2012-011459	Prophylaxis	Gardasil	.5 ml	Eyelid oedema
2012-011468	Prophylaxis	Gardasil	.5 ml	Exposure during pregnancy No adverse event
2012-011474	Prophylaxis	Gardasil	.5 ml .5 ml	Urticaria Rash pruritic Injection site rash
2012-011475	Prophylaxis	Gardasil	.5 ml	Dizziness Fatigue Chest discomfort Bronchospasm
2012-011737	Prophylaxis	Gardasil		Pyrexia Chest pain Vomiting Abdominal pain Lethargy
2012-011815	Prophylaxis	Gardasil		Face oedema Acne Eyelid oedema Reaction to preservatives
2012-012043	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Dizziness Pallor
2012-012050	Prophylaxis	Gardasil	.5 ml	Nausea Decreased appetite
2012-012128	Acne Prophylaxis Prophylaxis	Gardasil Yasmin		Pulmonary embolism Upper respiratory tract infection Cough Chest discomfort
2012-012353	Prophylaxis	Gardasil	.5 ml	Hypersensitivity Rash pruritic Erythema Swollen tongue Swelling face
2012-012879	Prophylaxis	Gardasil	.5 ml .5 ml	Fatigue Lethargy Somnolence
2012-012935	Prophylaxis	Gardasil	.5 ml	Fatigue Pain Epistaxis Headache
2012-013357	Prophylaxis	Gardasil	.5 ml	No adverse event
2012-013360	Prophylaxis	Gardasil	.5 ml	Exposure during pregnancy No adverse event
2012-013815	Prophylaxis	Gardasil		Henoch-Schonlein purpura
2012-013841	Prophylaxis	Gardasil	.5 ml	Rash macular Rash papular
2012-013856	Prophylaxis	Gardasil		Exposure during pregnancy No adverse event
2012-014348	Prophylaxis	Gardasil	.5 ml	Vomiting
2012-014351	Prophylaxis	Gardasil		Pain in extremity Dizziness

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Abdominal discomfort Anxiety
2012-014396	Prophylaxis	Gardasil	.5 ml	Anaphylactic reaction Syncope Rash Pulse abnormal Hypopnoea
2012-014409	Prophylaxis	Gardasil	.5 ml	Dizziness Nausea
2012-014418	Prophylaxis	Gardasil	.5 ml	Presyncope
2012-014420	Prophylaxis	Gardasil	.5 ml	Presyncope Nausea Abdominal pain upper Musculoskeletal pain
2012-014481	Prophylaxis	Gardasil		Alopecia
2012-014493	Prophylaxis	Gardasil	.5 ml	Anaphylactic reaction Circulatory collapse Chest discomfort Dyspnoea Rash Syncope Fatigue Somnolence Hypoaesthesia oral Myalgia Influenza like illness Cough Tracheitis Dizziness Vertigo
2012-014508	Prophylaxis	Gardasil	.5 ml	Dizziness Asthenia Nausea
2012-014519	Prophylaxis	Gardasil	.5 ml	Dizziness Asthenia
2012-014520	Prophylaxis	Gardasil	.5 ml	Syncope
2012-014545	Prophylaxis	Gardasil	.5 ml	Throat tightness Dysphagia Dyspnoea
2012-014546	Prophylaxis	Gardasil	.5 ml	Rash erythematous Feeling hot Rash pruritic Dizziness
2012-014587	Prophylaxis	Gardasil	.5 ml	Epilepsy
2012-014588	Prophylaxis	Gardasil	.5 ml	Abdominal pain Thyroid function test abnormal
2012-014589	Prophylaxis	Gardasil	.5 ml	Vestibulitis
2012-014591	Prophylaxis	Gardasil	.5 ml	Seizure
2012-014594	Prophylaxis	Gardasil	.5 ml .5 ml	Malaise Oropharyngeal pain Rash Abdominal pain Flushing
2012-014719	Prophylaxis	Gardasil		Lower respiratory tract infection
2012-014752	Prophylaxis	Gardasil	.5 ml	Asthenia Vomiting Headache Rash
2012-014766	Prophylaxis	Gardasil		Headache
2012-014809	Prophylaxis	Gardasil	.5 ml	Syncope
2012-014824	Prophylaxis	Gardasil	.5 ml	Syncope
2012-014825	Prophylaxis	Gardasil	.5 ml	Syncope Myoclonus
2012-014832	Prophylaxis	Gardasil	.5 ml	Syncope
2012-014840	Prophylaxis	Gardasil	.5 ml	Dizziness

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Syncope
2012-014842	Prophylaxis	Gardasil		Lymphadenopathy Face oedema Local reaction Eye oedema Pyrexia Infectious mononucleosis Injection site erythema Intentional self-injury Lethargy Fatigue Depression Attention deficit/hyperactivity Oropharyngeal pain Pharyngitis Vomiting Cyst Pain Headache Feeling abnormal
2012-014874	Prophylaxis	Gardasil	.5 ml	Syncope
2012-014907	Prophylaxis	Gardasil	.5 ml	Panic attack
2012-014915	Prophylaxis	Gardasil	.5 ml	Pain in extremity Injection site pain
2012-014992	Prophylaxis	Gardasil	.5 ml	Purpura Chest discomfort
2012-015012	Prophylaxis	Gardasil		Erythema nodosum
2012-015026	Prophylaxis	Gardasil	.5 ml	Syncope
2012-015027	Prophylaxis	Gardasil	.5 ml	Dizziness Hyperventilation
2012-015031	Prophylaxis	Gardasil	.5 ml	Syncope Tonic clonic movements
2012-015041	Prophylaxis	Gardasil	.5 ml	Pallor Asthenia Headache Vomiting
2012-015042	Prophylaxis	Gardasil	.5 ml	Pallor Asthenia Disorientation Dyskinesia Fatigue Muscle twitching
2012-015051	Prophylaxis	Gardasil	.5 ml	Abdominal pain Diarrhoea Pyrexia
2012-015057	Prophylaxis	Gardasil	.5 ml	Hypersensitivity Pain in extremity Agitation Flushing
2012-015132	Prophylaxis	Gardasil		Exposure during pregnancy
2012-015150	Prophylaxis	Gardasil		Rash pruritic
2012-015245	Prophylaxis	Gardasil	.5 ml	Facial paralysis
2012-015357	Prophylaxis	Gardasil	.5 ml	Pityriasis rosea
2012-015359	Prophylaxis	Gardasil	.5 ml	Urticaria Pruritus
2012-015453	Prophylaxis	Gardasil	.5 ml	Headache
2012-015454	Prophylaxis	Gardasil	.5 ml	Headache
2012-015455	Prophylaxis	Gardasil	.5 ml	Influenza like illness Arthralgia
2012-015458	Prophylaxis	Gardasil	.5 ml	Pain in extremity Injection site joint pain Injection site joint swelling
2012-015459	Prophylaxis	Gardasil	.5 ml	Headache
2012-015460	Prophylaxis	Gardasil	.5 ml	Vomiting
2012-015461	Prophylaxis	Gardasil	.5 ml	Anaphylactic reaction

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Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2012-015476	Prophylaxis	Gardasil		Vision blurred Headache Paraesthesia
2012-015481	Prophylaxis	Gardasil		Headache Dizziness Back pain
2012-015483	Prophylaxis	Gardasil		Pyrexia
2012-015486	Prophylaxis	Gardasil	.5 ml	Urticaria
2012-015487	Prophylaxis	Gardasil	.5 ml	Injection site pain
2012-015488	Prophylaxis	Gardasil	.5 ml	Syncope
2012-015526	Prophylaxis	Gardasil	1 Dosage	Alopecia
2012-015527	Prophylaxis	Gardasil	.5 ml	Urticaria Dizziness Syncope Somnolence Decreased appetite
2012-015528	Prophylaxis	Gardasil		Visual impairment Eye pain
2012-015529	Prophylaxis	Gardasil	1 Dosage forms	Rash pruritic Asthenia Nausea Decreased appetite Fatigue Liver function test increased
2012-015530	Prophylaxis	Gardasil	.5 ml	Headache
2012-015531	Prophylaxis	Gardasil	.5 ml	Oral mucosal blistering
2012-015532	Prophylaxis	Gardasil	.5 ml	Injection site pain
2012-015536	Prophylaxis	Gardasil	.5 ml	Asthma
2012-015553	Prophylaxis	Gardasil	.5 ml	Extrasystoles Palpitations
2012-015603	Prophylaxis	Gardasil	.5 ml	Headache
2012-015604	Prophylaxis	Gardasil	.5 ml	Hot flush Insomnia Urticaria Lymphadenopathy
2012-015609	Prophylaxis	Gardasil		Exposure during pregnancy No adverse event
2012-015610	Prophylaxis	Gardasil	.5 ml	Headache
2012-015649	Prophylaxis	Gardasil	.5 ml	Pain in extremity Injection site erythema Injection site warmth Injection site pain Insomnia Monoplegia
2012-015659	Prophylaxis	Gardasil	.5 ml	Exposure during pregnancy No adverse event
2012-015662	Prophylaxis	Gardasil		Extensive swelling of vaccinated
2012-015694	Prophylaxis	Gardasil		Presyncope Loss of consciousness
2012-015695	Prophylaxis	Gardasil		Pain in extremity Muscular weakness Sensory disturbance Neuralgia
2012-015700	Prophylaxis	Gardasil	.5 ml	Eye irritation Hallucination Eye swelling Chest discomfort
2012-015718	Prophylaxis	Gardasil Boostrix		Anaphylactic reaction Dyspnoea Pallor Cough Tachycardia
2012-015720	Prophylaxis	Gardasil	.5 ml	Urticaria Eyelid oedema
2012-015799	Prophylaxis	Gardasil		Urticaria

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HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2012-015805	Prophylaxis	Gardasil		Feeling hot Hypoaesthesia Dizziness Disorientation Decreased appetite Pallor Hyperhidrosis Somnolence
2012-015824	Prophylaxis	Gardasil	.5 ml	Rash erythematous Swelling face
2012-015851	Prophylaxis	Gardasil	.5 ml	Urticaria
2012-015852	Prophylaxis	Gardasil Priorix.		Pyrexia Oropharyngeal pain Malaise Asthenia Pain
2013-015918	Prophylaxis	Boostrix Gardasil	.5 ml .5 ml	Personality change Inappropriate affect Somnolence Dysarthria
2013-015940	Prophylaxis	Gardasil	1 Dosage forms	Pyrexia Vomiting Headache Abdominal pain Muscle spasms
2013-015946	Prophylaxis	Gardasil	.5 ml	Peripheral swelling
2013-015947	Prophylaxis	Gardasil	.5 ml	Headache
2013-015959	Prophylaxis	Gardasil	.5 ml	Eye pain Chills Arthralgia Pyrexia Headache Pain in extremity Photophobia
2013-015968	Prophylaxis	Gardasil		Rash pruritic
2013-015987	Prophylaxis	Gardasil	.5 ml	Malaise Headache Pain Pain in extremity
2013-016024	Prophylaxis	Gardasil	.5 ml	Medication error
2013-016065	Prophylaxis	Gardasil	.5 ml	Sneezing Eye pruritus Influenza like illness
2013-016066	Prophylaxis	Gardasil	.5 ml	Sneezing Eye pruritus Influenza like illness
2013-016207	Prophylaxis	Gardasil		Respiratory distress Pyrexia Blister Oropharyngeal pain Cough
2013-016280	Prophylaxis	Gardasil	.5 ml .5 ml	Dizziness Influenza like illness Nausea Somnolence Fatigue Headache Narcolepsy Hypersomnia Syncope Fatigue Platelet count increased Chronic fatigue syndrome Post viral fatigue syndrome Arthralgia

