

Summary listing of suspected adverse reactions and events associated with use of Gardasil 01/06/2015-31/12/2015

HPRA ID	Indications	Medicinal Product(s)	Dose	Adverse Reaction(s)/Event(s) (MedDRA PT)
2015-023780	Prophylaxis	GARDASIL	.5 ml	Injection site swelling Rash
2015-023788	Prophylaxis	GARDASIL	Not Stated	Dizziness Asthenia Transient immobility Myalgia Seizure Headache Nausea Abdominal pain Visual acuity reduced 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	GARDASIL	.5 ml	Seizure Vision blurred Pain Headache Aphonia Muscle spasms Musculoskeletal stiffness Nausea Fatigue 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 Activities of daily living impaired
2015-023819	Prophylaxis	GARDASIL	Not Stated	Dizziness Asthenia
2015-023820	Prophylaxis	GARDASIL	Not Stated	Dizziness Fatigue Asthenia Headache Nausea Abdominal pain Post viral fatigue syndrome
2015-023821	Prophylaxis	GARDASIL	Not Stated	Dizziness Fatigue Fibromyalgia Ovarian cyst Headache Pain Eye disorder Hyperacusis Food intolerance Transient memory impairment Disturbance in attention Post viral fatigue syndrome Chronic fatigue syndrome

Please also refer to the caveat document enclosed.

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2015-023833	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Seizure Visual impairment Eye movement disorder Abdominal pain upper Chest pain Muscular weakness Nausea Fatigue Headache Skin discolouration Aphasia Joint swelling Dizziness Dyskinesia Feeling abnormal Facial pain Eye pain Pain in extremity
2015-023835	Prophylaxis	GARDASIL	Not Stated	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	Not Stated	Fatigue Seizure Panic attack Chest pain Ovarian cyst Depressed mood
2015-023847	Prophylaxis	GARDASIL MENJUGATE	Not Stated	Myalgia Arthralgia
2015-023920	Prophylaxis	GARDASIL MENJUGATE	Not Stated	Musculoskeletal pain Hypoesthesia
2015-024024	Prophylaxis	GARDASIL	.5 ml .5 ml	Headache Alopecia
2015-024198	Prophylaxis	GARDASIL	Not Stated	Palpitations
2015-024209	Prophylaxis	GARDASIL	.5 ml .5 ml .5 ml	Myalgia Erythema Neuralgia Joint swelling Pain
2015-024219	Prophylaxis	GARDASIL	Not Stated	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	Not Stated	Injection site erythema Injection site swelling

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2015-024347	Prophylaxis	GARDASIL	Not Stated	Malaise Pyrexia Headache Oropharyngeal pain Musculoskeletal stiffness Hallucination Vomiting
2015-024348	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Syncope Hypotension Pallor Cold sweat
2015-024349	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Asthenia Pallor Cold sweat
2015-024350	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Syncope
2015-024351	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Asthenia Nausea Pallor
2015-024352	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Asthenia Feeling cold Cold sweat Syncope Generalised tonic-clonic seizure
2015-024379	Prophylaxis	GARDASIL	Not Stated	Arthralgia Somnolence Oropharyngeal pain
2015-024394	Prophylaxis	GARDASIL	Not Stated	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

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HPRA ID	Indications	Medicinal Product(s)	Dose	Adverse Reaction(s)/Event(s) (MedDRA PT)
2015-024429	Prophylaxis	GARDASIL	Not Stated	Chronic fatigue syndrome Insomnia Cognitive disorder Amnesia Obsessive-compulsive disorder Anxiety Disturbance in attention Arthralgia Myalgia Nausea Vomiting Fatigue Menorrhagia Asthma Weight decreased Dizziness Hypotension Immune system disorder Chills Oropharyngeal pain Headache Muscle atrophy Activities of daily living impaired Influenza like illness Pneumonia Home care
2015-024438	Prophylaxis	GARDASIL	Not Stated	Seizure Chest pain Visual impairment Hypotension Gastroesophageal reflux disease Fatigue Asthenia Pulse abnormal
2015-024452	Prophylaxis	GARDASIL	Not Stated	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	Not Stated	Muscle spasms Seizure Immunodeficiency
2015-024525	Prophylaxis	GARDASIL	Not Stated	Back pain Erythema Inflammation