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Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Chest pain Hypertension Myalgia Abdominal pain upper Menstrual disorder Decreased appetite Paralysis Joint hyperextension Palpitations Disturbance in attention Eye disorder Depression Anxiety Social anxiety disorder Dyspnoea Mood swings Insomnia Bedridden Cardiac disorder Hypoaesthesia Feeling abnormal Confusional state Amnesia Respiratory disorder Social problem Memory impairment
2013-016360	Prophylaxis	Gardasil	.5 ml	Headache Dizziness
2013-016556	Prophylaxis	Gardasil		Pain Decreased appetite Erythema Headache
2013-016588	Prophylaxis	Gardasil	.5 ml	Lethargy Pain in extremity Headache
2013-016589	Prophylaxis	Gardasil	.5 ml	Lethargy Pain in extremity Headache Pyrexia
2013-016600	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml .5 ml .5 ml	Anaphylactic reaction Dizziness Pallor Chest discomfort Wheezing Tongue oedema Hypotension
2013-016625	Prophylaxis	Gardasil	.5 ml	Malaise Body temperature increased Arthralgia Facial paralysis
2013-016643	Prophylaxis	Gardasil	.5 ml	Erythema Flushing
2013-016695	Prophylaxis	Gardasil	.5 ml	Pyrexia Musculoskeletal stiffness Lethargy Fatigue Nausea Feeling of body temperature Malaise Flushing
2013-016711	Prophylaxis	Gardasil	1 Dosage forms	Erythema Pain in extremity
2013-016713	Prophylaxis	Gardasil	1 Dosage forms	Syncope Fall
2013-016717	Prophylaxis	Gardasil		Tenderness

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2013-016719	Prophylaxis	Gardasil	.5 ml	Pain in extremity Erythema
2013-016723	Prophylaxis	Gardasil		Pain in extremity
2013-016758	Prophylaxis	Gardasil	.5 ml	Rash pruritic Feeling hot Rash macular Rash erythematous
2013-016803	Prophylaxis	Gardasil		Pain in extremity
2013-016853	Prophylaxis	Gardasil		Pain in extremity Tenderness
2013-016863	Prophylaxis	Gardasil	.5 ml	Rash pruritic Urticaria
2013-016869	Prophylaxis	Gardasil		Postural orthostatic tachycardia Palpitations
2013-016871	Prophylaxis	Boostrix Gardasil	1 Dosage forms 1 Dosage forms 1 Dosage forms	Feeling hot Dizziness Malaise Dysphagia Flushing Urticaria Throat tightness Hypersensitivity
2013-016877	Prophylaxis	Boostrix Gardasil	1 Dosage forms 1 Dosage forms	Headache Feeling hot Flushing Urticaria Dysphagia Hypersensitivity
2013-016890	Prophylaxis	Gardasil	1 Dosage	Peripheral swelling
2013-016896	Prophylaxis	Gardasil		Nausea
2013-016907	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Urticaria Pruritus
2013-016909	Prophylaxis	Gardasil		Rash erythematous Urticaria
2013-016932	Prophylaxis	Gardasil		Injection site pain Musculoskeletal stiffness
2013-016974	Prophylaxis	Gardasil	.5 ml	Exposure during pregnancy
2013-016975	Prophylaxis	Gardasil	.5 ml	Headache
2013-016993	Prophylaxis	Gardasil		Exposure during pregnancy
2013-017000	Prophylaxis	Gardasil	.5 ml .5 ml	Exposure during pregnancy No adverse event
2013-017091	Prophylaxis	Gardasil	.5 ml	Abdominal pain Back pain Decreased appetite Pyrexia
2013-017100	Prophylaxis	Gardasil		Rash
2013-017119	Prophylaxis	Gardasil		Psoriasis
2013-017126	Prophylaxis	Gardasil	1 Dosage forms	Influenza like illness Headache Myalgia Arthralgia Lethargy Sinusitis
2013-017185	Prophylaxis	Boostrix Gardasil	.5 ml .5 ml	Headache Fatigue Dizziness
2013-017198	Prophylaxis	Gardasil		Exposure during pregnancy No adverse event
2013-017202	Prophylaxis	Gardasil		Exposure during pregnancy No adverse event
2013-017285	Prophylaxis	Gardasil	.5 ml	Epilepsy Asthenia Syncope Tonic clonic movements Fatigue

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HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Headache
2013-017346	Prophylaxis	Gardasil		Seizure
2013-017358	Prophylaxis	Gardasil		Influenza like illness Pain Body temperature increased Headache Oropharyngeal pain Musculoskeletal stiffness
2013-017433	Prophylaxis	Gardasil		Nausea Headache Body temperature increased Face oedema Dysphagia
2013-017446	Prophylaxis	Gardasil	.5 ml	Fatigue Lymphadenopathy Pyrexia
2013-017672	Prophylaxis	Gardasil	.5 ml	Injection site pain
2013-017770	Prophylaxis	Gardasil	1 Dosage forms	No adverse event Inappropriate schedule of drug
2013-017835	Prophylaxis	Gardasil Boostrix		Pallor Cold sweat Hypotension
2013-017837	Prophylaxis	Gardasil		Syncope
2013-017839	Prophylaxis	Gardasil		Presyncope Syncope
2013-017840	Prophylaxis	Gardasil		Syncope Hypotension
2013-018105	Prophylaxis	Pandemrix Gardasil		Fatigue Somnolence Headache Dizziness Chronic fatigue syndrome
2013-018229	Prophylaxis	Gardasil		Dizziness Nausea
2013-018254	Prophylaxis	Gardasil		Nausea
2013-018275	Prophylaxis	Gardasil		Sensation of foreign body Rash erythematous Tachycardia Headache
2013-018284	Prophylaxis	Gardasil		Malaise Pyrexia Oropharyngeal pain Peripheral swelling
2013-018290	Prophylaxis	Gardasil		Syncope
2013-018292	Prophylaxis	Gardasil		Syncope
2013-018296	Prophylaxis	Gardasil		Syncope
2013-018297	Prophylaxis	Gardasil		Panic attack
2013-018299	Prophylaxis	Gardasil		Syncope
2013-018309	Prophylaxis	Gardasil		Body temperature increased
2013-018316	Prophylaxis	Gardasil		Headache Stress Dizziness Panic attack
2013-018317	Prophylaxis	Gardasil		Headache Amnesia Syncope Fall
2013-018318	Prophylaxis	Gardasil	.5 ml	Rash Hypersensitivity
2013-018319	Prophylaxis	Gardasil	.5 ml	Hypersensitivity Rash pruritic
2013-018320	Prophylaxis	Gardasil	.5 ml	Hypersensitivity Rash pruritic
2013-018321	Prophylaxis	Gardasil	.5 ml	Hypersensitivity Rash

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Nausea
2013-018323	Prophylaxis	Gardasil	.5 ml	Hypersensitivity Rash pruritic Nausea
2013-018339	Prophylaxis	Gardasil		Pain in extremity Headache Pyrexia Asthenia Fatigue Injection site warmth
2013-018349	Prophylaxis	Gardasil	.5 ml .5 ml	Extra dose administered No adverse event
2013-018354	Prophylaxis	Gardasil		Syncope Dizziness
2013-018355	Prophylaxis	Gardasil		Nausea
2013-018357	Prophylaxis	Gardasil	.5 ml	Asthenia Pain in extremity Asthma Body temperature increased
2013-018363	Prophylaxis	Gardasil		Fatigue
2013-018377	Prophylaxis	Gardasil		Vomiting
2013-018378	Prophylaxis	Gardasil		Syncope
2013-018379	Prophylaxis	Gardasil		Headache
2013-018386	Prophylaxis	Gardasil	.5 ml	Vomiting Retching Syncope Headache
2013-018389	Prophylaxis	Gardasil	.5 ml	Erythema nodosum Oropharyngeal pain Fatigue
2013-018391	Prophylaxis	Gardasil	.5 ml	Nasal congestion Eye swelling
2013-018415	Prophylaxis	Gardasil	.5 ml	Rash erythematous
2013-018416	Prophylaxis	Gardasil	.5 ml	Rash macular Dizziness Butterfly rash Pallor
2013-018448	Prophylaxis	Gardasil		Syncope
2013-018450	Prophylaxis	Gardasil		Urticaria
2013-018453	Prophylaxis	Gardasil		Rash pruritic
2013-018462	Prophylaxis	Gardasil	.5 ml	Extra dose administered Malaise
2013-018464	Prophylaxis	Gardasil		Syncope
2013-018465	Prophylaxis	Gardasil		Dizziness
2013-018467	Prophylaxis	Gardasil	.5 ml	Extra dose administered No adverse event
2013-018468	Prophylaxis	Gardasil		Asthenia Nausea Lethargy
2013-018480	Prophylaxis	Gardasil		Syncope
2013-018481	Prophylaxis	Gardasil		Syncope
2013-018490	Prophylaxis	Gardasil	.5 ml	Nausea Asthenia Syncope Presyncope
2013-018505	Prophylaxis	Gardasil	1 Dosage forms	Limb discomfort Pain in extremity Pyrexia Syncope Vision blurred Hyperhidrosis Vomiting
2013-018525	Prophylaxis	Gardasil		Dizziness Pallor Asthenia

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HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Cold sweat
2013-018536	Prophylaxis	Gardasil	.5 ml	Rash pustular
2013-018541	Prophylaxis	Gardasil	.5 ml	Peripheral swelling
2013-018584	Prophylaxis	Gardasil	.5 ml	Tachycardia Headache Flushing Heart rate irregular Dizziness
2013-018751	Prophylaxis	Gardasil		Herpes zoster
2013-018774	Prophylaxis	Gardasil Boostrix		Syncope Post viral fatigue syndrome Pain
2013-018788	Prophylaxis	Gardasil	.5 ml	Extra dose administered No adverse event
2013-018789	Prophylaxis	Gardasil	.5 ml	Extra dose administered No adverse event
2013-018829	Prophylaxis	Gardasil		Pallor Cold sweat Tremor Syncope
2013-018856	Prophylaxis	Gardasil		Headache Dizziness Muscular weakness Myalgia
2013-018857	Prophylaxis	Gardasil		Headache
2013-018889	Prophylaxis	Gardasil		Headache
2013-018890	Prophylaxis	Gardasil		Nausea Dizziness
2013-018897	Prophylaxis	Gardasil		Headache Dizziness
2013-018899	Prophylaxis	Gardasil		Vomiting
2013-018929	Prophylaxis	Gardasil		Peripheral swelling
2013-018950	Prophylaxis	Gardasil	.5 ml	Urticaria
2013-018966	Prophylaxis	Gardasil		Headache Dizziness Anxiety Depression Mood swings Quality of life decreased Vomiting Abnormal behaviour Memory impairment Confusional state Tremor
2013-018980	Prophylaxis	Gardasil	.5 ml	Lip swelling Joint swelling Rash Throat tightness
2013-019017	Prophylaxis	Gardasil	.5 ml	Injection site paraesthesia Muscle spasms Dyspnoea
2013-019028	Prophylaxis	Gardasil		Headache Dyspepsia
2013-019033	Prophylaxis	Gardasil	.5 ml	Syncope Headache Urticaria
2013-019103	Prophylaxis	Gardasil		Headache Dizziness Nausea
2013-019150	Prophylaxis	Gardasil		Drug prescribing error No adverse event
2013-019180	Prophylaxis	Gardasil	.5 ml	Cough Throat tightness Wheezing
2013-019223	Prophylaxis	Gardasil	.5 ml	Immune thrombocytopenic

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Haemorrhage
2014-019231	Prophylaxis	Gardasil	.5 ml .5 ml	Platelet count decreased Mucosal haemorrhage Immune thrombocytopenic
2014-019235	Prophylaxis	Gardasil		Haemorrhage Contusion Thrombocytopenia Immune thrombocytopenic
2014-019311	Prophylaxis	Gardasil		Diarrhoea Colitis
2014-019334	Prophylaxis	Gardasil		Headache
2014-019336	Prophylaxis	Gardasil		Headache Malaise
2014-019345	Prophylaxis	Gardasil		Nausea Dizziness
2014-019368	Prophylaxis	Gardasil		Headache
2014-019429	Prophylaxis	Gardasil	.5 ml	Periorbital oedema Swelling face Vision blurred Swelling
2014-019430	Prophylaxis	Gardasil	.5 ml	Peripheral swelling Erythema Pruritus
2014-019580	Prophylaxis	Gardasil	.5 ml	Headache Pyrexia Rash papular
2014-019586	Prophylaxis	Gardasil		Migraine with aura Asthenia Amnesia Aphasia Headache
2014-019844	Prophylaxis	Gardasil		Nausea Headache Vomiting Asthenia Fatigue Decreased appetite
2014-019893	Prophylaxis	Gardasil		Extra dose administered No adverse event
2014-020050	Prophylaxis	Gardasil		Disorientation Abnormal behaviour Memory impairment Fatigue Malaise Syncope
2014-020057	Prophylaxis	Gardasil		Nausea
2014-020058	Prophylaxis	Gardasil		Headache
2014-020073	Prophylaxis	Gardasil		Headache Dizziness Feeling cold Muscular weakness Lethargy Fatigue Pharyngitis
2014-020190	Prophylaxis	Gardasil	.5 ml	Trance Muscle twitching Headache
2014-020199	Prophylaxis	Gardasil		Vomiting
2014-020200	Prophylaxis	Gardasil Priorix.		Vomiting Dizziness
2014-020210	Prophylaxis	Gardasil		Limb discomfort Injection site streaking Skin hypopigmentation Acne
2014-020212	Prophylaxis	Gardasil	.5 ml	Psychomotor hyperactivity

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2014-020218	Prophylaxis	Gardasil	.5 ml	Syncope
2014-020224	Prophylaxis	Gardasil Boostrix		Asthenia Vomiting Pain in extremity Pyrexia Malaise
2014-020231	Prophylaxis	Gardasil		Headache
2014-020232	Prophylaxis	Gardasil Boostrix		Syncope Asthenia
2014-020233	Prophylaxis	Gardasil		Peripheral swelling Tenderness Erythema
2014-020234	Prophylaxis	Gardasil		Syncope
2014-020235	Prophylaxis	Gardasil		Nausea
2014-020263	Prophylaxis	Gardasil		Pyrexia Vomiting Nausea Erythema Arthralgia
2014-020267	Prophylaxis	Gardasil		Syncope Headache Seizure Hyperventilation Vision blurred Nausea Muscular weakness Sensory loss Loss of consciousness Fatigue Pain Bedridden Muscle twitching Chest pain Dyspnoea Amnesia Menstruation irregular Loss of personal independence in
2014-020397	Prophylaxis	Gardasil	.5 ml	Fatigue Dizziness Headache Abdominal pain Nausea Influenza like illness Feeling hot
2014-020434	Acne	Gardasil		Thrombosis
2014-020488		Gardasil		Blister Rash
2014-020513	Prophylaxis	Gardasil		Sensation of foreign body Dysphagia Cough Dry mouth
2014-020540	Prophylaxis	Gardasil Priorix.		Pyrexia Lethargy
2014-020602	Prophylaxis	Gardasil		Hypoaesthesia Panic attack Hyperventilation
2014-020603	Prophylaxis	Gardasil		Injection site erythema Injection site pain
2014-020606	Prophylaxis	Gardasil		Nausea
2014-020607	Prophylaxis	Gardasil		Urticaria
2014-020821	Prophylaxis	Gardasil Boostrix		Dizziness Flushing Decreased appetite Fatigue
2014-021036	Prophylaxis	Gardasil		Papilloma viral infection

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2014-021042	Prophylaxis	Gardasil		Syncope
2014-021212	Prophylaxis	Gardasil	.5 ml	Headache Asthenia Confusional state Otitis media Body temperature increased
2014-021605	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Sleep disorder Headache Fatigue Disturbance in attention Hyperacusis Personality change Pain in extremity Seizure Loss of consciousness Visual impairment Mouth ulceration Memory impairment Alopecia Asthenia Dyspnoea Muscular weakness Pain Clumsiness Malaise Chills Hyperhidrosis Dizziness Syncope Paraesthesia Menstrual disorder Urticaria Pruritus Dry skin Heart rate increased Chest pain Panic attack Vomiting Arthralgia Abdominal pain upper Neck pain Back pain Dysstasia Bedridden Loss of personal independence in
2014-021628	Prophylaxis	Gardasil		Pruritus Insomnia Rash generalised Contusion Blister Hypersensitivity
2014-021639	Prophylaxis	Gardasil	.5 ml	Syncope
2014-021640	Prophylaxis	Gardasil	.5 ml	Syncope
2014-021641	Prophylaxis	Gardasil	.5 ml	Syncope
2014-021665	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Syncope Haematoma
2014-021666	Prophylaxis	Gardasil	.5 ml	Syncope
2014-021779	Prophylaxis	Gardasil		Peripheral swelling Pain in extremity Hodgkin's disease
2014-021799	Prophylaxis	Gardasil		Tonsillitis Hyperaesthesia Skin discolouration Fatigue Headache

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2014-022114	Prophylaxis	Gardasil Tetravac Diphtheria,		Seizure Malaise
2014-022215	Prophylaxis	Gardasil		Headache Chest pain Fatigue Dizziness Malaise Insomnia
2014-022243	Prophylaxis	Gardasil	.5 ml	Medication error Emotional distress Fatigue
2014-022438	Prophylaxis Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Ehlers-Danlos syndrome Postural orthostatic tachycardia Syncope Hypotension Adenovirus infection Asthenia Fatigue Seizure Amnesia Confusional state Mast cell activation syndrome Headache Arthralgia Pain Syncope Circulatory collapse Orthostatic hypotension Heart rate abnormal Dizziness Chest pain Nausea Disturbance in attention Inappropriate schedule of drug Vaccination error Fatigue
2014-022442	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Asthenia Dysstasia Aphasia Asthenia
2015-022601	Prophylaxis	Boostrix Gardasil		Pyrexia Chills Hallucination
2015-022720	Prophylaxis	Gardasil	1 Dosage forms 1 Dosage forms 1 Dosage forms	Chronic fatigue syndrome Lymphatic disorder Headache Fatigue Bedridden Pain Loss of personal independence in Limb deformity Blindness transient Visual field defect Injection site haemorrhage Injection site mass Oropharyngeal pain Lymphadenopathy Weight increased Somnolence Pain Vomiting Diarrhoea Dizziness Fatigue Vision blurred

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Nausea Disturbance in attention Muscular weakness Chest discomfort Skin discomfort Arthralgia Eye pain Amenorrhoea Abdominal pain lower
2015-023381	Prophylaxis	Gardasil	.5 ml	Type III immune complex Injection site induration Injection site erythema Injection site pruritus Purpura
2015-023382	Prophylaxis	Gardasil Menjugate Kit	.5 ml .5 ml	Injection site reaction Oedema peripheral Rash Erythema Pruritus Skin warm Contusion
2015-023418	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Headache Fatigue
2015-023478	Prophylaxis	Gardasil		Pyrexia
2015-023576	Prophylaxis	Gardasil	.5 ml	Alopecia
2015-023577	Prophylaxis	Gardasil	.5 ml	Alopecia
2015-023609	Prophylaxis	Gardasil		Urticaria
2015-023619	Prophylaxis	Gardasil	.5 ml	Injection site pain
2015-023703	Prophylaxis	Gardasil	.5 ml	Basedow's disease
2015-023715	Prophylaxis	Gardasil Boostrix		Urticaria Eye swelling Lip swelling Chronic spontaneous urticaria
2015-023733	Prophylaxis	Gardasil		Amnesia Disturbance in attention Food intolerance Visual impairment Hyperacusis Myalgia Arthralgia General physical health Loss of personal independence in Injury Post viral fatigue syndrome Chronic fatigue syndrome Headache Cognitive disorder Abdominal discomfort Neuralgia Sleep disorder Photophobia Bedridden Asthenia Fatigue
2015-023734	Prophylaxis	Gardasil		Post viral fatigue syndrome Chronic fatigue syndrome Fibromyalgia Cognitive disorder Abdominal discomfort Neuralgia Sleep disorder Bedridden Asthenia Pain Fatigue

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Feeling abnormal Back disorder Skin disorder Fatigue Back pain Depression Hypokinesia Headache Gait disturbance Autoimmune disorder Pallor Pain Arthropathy Hypothyroidism Thyroid disorder Musculoskeletal pain Photophobia Heart rate abnormal Menstrual disorder Raynaud's phenomenon Lyme disease Intervertebral disc degeneration Peripheral coldness Paraesthesia Loss of personal independence in Disturbance in attention Neurological symptom Arthralgia Rash erythematous Tachycardia Hiccups
2015-023780	Prophylaxis	Gardasil	.5 ml	Injection site swelling Rash
2015-023788	Prophylaxis	Gardasil		Dizziness Asthenia Immobile Myalgia Seizure Headache Nausea Abdominal pain Visual impairment Depression Chronic fatigue syndrome Mental disorder Pallor Malaise Dyspnoea Dyskinesia Pyrexia Pharyngitis streptococcal Muscular weakness Gait disturbance Psychiatric symptom Disturbance in attention Fatigue
2015-023805	Prophylaxis Prophylaxis	Gardasil	.5 ml	Seizure Vision blurred Pain Headache Aphonia Muscle spasms Musculoskeletal stiffness Nausea Fatigue

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Asthenia Anxiety Chest pain Paralysis Muscle spasms Insomnia Gait disturbance Feeling cold Helicobacter infection Gastrointestinal inflammation Gastroesophageal reflux disease Hypotension Heart rate increased Blood glucose decreased Fatigue Loss of personal independence in Epilepsy Fatigue Pain in extremity Headache Photosensitivity reaction Heart rate decreased Migraine Palpitations Tachycardia Syncope Bedridden Somnolence Arthralgia Postural orthostatic tachycardia Malaise
2015-023819	Prophylaxis	Gardasil		Dizziness Asthenia
2015-023820	Prophylaxis	Gardasil		Dizziness Fatigue Asthenia Headache Nausea Abdominal pain Post viral fatigue syndrome
2015-023821	Prophylaxis	Gardasil		Dizziness Fatigue Fibromyalgia Ovarian cyst Headache Pain Eye disorder Hyperacusis Food intolerance Memory impairment Disturbance in attention Post viral fatigue syndrome Chronic fatigue syndrome
2015-023833	Prophylaxis Prophylaxis	Gardasil Boostrix		Seizure Visual impairment Eye movement disorder Abdominal pain upper Chest pain Muscular weakness Nausea Fatigue Headache Skin discolouration Aphasia Joint swelling