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2015-024532	Prophylaxis	GARDASIL	Not Stated	Nausea Headache Vomiting Pain Muscular weakness Vision blurred Dyspnoea
2015-024552	Prophylaxis	GARDASIL	Not Stated	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 positive
2015-024559	Prophylaxis	GARDASIL	Not Stated	Pancreatitis acute Appendicitis Nausea Dizziness Hot flush Headache Trismus Epistaxis Fatigue Rash Eating disorder Coordination abnormal Myalgia Pain in extremity Social avoidant behaviour Pallor Pain Balance disorder Abdominal pain upper Syncope Lethargy Balance disorder Hypotension Activities of daily living impaired Back pain Neck pain Vitamin D deficiency Skin striae
2015-024571	Prophylaxis	GARDASIL	Not Stated	Dizziness Feeling abnormal Chest pain Tremor Volume blood decreased Altered visual depth perception Syncope Seizure

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2015-024575	Prophylaxis	GARDASIL	Not Stated	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
2015-024628	Prophylaxis	GARDASIL	.5 ml	Complex regional pain syndrome
2015-024638	Prophylaxis	GARDASIL	.5 ml	Muscular weakness Hypoesthesia Sensory loss
2015-024660	Prophylaxis	GARDASIL	Not Stated	Nausea Vomiting Fatigue Anxiety Dizziness Food intolerance Amnesia Pain Abdominal pain Sleep disorder Disturbance in attention Depression Menstrual disorder
2015-024667	Prophylaxis	GARDASIL BOOSTRIX	.5 ml Not Stated	Visual impairment transient
2015-024674	Prophylaxis	GARDASIL	Not Stated	Palpitations Asthenia Hypertension Hypotension Cold sweat Tremor Headache Fatigue Pain Syncope Dizziness
2015-024684	Prophylaxis	GARDASIL	Not Stated	Fatigue Seizure Arthralgia
2015-024689	Prophylaxis	GARDASIL	.5 ml	Myalgia Fatigue
2015-024698	Prophylaxis	GARDASIL DIPHTHERIA/TETANUS/P ERTUSSIS VACCINE	Not Stated	Injection site pain Pain in extremity Myalgia Photophobia Chest pain

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2015-024703	Prophylaxis	GARDASIL BOOSTRIX	.5 ml .5 ml	Fatigue Insomnia Pain in extremity Diarrhoea Malaise
2015-024720	Prophylaxis	GARDASIL	Not Stated	Influenza like illness Oropharyngeal pain Vision blurred Vomiting Epistaxis Chest pain Arthralgia Myalgia Dysmenorrhoea Hormone level abnormal Dizziness Fibromyalgia Feeling abnormal Peripheral coldness Skin striae Varicose vein Oral fungal infection Breath odour Hyperhidrosis Flushing Glassy eyes Lacrimation increased Post viral fatigue syndrome
2015-024730	Prophylaxis	GARDASIL BOOSTRIX	.5 ml	Headache Pyrexia Nausea
2015-024743	Prophylaxis	GARDASIL	.5 ml	Headache Photophobia Malaise Panic attack Irlen syndrome
2015-024760	Prophylaxis	GARDASIL	Not Stated	Back pain Amnesia Autoimmune disorder Connective tissue disorder Arthralgia Fatigue Joint swelling Alopecia Headache Mouth ulceration Gait disturbance Depressed mood
2015-024763	Prophylaxis	GARDASIL	Not Stated	Neurological symptom Palpitations Migraine Fatigue Dizziness Syncope Dyspnoea Hypoaesthesia Paraesthesia Pain Visual impairment Chest pain Disturbance in attention Depression Anxiety
2015-024790	Prophylaxis	GARDASIL	Not Stated	Epilepsy Seizure