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Dizziness Dyskinesia Feeling abnormal Facial pain Eye pain Pain in extremity Musculoskeletal stiffness Hypokinesia Arthralgia Malaise
2015-023835	Prophylaxis	Gardasil		Injection site swelling Cataplexy Chronic fatigue syndrome Abdominal pain Arthralgia Disturbance in attention Menstrual disorder Mood swings Dizziness Photosensitivity reaction Pyrexia
2015-023837	Prophylaxis	Gardasil		Fatigue Seizure Panic attack Chest pain Ovarian cyst Depressed mood
2015-023847	Prophylaxis	Menjugate Kit Gardasil		Myalgia Arthralgia
2015-023920	Prophylaxis	Gardasil Menjugate Kit		Musculoskeletal pain Hypoesthesia
2015-024024	Prophylaxis	Gardasil	.5 ml .5 ml	Headache Alopecia
2015-024198	Prophylaxis	Gardasil		Palpitations
2015-024209	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Myalgia Erythema Neuralgia Joint swelling Pain
2015-024219	Prophylaxis	Gardasil		Syncope Asthenia Malaise Quality of life decreased
2015-024241	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Headache Dizziness Oropharyngeal pain Syncope Limb discomfort Abdominal pain upper Depressed mood Hypoesthesia Paraesthesia
2015-024338	Prophylaxis	Gardasil Boostrix		Injection site erythema Injection site swelling
2015-024347	Prophylaxis	Gardasil		Malaise Pyrexia Headache Oropharyngeal pain Musculoskeletal stiffness Hallucination Vomiting
2015-024348	Prophylaxis	Gardasil Boostrix		Syncope Hypotension Pallor Cold sweat

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2015-024349	Prophylaxis	Gardasil Boostrix		Asthenia Pallor Cold sweat
2015-024350	Prophylaxis	Gardasil		Syncope
2015-024351	Prophylaxis	Gardasil Boostrix		Asthenia Nausea Pallor
2015-024352	Prophylaxis	Gardasil Boostrix		Asthenia Feeling cold Cold sweat Syncope Generalised tonic-clonic seizure
2015-024379	Prophylaxis	Gardasil		Arthralgia Somnolence Oropharyngeal pain
2015-024394	Prophylaxis	Gardasil		Seizure Rash Arthralgia Migraine Oropharyngeal pain Gastroesophageal reflux disease Irritable bowel syndrome Fatigue Dizziness Vision blurred Blood iron decreased Menorrhagia Tremor
2015-024427	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Headache Diarrhoea Constipation Fatigue Feeling cold Pain in extremity Nausea Poor quality sleep Chapped lips Dry skin Somnolence Menstruation irregular Vulvovaginal pain Vaginal discharge Urinary tract infection Weight increased Dizziness Dyspnoea Thirst Arthralgia
2015-024429	Prophylaxis	Gardasil		Chronic fatigue syndrome Cognitive disorder Disturbance in attention Immune system disorder Amnesia Obsessive-compulsive disorder Insomnia Anxiety Loss of personal independence in Menorrhagia Asthma Weight decreased Oropharyngeal pain Arthralgia Myalgia Nausea Dizziness

Please also refer to the caveat document enclosed.

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Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Chills Hypotension Headache Vomiting Fatigue Influenza like illness Pneumonia Muscle atrophy Home care Circulatory collapse Ear pain Vision blurred Decreased appetite Pain Lethargy Seizure Swelling
2015-024438	Prophylaxis	Gardasil		Seizure Seizure Chest pain Visual impairment Hypotension Gastroesophageal reflux disease Fatigue Asthenia Pulse abnormal
2015-024452	Prophylaxis	Gardasil		Myalgia Fatigue Depression Panic attack Arthralgia Dizziness Palpitations Migraine Feeling abnormal Anxiety Tremor Visual impairment Chest pain Poor quality sleep Dyspnoea Pain Body temperature fluctuation Skin sensitisation Joint stiffness Muscle spasms Muscular weakness Mobility decreased Headache Gastrointestinal disorder Fibromyalgia Irritable bowel syndrome Developmental hip dysplasia Stress Hyperkeratosis
2015-024453	Prophylaxis	Gardasil		Muscle spasms Seizure Immunodeficiency
2015-024525	Prophylaxis	Gardasil		Back pain Erythema Inflammation
2015-024532	Prophylaxis	Gardasil		Nausea Headache Vomiting Pain

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Muscular weakness Vision blurred Dyspnoea
2015-024552	Prophylaxis	Gardasil		Neck pain Headache Arthralgia Contusion Photophobia Lethargy Dizziness Pyrexia Meningitis viral Orthostatic hypotension Vomiting Sinusitis Nasal polyps Rash Muscle spasms Diarrhoea Decreased appetite Sleep terror Panic attack Palpitations Heart rate irregular Muscular weakness Anxiety Depression Irritable bowel syndrome Fatigue Myalgia Constipation Nausea Epstein-Barr virus antibody Infectious mononucleosis
2015-024559	Prophylaxis	Gardasil		Pancreatitis Appendicitis Nausea Dizziness Hot flush Headache Trismus Epistaxis Fatigue Rash Coordination abnormal Malaise Myalgia Pain in extremity Pallor Pain Balance disorder Abdominal pain upper Syncope Asthenia Hypotension Loss of personal independence in Arthralgia Palpitations Photophobia Hyperacusis Amnesia Disturbance in attention Inflammation Eye infection Muscle fatigue

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Immune system disorder Decreased appetite Skin striae General physical health Lethargy Back pain Neck pain Vitamin D deficiency
2015-024571	Prophylaxis	Gardasil		Dizziness Feeling abnormal Chest pain Tremor Volume blood decreased Altered visual depth perception Syncope Seizure Malaise Fatigue Arthralgia Headache Disorientation Palpitations Pain Peripheral swelling Bone pain Bedridden Joint stiffness Abdominal discomfort Skin discolouration Immune system disorder Contusion Fall Gait disturbance
2015-024575	Prophylaxis	Gardasil		Dizziness Vision blurred Headache Pain in extremity Vomiting Panic attack Anxiety Back pain Hypotension Syncope Pain Fatigue Nightmare Diplopia Malaise Amnesia Dyspnoea Confusional state Myalgia Muscular weakness Lymphadenopathy Cyanosis Pyrexia Diarrhoea Pneumonia chlamydial Epstein-Barr viraemia Immunosuppression Bacterial infection
2015-024628	Prophylaxis	Gardasil	.5 ml	Complex regional pain syndrome
2015-024638	Prophylaxis	Gardasil	.5 ml	Muscular weakness Hypoesthesia Sensory loss

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2015-024660	Prophylaxis	Gardasil		Nausea Vomiting Fatigue Anxiety Dizziness Food intolerance Amnesia Pain Abdominal pain Sleep disorder Disturbance in attention Depression Menstrual disorder Headache Photophobia Hyperacusis Arthralgia Arthritis Bone pain Osteitis Myalgia Myositis Hypoaesthesia Skin infection Cognitive disorder Mood altered Feeling abnormal Kidney infection Respiratory tract infection Temperature regulation disorder Chills Pyrexia Lymphadenopathy Oropharyngeal pain Visual impairment
2015-024667	Prophylaxis	Gardasil	.5 ml	Blindness transient
2015-024674	Prophylaxis	Gardasil		Palpitations Asthenia Hypertension Hypotension Cold sweat Tremor Headache Fatigue Pain Syncope Dizziness
2015-024684	Prophylaxis	Gardasil		Fatigue Seizure Arthralgia
2015-024689	Prophylaxis	Gardasil	.5 ml .5 ml	Myalgia Fatigue
2015-024698	Prophylaxis	Diphtheria/Tetanus/Pertussis Vaccine Gardasil		Injection site pain Pain in extremity Myalgia Photophobia Chest pain
2015-024703	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Fatigue Insomnia Pain in extremity Diarrhoea Malaise
2015-024720	Prophylaxis	Gardasil		Influenza like illness Oropharyngeal pain Vision blurred

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Vomiting Epistaxis Chest pain Arthralgia Myalgia Dysmenorrhoea Hormone level abnormal Dizziness Fatigue Feeling abnormal Peripheral coldness Skin striae Varicose vein Oral fungal infection Breath odour Hyperhidrosis Flushing Glassy eyes Lacrimation increased Post viral fatigue syndrome Fibromyalgia Malaise Body temperature decreased Cyanosis Seizure Autoimmune disorder Fatigue Pain Memory impairment Headache Aphonia
2015-024730	Prophylaxis	Gardasil Boostrix	.5 ml	Headache Pyrexia Nausea
2015-024743		Gardasil	.5 ml	Headache Photophobia Malaise Panic attack Irlen syndrome
2015-024760		Gardasil		Back pain Amnesia SLE arthritis Connective tissue disorder Arthralgia Fatigue Joint swelling Alopecia Headache Mouth ulceration Gait disturbance Depressed mood
2015-024763	Prophylaxis	Gardasil		Neurological symptom Palpitations Migraine Fatigue Dizziness Syncope Dyspnoea Hypoaesthesia Paraesthesia Pain Visual impairment Chest pain Disturbance in attention Depression

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Anxiety
2015-024790	Prophylaxis	Gardasil		Epilepsy Seizure
2015-024791	Prophylaxis	Gardasil		Postural orthostatic tachycardia Pain Fatigue Abdominal discomfort Swelling Swelling face Peripheral swelling Allodynia Palpitations Amenorrhoea Headache Fatigue Feeling abnormal Dizziness Tachycardia Insomnia Hyperhidrosis Abdominal pain Dyspepsia Nausea Pneumonia chlamydial Cough Dyspnoea Blood pressure abnormal Photophobia Hyperacusis Sinus disorder Viral infection Fibromyalgia Swelling Choking Pharyngeal oedema Oropharyngeal pain Amnesia Rash Skin striae Acne Muscular weakness Inappropriate affect Inappropriate affect Mental disorder Anxiety Loss of consciousness Adverse drug reaction
2015-024801	Prophylaxis	Gardasil		Dizziness Headache Pneumonia aspiration Fatigue Hypersomnia Seizure Dysmenorrhoea Fibromyalgia Postural orthostatic tachycardia Memory impairment Mental impairment Photophobia Hyperacusis
2015-024806	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Menstrual disorder Headache Syncope Seizure Oropharyngeal pain

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Fatigue Feeling cold
2015-024826	Prophylaxis	Gardasil		Postural orthostatic tachycardia Dizziness Nausea Headache Vomiting Nasopharyngitis Syncope Abdominal migraine Fatigue Sleep disorder Disturbance in attention Ear pain Blepharitis Tremor Dyspnoea Chest pain Body temperature fluctuation Skin discolouration Abdominal distension Menstruation irregular Tachycardia
2015-024833	Prophylaxis	Gardasil		Seizure Pain in extremity Fatigue Arthralgia Panic attack
2015-024850	Prophylaxis	Gardasil		Muscle spasms Dyskinesia Blepharospasm Headache Fatigue Loss of consciousness Sleep disorder Nightmare Feeling cold Seizure Myalgia
2015-024893	Prophylaxis	Gardasil Boostrix	5 ml .5 ml	Influenza like illness Headache Lip swelling Eye swelling Pruritus Peripheral swelling Injection site swelling Malaise
2015-024908	Prophylaxis	Gardasil	1 Dosage forms 1 Dosage	Gastric disorder Gastrointestinal disorder Fatigue
2015-024912	Prophylaxis	Gardasil	.5 ml	Rash Migraine Gastrointestinal disorder
2015-024939	Prophylaxis	Gardasil	.5 ml	Syncope Fatigue Pain in extremity Hypoaesthesia Seizure Dizziness Muscle spasms Headache Arthralgia Abdominal pain upper Rash Migraine

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Poor peripheral circulation Contusion
2015-024982	Prophylaxis	Gardasil	.5 ml	Fall Seizure Bite Loss of consciousness
2015-024996	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Headache Visual impairment Chest pain Palpitations Myalgia Pain in extremity Reflux gastritis Sensory disturbance Cognitive disorder Fatigue Dizziness Arthralgia Hypoaesthesia Paraesthesia Balance disorder Skin striae Menstrual disorder Amnesia
2015-025002	Prophylaxis	Gardasil		Syncope
2015-025026	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Muscle spasms Asthenia Hypersomnia Gastrointestinal disorder
2015-025099	Prophylaxis	Gardasil		Pain Syncope
2015-025152	Prophylaxis	Gardasil		Menstrual disorder Dysmenorrhoea Fatigue Diarrhoea Depression
2015-025160	Prophylaxis	Gardasil		Paraesthesia Asthenia Drop attacks Muscular weakness Fatigue Rash Dyskinesia Muscle spasms
2015-025223	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Pain Fatigue Asthenia
2015-025259	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Visual impairment Vision blurred
2015-025392	Prophylaxis	Gardasil		Hypoaesthesia Dizziness Rash Fatigue Pain Eye pain
2015-025396	Prophylaxis	Gardasil		Migraine Dizziness Pain Fatigue Nausea Vein rupture Ovarian cyst Malaise Pharyngitis Palpitations

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Dyspnoea Photophobia Visual acuity reduced Nightmare Chest pain Myalgia Limb discomfort Hypersomnia
2015-025405	Prophylaxis	Gardasil		Seizure Syncope Fall Pain in extremity Peripheral coldness Musculoskeletal stiffness Muscle rigidity
2015-025416	Prophylaxis	Gardasil		Fatigue Haematochezia Chest pain Anxiety Panic attack Insomnia Nausea Heart rate increased
2015-025428	Prophylaxis	Gardasil	.5 ml	Asthenia Dizziness Dysstasia Presyncope Malaise Headache Tremor Pyrexia Arthralgia Rash papular Bedridden Fatigue Feeling of body temperature Back pain Abdominal pain upper Gait disturbance Hair colour changes
2015-025438	Prophylaxis	Gardasil	.5 ml .5 ml	Syncope Loss of consciousness Abdominal pain Pain in extremity Headache Nausea Photophobia
2015-025439	Prophylaxis	Gardasil		Complex regional pain syndrome Peripheral swelling Pain Neck pain Headache Insomnia Fatigue
2015-025443	Prophylaxis	Gardasil		Headache Nausea Migraine Asthenia
2015-025450	Prophylaxis	Gardasil	.5 ml .5 ml	Fatigue Headache Myalgia Depression Disturbance in attention Back pain
2015-025474	Prophylaxis	Gardasil		Seizure

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2015-025478	Prophylaxis	Gardasil		Fatigue Headache Malaise Disturbance in attention Arthralgia Feeling abnormal
2015-025491	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Endometriosis Fatigue Syncope Menorrhagia Dizziness Headache Injury
2015-025494	Prophylaxis	Gardasil		Pain Raynaud's phenomenon Fibromyalgia Fatigue Arthralgia Dizziness Headache Hypermobility syndrome
2015-025495	Prophylaxis	Gardasil	.5 ml	Systemic lupus erythematosus
2015-025496	Prophylaxis	Gardasil		Decreased appetite Depression Abdominal pain Fatigue
2015-025497	Prophylaxis	Gardasil		Syncope Seizure like phenomena Dizziness Fatigue
2015-025499	Prophylaxis	Gardasil Boostrix		Syncope Migraine Irritable bowel syndrome Postural orthostatic tachycardia Loss of consciousness
2015-025523	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Hypoaesthesia Headache Dizziness Contusion Immune thrombocytopenic
2015-025524	Prophylaxis	Gardasil	.5 ml	Limb discomfort Influenza like illness Nasopharyngitis Pain Headache Fatigue
2015-025547	Prophylaxis	Gardasil		Fatigue Asthenia Asthenia Palpitations Chest pain Asthenia
2015-025559	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Lichen sclerosus Dysuria Dyschezia Tonsillitis Candida infection
2015-025574	Prophylaxis Prophylaxis	Gardasil		Headache Nausea Chest pain Dyspnoea Back pain Rash Abdominal pain upper Arthralgia

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Dizziness Syncope Fatigue Lethargy Feeling abnormal Sleep disorder Gluten sensitivity Irritable bowel syndrome Menstruation irregular Dysmenorrhoea Migraine Depression Insomnia Abdominal distension Anxiety Decreased appetite Weight decreased Food allergy Depressed mood Asthenia Disturbance in social behaviour Chest discomfort Malaise Ovarian cyst ruptured Diarrhoea Vomiting Chronic fatigue syndrome Ovarian cyst
2016-025590	Prophylaxis	Gardasil		Fatigue Headache Viral infection
2016-025594	Prophylaxis	Gardasil Boostrix Meningococcal Polysaccharide Group C		Limb discomfort Fatigue Hypoesthesia Nausea Menstrual disorder Gastrointestinal disorder Feeling abnormal Alopecia Tremor Oropharyngeal pain Pallor Flushing Anxiety Hyperaesthesia Post viral fatigue syndrome Lethargy Asthenia Depression
2016-025595	Prophylaxis	Gardasil		Depression Flushing Syncope Malaise Migraine Fatigue Heart rate increased Depressed mood
2016-025640	Prophylaxis	Gardasil		Malaise Epistaxis Decreased appetite Weight decreased Pain Temporomandibular joint
2016-025641	Prophylaxis	Gardasil	.5 ml	Seizure
2016-025642	Prophylaxis	Gardasil	.5 ml	Syncope

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2016-025643	Prophylaxis	Gardasil	.5 ml	Pallor
2016-025645	Prophylaxis	Gardasil		Chest pain Pain Monoplegia Musculoskeletal stiffness Heart rate increased Hypertension Syncope Aphasia Palpitations Supraventricular tachycardia
2016-025648	Prophylaxis	Gardasil		Weight decreased Pain Malaise Syncope Dizziness Pain in extremity Back pain
2016-025651	Prophylaxis	Gardasil	.5 ml	Swelling Nausea Eating disorder Sleep disorder Arthralgia Heart rate irregular Blood pressure fluctuation Postural orthostatic tachycardia
2016-025695	Prophylaxis	Gardasil	.5 ml	Tremor Fatigue Cluster headache Vomiting Asthenia Pyrexia Malaise Bedridden Body temperature fluctuation Arthralgia Asthenia Nausea Abdominal pain upper Viral infection Limb discomfort
2016-025696	Prophylaxis	Gardasil		Myalgia Arthralgia Asthenia Fatigue Headache Dysstasia Disturbance in attention Photophobia Phonophobia Dizziness Insomnia
2016-025731	Prophylaxis	Gardasil		Syncope Palpitations Myalgia Headache
2016-025742	Prophylaxis	Gardasil	.5 ml .5 ml	Headache Limb discomfort Injection site erythema Fatigue Myalgia Muscular weakness Abdominal pain Ovarian cyst Dizziness postural

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Alopecia Body temperature decreased Peripheral coldness Muscle spasms Lymphadenopathy Paraesthesia Tremor Memory impairment Chest pain Tachycardia Temporomandibular joint Fibromyalgia Oropharyngeal pain Rhinorrhoea Dysphagia Asthenia Back pain Pharyngitis Disturbance in attention Aphasia Joint crepitation Pneumonia Lyme disease Diplegia Syncope Malaise Immune system disorder Infection Bedridden Insomnia Feeling abnormal Ovarian cyst ruptured Ovariocentesis Back pain Neck pain Musculoskeletal pain Hypoesthesia Complex regional pain syndrome Migraine Skin striae Menstruation irregular Food intolerance Skin papilloma Viral infection Pneumonia chlamydial
2016-025747	Prophylaxis	Gardasil		Syncope Fatigue Dizziness Abdominal pain Epistaxis Insomnia Palpitations Feeling abnormal Menorrhagia Dry skin Gastrointestinal disorder Asthenia Headache
2016-025748	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Headache Malaise Fatigue Neck pain Back pain Influenza like illness Arthralgia

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Muscle spasms Pain in extremity
2016-025802	Prophylaxis	Gardasil		Arthralgia Myalgia Headache Fatigue Dizziness Confusional state Menstrual disorder Palpitations Abdominal pain upper Chest pain Back pain Urticaria Nausea Chills Fibromyalgia Raynaud's phenomenon Skin striae Paraesthesia Pain in extremity Photophobia Ear pain Insomnia Pain Pruritus Feeling abnormal Irritability Disturbance in attention Erythema Pain of skin Asthenia Seasonal allergy Eczema Pruritus Balance disorder Dysphemia Muscular weakness Food intolerance Hyperhidrosis Paralysis Skin discolouration Hyperacusis Hyperaesthesia Body temperature fluctuation Tinnitus Excessive cerumen production Tremor Pain Wheelchair user Influenza like illness Amnesia Pain in extremity Spinal pain Hypersomnia Autoimmune disorder Helplessness Scar pain Mental impairment Injury General physical health Seizure Syncope Feeling abnormal Muscular weakness

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Bedridden Ovarian cyst Immune system disorder Adverse event Petit mal epilepsy Monoplegia Pain Malaise
2016-025803	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Dyskinesia Paralysis Amnesia Disturbance in attention Disorientation Neck pain Body temperature fluctuation Intentional self-injury Dysarthria Drooling Paraesthesia Insomnia Heart rate increased Tachycardia Spinal pain Tourette's disorder Myoclonus Fatigue Ovarian cyst Vitamin B12 deficiency Diplopia
2016-025829	Prophylaxis	Gardasil		Malaise Dizziness Migraine Myalgia Abdominal pain Fatigue Nasopharyngitis Pharyngitis Abdominal discomfort Dyspepsia Raynaud's phenomenon Psoriasis Alopecia Back pain
2016-025843	Prophylaxis	Gardasil		Pain in extremity Restless legs syndrome Fatigue Decreased appetite Ovarian cyst Abdominal pain Pyrexia
2016-025846	Prophylaxis	Gardasil		Headache Myalgia Muscle spasms Pain Abnormal loss of weight Blood pressure decreased Visual impairment Fatigue Dizziness Menorrhagia Dysmenorrhoea Bacterial infection Immune system disorder
2016-025854	Prophylaxis	Gardasil		Depression Panic attack

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Insomnia Anxiety disorder Memory impairment Mood swings Headache Abdominal pain upper Rash erythematous Decreased appetite Eye disorder Gait disturbance Discomfort Loss of personal independence in Swelling
2016-025873	Prophylaxis	Gardasil		Headache Fatigue Decreased appetite Cold sweat Abdominal pain Chest pain Cough Oropharyngeal pain Nasal congestion Kidney infection Pyrexia Arthralgia Amnesia Disturbance in attention
2016-025874	Prophylaxis	Gardasil		Malaise Arthralgia Pyrexia Headache Decreased appetite Asthenia
2016-025878	Prophylaxis	Gardasil		Fatigue Arthralgia Skin striae Abdominal pain Pyrexia Headache Cognitive disorder
2016-025892	Prophylaxis	Gardasil		Fibromyalgia Synovial cyst Intervertebral disc degeneration Arthralgia General physical health Hypersomnia Depression Panic attack Skin striae Hypothyroidism Fatigue Malaise
2016-025914	Prophylaxis	Gardasil		Asthenia Dizziness Dyspnoea Palpitations Fatigue Pallor
2016-025942	Prophylaxis	Gardasil		Peroneal nerve injury Fatigue Weight decreased Amenorrhoea
2016-025943	Prophylaxis	Gardasil		Dizziness Nausea Fatigue

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Menstrual disorder
2016-025951	Prophylaxis	Gardasil	.5 ml	Urinary incontinence Blood urine present Myalgia Arthralgia Muscular weakness
2016-025988	Prophylaxis	Gardasil		Fatigue Syncope Seizure Paraesthesia Hypoesthesia Skin disorder Headache Muscle twitching Amnesia Muscle spasms Dizziness Disturbance in attention
2016-025996	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Headache Nausea Lethargy Malaise Abdominal pain Fatigue
2016-026014	Prophylaxis	Gardasil		Fatigue Alopecia Syncope Polycystic ovaries
2016-026027	Prophylaxis	Gardasil		Fatigue Feeling abnormal Headache Arthralgia Insomnia Abdominal discomfort Feeling of body temperature Dizziness Nausea Gait disturbance Migraine Abdominal pain upper Back pain Blindness transient Myalgia Anaemia Carpal tunnel syndrome
2016-026042	Prophylaxis	Gardasil		Abdominal pain Abdominal distension Swelling Hyperhidrosis Fatigue Insomnia Headache Tremor Vomiting Disturbance in attention
2016-026069	Prophylaxis	Gardasil		Syncope Rash
2016-026118	Prophylaxis	Gardasil		Chronic fatigue syndrome Dizziness Viral infection Asthenia Arthralgia Headache Photophobia Oropharyngeal pain

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Ear pain Feeling abnormal Developmental regression Pityriasis rosea Immune system disorder Bacterial infection Lyme disease
2016-026120	Prophylaxis	Gardasil		Pancreatitis acute Pancreatitis chronic Appendicectomy Tonsillitis Pharyngitis streptococcal Tonsillectomy Pharyngitis Abdominal rigidity Abdominal pain upper Rash Mouth ulceration Menstrual disorder Vitamin D decreased Food allergy Seasonal allergy Weight increased Headache
2016-026155	Prophylaxis	Gardasil		Fatigue Dizziness Visual impairment Hyperhidrosis Palpitations Asthenia Dyspnoea Rash Candida infection
2016-026170	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Fatigue Dizziness
2016-026211	Prophylaxis	Gardasil		Autoimmune disorder Fatigue Cognitive disorder Amnesia Disturbance in attention Depression Anxiety Feeling abnormal Aphasia Panic attack Headache Myalgia Neck pain Back pain Poor quality sleep Nightmare Asthenia Attention deficit/hyperactivity Intentional self-injury Suicide attempt
2016-026214	Prophylaxis	Gardasil		Fatigue Somnolence Abdominal pain Asthenia Syncope
2016-026331	Prophylaxis	Gardasil		Postural orthostatic tachycardia Mental disorder Dizziness Tachycardia Fatigue

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Insomnia Hyperhidrosis Abdominal pain Nausea Petit mal epilepsy Epilepsy Pneumonia Pneumonia Cough Costochondritis Dyspnoea Visual acuity reduced Photosensitivity reaction Vitreous floaters Hyperacusis Sinusitis Headache Fibromyalgia Vision blurred Menstruation irregular Ovulation pain Swelling Oropharyngeal pain Peripheral swelling Pain in extremity Peripheral swelling Feeling abnormal Memory impairment Disturbance in attention Rash Eczema Fungal infection Skin striae Acne Temperature regulation disorder Hypoaesthesia Hypoaesthesia Asthenia Reaction to excipient
2016-026437	Prophylaxis	Gardasil		Malaise Premature menopause Thyroiditis Hypothyroidism Autoimmune disorder Pain Lethargy
2016-026466	Prophylaxis	Gardasil Menjugate Kit		Dizziness Swelling face Erythema Urticaria Asthenia
2016-026477	Prophylaxis	Gardasil		Headache Injection site swelling Dyspnoea Chest pain Postural orthostatic tachycardia Palpitations Seizure Syncope Fatigue
2016-026479	Prophylaxis	Gardasil Menjugate Kit	.5 ml .5 ml	Dizziness Conversion disorder Blepharospasm
2016-026481	Prophylaxis	Gardasil Menjugate Kit	.5 ml .5 ml	Malaise Pain in extremity

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Arthralgia Nausea Pyrexia Dysarthria Confusional state Photophobia Neck pain Back pain Paraesthesia Headache Asthenia
2016-026490	Prophylaxis	Gardasil		Wheelchair user Influenza like illness Amnesia Nausea
2016-026495	Prophylaxis	Gardasil	.5 ml	Diarrhoea
2016-026512	Prophylaxis	Gardasil		Asthenia Dizziness Headache Abdominal pain Pallor Discomfort Pharyngitis Tonsillitis Lethargy Fatigue Muscular weakness Feeling abnormal Abdominal migraine Myalgia Arthralgia Chest pain Exercise tolerance decreased Bedridden Loss of personal independence in Malaise Ill-defined disorder Condition aggravated
2016-026518	Prophylaxis	Gardasil		Headache Asthenia Disturbance in attention Nausea Pyrexia
2016-026520	Prophylaxis	Gardasil		Seizure Gait inability Insomnia
2016-026526	Prophylaxis	Gardasil		Bedridden Fatigue Pallor Hypopnoea Dyspnoea Pain in extremity Peripheral swelling Chest discomfort Anxiety Ovarian cyst Headache Breast mass Oropharyngeal pain Chronic fatigue syndrome Myalgia Hypoaesthesia Paraesthesia Arthralgia Chest pain

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Palpitations Palpitations Photosensitivity reaction Peripheral coldness Abdominal pain Rash Memory impairment Disturbance in attention Syncope Vomiting Suicidal behaviour Menstrual disorder Pollakiuria Insomnia Temperature regulation disorder Cyst Cerebral cyst Hyperhidrosis Influenza like illness
2016-026527	Prophylaxis	Gardasil		Bedridden Fatigue Pallor Hypopnoea Dyspnoea Pain in extremity Peripheral swelling Chest discomfort Anxiety Immune system disorder Ovarian cyst Headache Breast mass Oropharyngeal pain Chronic fatigue syndrome Myalgia Hypoaesthesia Paraesthesia Arthralgia Chest pain Palpitations Palpitations Photosensitivity reaction Peripheral coldness Abdominal pain Rash Memory impairment Disturbance in attention Syncope Vomiting Suicidal behaviour Menstrual disorder Hyperhidrosis Pollakiuria Insomnia Temperature regulation disorder Cyst Cerebral cyst
2016-026529	Prophylaxis	Gardasil		Dizziness Nausea Headache Groin pain Syncope Muscle twitching Pain in extremity Disturbance in attention

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Psychogenic seizure
2016-026543	Prophylaxis	Gardasil Menjugate Kit	.5 ml .5 ml	Malaise Menstruation irregular Headache Dizziness Dyspnoea Pain Abdominal pain upper Oropharyngeal pain Hypotension Syncope Asthenia
2016-026592	Prophylaxis	Gardasil Menjugate Kit		Malaise Nausea Dizziness Vertigo
2016-026622	Prophylaxis	Gardasil		Dizziness Feeling abnormal Unresponsive to stimuli Asthenia Disturbance in attention
2016-026652	Prophylaxis	Gardasil Menjugate Kit		Somnolence Eye movement disorder Diplopia Slow response to stimuli Peripheral coldness Heart rate irregular
2016-026653	Prophylaxis	Gardasil Menjugate Kit		Rash erythematous Rash pruritic
2016-026661	Prophylaxis	Gardasil		Nausea Headache Fatigue Muscular weakness Syncope Dyspnoea Confusional state Dizziness Arthralgia Myalgia Malaise Amnesia Depression Anxiety Nightmare Agitation Sleep paralysis Disturbance in attention
2016-026698	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Malaise Vomiting Peripheral swelling Pyrexia Pain in extremity
2016-026709	Prophylaxis	Gardasil	.5 ml	Eye swelling
2016-026715	Prophylaxis	Gardasil		Malaise Influenza like illness Hypoaesthesia Monoplegia Fatigue Headache Dizziness Polymenorrhoea Syncope Poor quality sleep Pyrexia Vomiting

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2016-026738	Prophylaxis	Gardasil		Postural orthostatic tachycardia Asthenia Syncope Pyrexia Palpitations Bedridden Food intolerance Disturbance in attention Viral infection
2016-026742	Prophylaxis	Gardasil		Cataplexy Narcolepsy Arrhythmia Arthralgia Insomnia Loss of personal independence in Abnormal loss of weight Syncope
2016-026770		Gardasil		Migraine Malaise Headache Vision blurred Abdominal pain Nausea Dyspepsia Asthenia Blood iron increased Liver function test abnormal Food intolerance Gastrooesophageal reflux disease Anxiety Panic attack Skin striae Myalgia Abdominal distension Photophobia
2016-026817	Prophylaxis	Gardasil Menjugate Kit	.5 ml .5 ml	Headache Fatigue Weight increased
2016-026877	Prophylaxis	Gardasil Meningitis C Vaccine		Syncope Dizziness
2016-026907	Prophylaxis	Gardasil		Panic attack Anxiety Psychiatric symptom Multiple sclerosis Menstrual disorder Hypomania Disorientation Weight decreased
2016-026921	Prophylaxis	Gardasil	.5 ml	Alopecia
2016-026932	Prophylaxis	Gardasil Menjugate Kit	.5 ml .5 ml	Headache Malaise Dizziness Fatigue
2016-026940	Prophylaxis	Gardasil		Fatigue
2016-027006	Prophylaxis	Gardasil		Bone pain Influenza like illness Dizziness Vision blurred Headache Fatigue Lower respiratory tract infection Asthma Vomiting Syncope Asthenia

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
2016-027069	Prophylaxis	Gardasil		Pyrexia Muscle twitching Tremor Vomiting Headache Photophobia Arthralgia Fatigue Pain
2016-027070	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Malaise Headache Arthralgia Fatigue Somnolence Hypermobility syndrome Condition aggravated
2016-027090	Prophylaxis	Gardasil		Headache Dizziness Muscular weakness Epistaxis Vision blurred Fatigue Hyperacusis Feeling abnormal Vomiting Nausea
2016-027099	Prophylaxis	Gardasil		Headache Arthralgia Malaise Myalgia Asthenia Confusional state Rash Chills Abdominal pain upper Menstrual disorder Urinary tract infection Haemorrhage Anaemia vitamin B12 deficiency Oropharyngeal pain Blood iron decreased Fatigue Sleep disorder Irritable bowel syndrome
2016-027114	Prophylaxis	Gardasil		Fatigue Arthralgia Headache Nausea Viral infection Menstrual disorder Malaise
2016-027167	Prophylaxis	Gardasil		Influenza like illness Fatigue Balance disorder Somnolence Headache Gait disturbance Malaise Limb discomfort Arthralgia Sinusitis Viral infection Temperature regulation disorder Peripheral coldness Amnesia

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Loss of consciousness Hyperacusis Photophobia Syncope Multiple sclerosis Weight decreased Spinal pain
2016-027174	Prophylaxis	Gardasil	.5 ml	Fatigue Pain Depression Anxiety Injection site swelling Headache Influenza like illness Cough Oropharyngeal pain Epigastric discomfort Eye discharge Lymphadenopathy Ear pain Chest pain Abdominal pain Arthralgia Gastritis Diarrhoea Abdominal tenderness Menorrhagia Mood swings Disturbance in attention Urticaria Eye pain Syncope Back pain Dizziness Nausea Feeling abnormal Alopecia Polycystic ovaries Menstruation irregular Muscle spasms Hypoaesthesia Pruritus Rash Increased tendency to bruise Wound haemorrhage Impaired healing Lip swelling Lip swelling Oral mucosal blistering Insomnia Muscle twitching Aphasia Hyperacusis Photophobia Temperature intolerance Irritability Pain in jaw Toothache Weight fluctuation Candida infection Pain in extremity Seizure Breast pain Heart rate increased Heart rate irregular

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Formication Lip infection Dyskinesia Arthralgia Pharyngeal oedema Injection site erythema Dermatitis Discomfort Gait disturbance Impaired quality of life Bedridden
2016-027206	Prophylaxis	Gardasil	.5 ml .5 ml .5 ml	Malaise Fatigue Alopecia
2016-027321	Prophylaxis	Gardasil		Lyme disease Coxsackie viral infection Herpes simplex
2016-027364	Prophylaxis	Gardasil		Nausea Dizziness Headache Heart rate increased Weight decreased
2016-027394	Prophylaxis	Gardasil	.5 ml	Asthenia Decreased appetite Self esteem decreased Insomnia Pharyngitis
2016-027683	Prophylaxis	Gardasil Boostrix		Syncope Fatigue Headache Nausea
2016-027687	Prophylaxis	Gardasil		Immunodeficiency Viral infection Pyrexia Headache Nausea Fatigue Pain Arthralgia
2016-027689	Prophylaxis	Gardasil		Intentional self-injury Disturbance in attention Eye movement disorder Neck pain Fatigue Headache Photophobia Oropharyngeal pain Pyrexia Anger Depression Anxiety Attention deficit/hyperactivity
2016-027690	Prophylaxis	Gardasil	.5 ml	Eczema Alopecia
2016-027691	Prophylaxis	Gardasil	.5 ml	Nausea Fatigue Pallor Dyspnoea Depressed mood Menstrual disorder
2016-027692	Prophylaxis	Gardasil Boostrix		Type 1 diabetes mellitus Malaise Fatigue Weight decreased Lethargy

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Pollakiuria
2016-027735	Prophylaxis	Gardasil Boostrix		Vomiting Muscle spasms Weight decreased Anxiety
2016-027736	Prophylaxis	Gardasil Boostrix		Rash Headache Syncope Fatigue Nausea Vomiting Chronic fatigue syndrome Insomnia Myalgia Asthenia
2016-027826	Prophylaxis	Gardasil		Ovarian cyst ruptured Malaise Diarrhoea Vomiting Migraine Chronic fatigue syndrome Gastrointestinal disorder
2016-027844	Prophylaxis	Gardasil		Injection site swelling Headache Pyrexia Nausea Lymphadenopathy Muscular weakness Paraesthesia Vomiting Arthralgia Myalgia Fatigue Chills Haemorrhagic diathesis Contusion Menstrual disorder Skin striae Rash Hypermobility syndrome Syncope Injection site pain Injection site bruising Fibromyalgia
2016-027877	Prophylaxis	Gardasil Boostrix	.5 ml	Fatigue Feeling abnormal Back pain Arthralgia Inflammation Bacterial infection Viral infection Lymphadenitis Gastrointestinal disorder Hypersensitivity Bronchospasm Stress Anxiety Abscess Furuncle
2016-027884	Prophylaxis	Gardasil	.5 ml	Asthenia Fatigue Pain
2016-027889	Prophylaxis	Gardasil		Feeling abnormal Arthralgia Lyme disease

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Pharyngeal ulceration Headache Migraine Sinusitis
2016-027910	Prophylaxis	Gardasil		Seizure Fatigue Vision blurred Swelling Headache Migraine Abdominal pain upper Abdominal distension Reflux gastritis Somnolence Feeling abnormal Loss of personal independence in
2016-027923	Prophylaxis	Gardasil		Fatigue Muscular weakness Gastric disorder Syncope Dizziness Feeling abnormal Headache Oropharyngeal pain Tonsillitis Anxiety Depression Insomnia Cystitis Rash Skin striae Ovarian cyst ruptured Menstrual disorder Nausea Motion sickness Pharyngitis Asthenia
2016-027933	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Rash Fatigue
2016-027976	Prophylaxis	Gardasil		Urticaria
2016-027978	Prophylaxis	Gardasil Boostrix		Urticaria Headache Nausea
2016-028017	Prophylaxis	Gardasil		Seizure Crying Headache Speech disorder Movement disorder
2016-028044	Prophylaxis	Gardasil		Malaise Tonsillitis Headache Dizziness Fatigue Pain Nausea Feeling hot Epistaxis Sleep paralysis Feeling cold Bruxism Hypotension Depressed mood Stress Dizziness Menorrhagia

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Rash Feeling abnormal Fibromyalgia Asthenia Oropharyngeal pain Headache Paraesthesia Anxiety Depression Vomiting Posture abnormal Pain in extremity Grip strength decreased Palpitations Hypovitaminosis
2016-028106	Prophylaxis	Gardasil		Asthenia Abdominal pain upper Lymphadenopathy Pyrexia Arthropathy Ear pain Fibromyalgia Sleep disorder
2016-028172	Prophylaxis	Gardasil		Postural orthostatic tachycardia Seizure Chronic fatigue syndrome Pain General physical health Malaise Viral infection Chest pain Back pain Headache Pain in extremity Gait disturbance Abdominal pain upper Asthenia Gastritis Feeling abnormal Alopecia Bedridden Immune system disorder
2016-028178	Prophylaxis	Gardasil		Headache Skin odour abnormal Blood glucose decreased Vision blurred Photophobia Tinnitus Diarrhoea Abdominal discomfort Palpitations Tremor Hypoaesthesia Paraesthesia Dizziness Mood swings Irritability Amnesia Disturbance in attention Weight decreased Fatigue Seizure Rash
2016-028194	Prophylaxis	Gardasil		Premature menopause
2016-028217	Prophylaxis	Gardasil		Syncope

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Headache Asthenia
2016-028227	Prophylaxis	Gardasil		Epilepsy Adverse drug reaction
2016-028294	Prophylaxis	Gardasil		Fatigue Autoimmune disorder Thyroid disorder Ovarian failure Addison's disease Autoimmune hypothyroidism Premature menopause Adrenal insufficiency
2016-028324	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Diarrhoea Pyrexia Fatigue Feeling abnormal
2016-028358	Prophylaxis	Gardasil Menjugate Kit		Headache Fatigue Dizziness
2016-028567	Prophylaxis	Gardasil Boostrix	.5 ml .5 ml	Nausea Headache Feeling cold Malaise Fatigue Arthralgia Stress Loss of personal independence in
2016-028638	Prophylaxis	Gardasil		Musculoskeletal pain Fatigue Menstrual disorder Alopecia Dizziness Decreased appetite Anxiety Depression Asthenia Photophobia Hyperacusis Tremor Peripheral coldness Disturbance in attention Lyme disease Neck pain
2016-028845	Prophylaxis	Gardasil		Blindness transient Central nervous system lesion Multiple sclerosis Optic neuritis
2016-028846	Prophylaxis	Gardasil		Headache Muscular weakness Arthralgia Dizziness Disturbance in attention Pruritus Sleep disorder Fatigue
2016-028948	Prophylaxis	Gardasil		Arthralgia Depressed mood Fatigue Headache Asthenia Somnolence Disturbance in attention Apathy Kidney infection Vision blurred

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Chest pain Gastrointestinal disorder Vomiting Pain
2016-029000	Prophylaxis Prophylaxis	Gardasil Boostrix	.5 ml	Malaise Tremor Pain in extremity Seizure Head injury
2017-029134	Prophylaxis	Gardasil		Asthma Paraparesis Gait disturbance Pain in extremity Paresis Headache Urinary retention Loss of consciousness Dysarthria Deafness transitory Photophobia Oropharyngeal pain Mood swings Burning sensation Blepharospasm Dysgeusia Parosmia Hypoacusis Paraesthesia Menstrual disorder Blindness transient Loss of personal independence in Muscular weakness Fatigue Dizziness Nausea Influenza like illness Migraine Sensory disturbance Sleep disorder Memory impairment Irritable bowel syndrome Hypertonic bladder Dyspnoea Pain Abdominal rigidity Weight fluctuation Feeling hot Feeling abnormal Feeling cold
2017-029318	Prophylaxis	Gardasil		Amnesia Facial paralysis Disorientation Fatigue Conversion disorder
2017-029563	Prophylaxis	Gardasil		Seizure Malaise
2017-029693	Prophylaxis	Gardasil		Menorrhagia
2017-029727	Prophylaxis	Gardasil		Injection site pruritus Headache Vision blurred Musculoskeletal stiffness Photophobia Migraine Visual impairment Abdominal pain

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Ovarian cyst ruptured Dysmenorrhoea Axillary mass Chest pain Dyspnoea Arthralgia Paraesthesia Dizziness Muscular weakness Decreased appetite Fatigue Anxiety Depression Endometriosis Muscular weakness Dry eye Exercise tolerance decreased Tinnitus Hypoesthesia Visual impairment Pelvic pain
2017-029789	Prophylaxis	Gardasil	.5 ml .5 ml	Fatigue Malaise Dizziness
2017-029989	Prophylaxis	Gardasil Menjugate Kit	.5 ml .5 ml	Injection site pain Fatigue Headache Asthenia Pallor
2017-030033	Prophylaxis	Gardasil		Pain in extremity Contusion Musculoskeletal stiffness
2017-030089	Prophylaxis	Gardasil Menjugate Kit		Pruritus Urticaria
2017-030193		Gardasil		Headache Dizziness Fatigue Insomnia Sleep terror Asthenia Blindness transient
2017-030199	Prophylaxis	Gardasil Menjugate Kit	.5 ml .5 ml	Fatigue Headache
2017-030277	Prophylaxis	Gardasil		Pyrexia Headache Hemiplegia Paraesthesia Vision blurred Fatigue Anxiety Chest discomfort Dizziness Depression Migraine Paraesthesia oral Depressed mood Depression Fatigue Vitamin D decreased Blood iron decreased Epstein-Barr virus infection Infectious mononucleosis
2017-030326	Prophylaxis	Gardasil		Syncope Tremor Vomiting

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Amnesia Fatigue Monoparesis Bedridden Feeling abnormal Seizure Pain Dizziness Diarrhoea Tonsillar disorder Dyspnoea Fibromyalgia Post viral fatigue syndrome
2017-030365	Prophylaxis	Gardasil	.5 ml	Pallor Abnormal behaviour Pain in extremity Erythema Menorrhagia Dysmenorrhoea
2017-030514	Prophylaxis	Gardasil		Bedridden Asthenia
2017-030562		Gardasil		Migraine Vomiting Irritable bowel syndrome Skin striae Dizziness Fatigue Arthralgia Arthritis Lymphadenopathy Tonsillitis Peripheral coldness Confusional state Disorientation Feeling abnormal Contusion Renal pain Pelvic pain Anxiety Asthma
2017-030584	Prophylaxis	Gardasil		Myalgia Headache Paraesthesia Tonsillitis Immune system disorder Fatigue Pain in extremity Rheumatoid arthritis Mobility decreased
2017-030749	Prophylaxis	Gardasil		Paraesthesia Neuropathy peripheral
2017-030919	Prophylaxis	Gardasil Boostrix		Headache Flank pain Dyspnoea Hypopnoea Palpitations Fatigue Somnolence Disturbance in attention Pyrexia Bone pain Paraesthesia Rash Diarrhoea Constipation

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Nausea Weight decreased Coeliac disease Abdominal pain Rash Back pain Fatigue Asthenia Hypokinesia Menstruation delayed Abdominal pain Ovarian cyst ruptured Appendicitis Musculoskeletal pain
2017-030936	Prophylaxis	Gardasil Boostrix		Headache Muscle spasms Menorrhagia Bone pain Neck pain Musculoskeletal pain Migraine Lymphadenopathy Pharyngitis streptococcal Tonsillitis Coeliac disease Fatigue Nausea Lower respiratory tract infection Abdominal pain Back pain Decreased activity Menorrhagia
2017-030981	Prophylaxis	Gardasil		Hypermobility syndrome Sleep disorder Fibromyalgia Osteoarthritis Arthropathy Polyarthritits Basilar migraine
2017-031018	Prophylaxis	Gardasil		Urticaria Immune system disorder Tonsillitis Hordeolum Fatigue Mental fatigue Fatigue Feeling abnormal
2017-031077	Prophylaxis	Gardasil		Depression Anxiety Apathy Feeling abnormal Food allergy Migraine
2017-031100	Prophylaxis	Gardasil Boostrix		Syncope Hypotension
2017-031155	Prophylaxis	Gardasil		General symptom
2017-031397	Prophylaxis	Gardasil	.5 ml .5 ml	Visual impairment Headache Joint dislocation Intestinal haemorrhage Abdominal pain upper Depressed mood Mood swings Depression
2017-031478	Prophylaxis	Boostrix		Abdominal pain

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
		Gardasil		Vomiting Asthenia Malaise Malaise Diarrhoea
2017-031515	Prophylaxis	Gardasil		Seizure Fatigue Amnesia
2017-031549	Prophylaxis	Gardasil		Abdominal pain Diarrhoea Fatigue Somnolence Post viral fatigue syndrome Oropharyngeal pain Vomiting Pallor Vomiting projectile Hypophagia Urinary retention Bladder disorder Functional gastrointestinal Constipation Appendix disorder Asthenia Balance disorder Gait disturbance Gastritis Blepharospasm Back pain Kidney infection Peripheral coldness Demyelination White blood cell count increased Neuromyelitis optica spectrum Decreased immune Bladder catheterisation Appendectomy Paraesthesia Lethargy Dizziness Nausea Reflux gastritis Speech disorder Eyelid ptosis Nystagmus
2017-031550	Prophylaxis	Gardasil		Headache Dizziness Vomiting Abdominal pain Lethargy Paraesthesia Hypoesthesia Fatigue Asthenia Nausea
2017-031631	Prophylaxis	Gardasil	.5 ml	Asthenia Vomiting Pain in extremity Depressed mood Depression Intentional self-injury Skin striae Myalgia Dysmenorrhoea Syncope

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Eczema Cyst Acne Tonsillitis Malaise Fatigue Somnolence Narcolepsy Sleep apnoea syndrome
2017-031733	Prophylaxis	Boostrix Gardasil	.5 ml .5 ml	Anxiety Oral disorder Flushing Lip swelling
2017-031768	Prophylaxis	Gardasil		Oropharyngeal pain Headache Abdominal pain Migraine Nausea Asthenia Disturbance in attention Photophobia Postural orthostatic tachycardia Hypersomnia Fatigue Anxiety Post viral fatigue syndrome
2017-031775	Prophylaxis	Gardasil		Poor quality sleep Pyrexia Rash pruritic Feeling cold
2017-031823	Prophylaxis	Gardasil		Lethargy Pain Headache Nausea Fatigue Malaise
2017-031824	Prophylaxis	Gardasil		Disturbance in attention Abdominal pain upper Headache Arthralgia
2017-031879	Prophylaxis	Gardasil	.5 ml	Dermatitis bullous
2017-032023	Prophylaxis Prophylaxis	Boostrix Gardasil		Arthralgia Asthenia Dizziness Nausea Vertigo Loss of consciousness Headache Lethargy Fatigue Disturbance in attention Myalgia Viral infection Middle ear disorder
2017-032046	Prophylaxis	Gardasil Boostrix		Musculoskeletal pain Fatigue Oropharyngeal pain Headache
2017-032198	Prophylaxis	Gardasil		Urticaria Raynaud's phenomenon
2017-032222		Gardasil		Hypoaesthesia Pain Fatigue Headache Head discomfort

Summary details of suspected adverse reactions/events associated with the use of Gardasil from 01/01/2010-31/12/2017

HPRA ID	Indications	Suspect Drug(s)	Dose	Adverse Reaction(s) (MedDRA PT)
				Abnormal behaviour
2017-032236		Gardasil	.5 ml .5 ml	Headache Dizziness Malaise Pyrexia Arthralgia Muscular weakness Fatigue Asthenia Lymphadenopathy Pain in extremity Rash Insomnia Anxiety Panic attack Menstrual disorder Vomiting Gait disturbance Social fear
2017-033136	Prophylaxis	Gardasil		Epilepsy
2017-033181	Prophylaxis	Gardasil	.5 ml	Abdominal pain Decreased appetite Crying
2017-033453	Prophylaxis	Gardasil 9 Gardasil	1 Dosage forms	Interchange of vaccine products Wrong drug administered

STATEMENT TO ACCOMPANY ADVERSE REACTION DATA RELEASED BY THE HPRA

Introduction

This document provides background information on the HPRA adverse reaction reporting system and provides advice on interpretation of information collected through this system.

Spontaneous adverse reaction reports

The spontaneous monitoring system was established in 1968. Reports of suspected adverse reactions are received from patients and consumers, healthcare professionals and pharmaceutical companies through the online reporting options accessible from the HPRA website, in hardcopy format via freepost or by telephone. Anonymised report details are included on a computerised database to facilitate processing and evaluation of reports.

Information collected through this system is an important method of monitoring drug safety in normal clinical practice, by increasing knowledge about known adverse reactions and also by acting as an early warning system for the identification of previously unrecognised adverse reactions. Such information is one of the tools used by the HPRA in its ongoing safety evaluation of marketed drugs and is vital in identifying drugs where a change in their authorisation (licence) status is required such as the addition of warnings and precautions for use, restriction in usage, or rarely, withdrawal from the marketplace.

The HPRA issues a Drug Safety Newsletter (DSN) which is distributed through professional organisations to healthcare professionals approximately six times a year, providing updated information on adverse reactions and providing advice on safe use of specific medicines. Copies of these newsletters are available from the HPRA website (www.hpra.ie) or from the Pharmacovigilance Department, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland. Phone 01-6764971, Fax 01-6767836.

Adverse reaction listings

- Lists all the reactions reported to have occurred in association with a suspected drug substance/product.
- Lists all reactions included on the original report (please note that many reports contain more than one reaction, therefore the total number of reactions may exceed the number of reports received for the drug). Each report relates to an individual patient.

Every effort has been made to ensure that the information contained in line listings is accurate and true. The content of line listings are believed to be correct at the time of compilation, and are a direct representation of the data currently held on our database. The Health Products Regulatory Authority, its servants, agents and employees disclaim all liability for the accuracy, completeness, or usefulness of any information and for any error or omission therein.

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- Lists reactions for a specific drug substance irrespective of whether the reporter provided the approved drug substance name or a brand name of that substance. Brand names are included in the listing if they have been provided.
- Includes data for reports when the drug substance is given either as a single constituent or combination (multi-constituent product). In the case of the latter it may not be always possible to identify which (if any) of the drug substances in the combination product was responsible for a particular reaction.
- Uses adverse reaction terms known as 'preferred terms'. This system is used in order to ensure consistency of terminology and facilitate exchange of information with pharmaceutical companies and international bodies.

Guidance on interpretation of adverse reaction listings

Interpretation of the data in an adverse reaction listing should take into account the following:

- Reports submitted to the HPRA in many instances arise from suspicions occurring during observation of an unexpected and/or unwanted event.
- In many cases only limited details about each suspected adverse reaction report are received.
- Numerical comparisons should not be made between reactions associated with different drugs on the basis of the data included in listings alone. Comparisons may be misleading because of the limitations of the data.
- The inclusion of a particular reaction on the listing does not necessarily mean it has been caused by the suspect drug. Many factors have to be taken into account in assessing a causal relationship including temporal association, the possible contribution of concomitant medication, and the underlying disease.
- Interpretation of reactions to medicines in cases where multiple other therapies have been used requires special care. This is particularly relevant for vaccines as many are administered in combination. In these circumstances it may be difficult to ascribe a causal reaction to an individual vaccine or drug.
- Certain reported reactions are conditions which often occur spontaneously. In these cases there may be a temporal relationship between the medicine and the reaction which is not necessarily causal. This applies particularly to vaccines.
- The number of reports received should not be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using the drug is known. Adverse reaction reporting rates are influenced by the seriousness

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of the reactions, their ease of recognition and the extent of use of a particular drug. Report rates may also be stimulated by promotion and publicity about a drug.

- Reporting tends to be highest for newly authorised medicines during the first one or two years on the market and then falls off over time.

Publication

If you wish to copy either this listing or circulate this listing or information contained within it to others please ensure a copy of this note is also provided. The HPRA encourages use of data from the reporting system in publications but wishes to facilitate interpretation of the data. For this reason, we request that a copy of any proposed publications should be sent to the HPRA in advance for review/comment. Copies of proposed manuscripts and requests to quote data should be addressed to the Director of Human Products Monitoring, at the above address. We shall endeavour to respond to all requests quickly.

ADVERSE REACTION REPORTING IS VITAL FOR DRUG SAFETY; PLEASE SUPPORT THE REPORTING SCHEME BY NOTIFYING SUSPECTED ADVERSE REACTIONS.

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