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2015-024791	Prophylaxis	GARDASIL	Not Stated	Postural orthostatic tachycardia syndrome Pain Fatigue Abdominal discomfort Swelling Swelling face Peripheral swelling Allodynia Palpitations Amenorrhoea Headache Feeling abnormal
2015-024801	Prophylaxis	GARDASIL	Not Stated	Dizziness Headache Pneumonia aspiration Fatigue Hypersomnia Seizure Dysmenorrhoea Fibromyalgia Postural orthostatic tachycardia syndrome Transient memory impairment Mental impairment Photophobia Hyperacusis
2015-024806	Prophylaxis	GARDASIL	.5 ml .5 ml .5 ml	Menstrual disorder Headache Syncope Seizure Oropharyngeal pain Fatigue Feeling cold
2015-024826	Prophylaxis	GARDASIL	Not Stated	Postural orthostatic tachycardia syndrome 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	Not Stated	Seizure Pain in extremity Fatigue Arthralgia Panic attack
2015-024850	Prophylaxis	GARDASIL	Not Stated	Muscle spasms Dyskinesia Blepharospasm Headache Fatigue Loss of consciousness Sleep disorder Nightmare Feeling cold Seizure Myalgia

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2015-024893	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Influenza like illness Headache Lip swelling Eye swelling Pruritus Peripheral swelling Injection site swelling Malaise
2015-024908	Prophylaxis	GARDASIL	1 DF 1 DF	Gastric disorder Functional 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
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
2015-025002	Prophylaxis	GARDASIL	Not Stated	Syncope
2015-025026	Prophylaxis	GARDASIL	.5 ml .5 ml .5 ml	Muscle spasms Asthenia Hypersomnia Gastrointestinal disorder
2015-025099	Prophylaxis	GARDASIL	Not Stated	Pain Syncope
2015-025152	Prophylaxis	GARDASIL	Not Stated	Menstrual disorder Dysmenorrhoea Fatigue Diarrhoea Depression
2015-025159	Prophylaxis	GARDASIL	Not Stated	Malaise Headache Asthenia Fatigue Thirst
2015-025160	Prophylaxis	GARDASIL	Not Stated	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 acuity reduced Vision blurred
2015-025392	Prophylaxis	GARDASIL	Not Stated	Hypoaesthesia Dizziness Rash Fatigue Pain Eye pain

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2015-025396	Prophylaxis	GARDASIL	Not Stated	Migraine Dizziness Pain Fatigue Nausea Vein rupture Ovarian cyst Pain Malaise Dyspnoea Nightmare
2015-025405	Prophylaxis	GARDASIL	Not Stated	Seizure Syncope Fall Pain in extremity Peripheral coldness Musculoskeletal stiffness Muscle rigidity
2015-025416	Prophylaxis	GARDASIL	Not Stated	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 change
2015-025438	Prophylaxis	GARDASIL	.5 ml .5 ml	Syncope Loss of consciousness Abdominal pain Pain in extremity Headache
2015-025439	Prophylaxis	GARDASIL	Not Stated	Complex regional pain syndrome Peripheral swelling Pain Neck pain Headache Insomnia Fatigue
2015-025443	Prophylaxis	GARDASIL	Not Stated	Headache Nausea
2015-025447	Prophylaxis	GARDASIL	Not Stated	Pain Seizure Autoimmune disorder Depression Hormone level abnormal Feeling abnormal Fibromyalgia Postural orthostatic tachycardia syndrome Headache Oropharyngeal pain Arthralgia Myalgia Memory impairment Menstrual disorder Psychiatric symptom Cardiac disorder Malaise Fatigue Dyspnoea Asthenia Dizziness

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				Epilepsy

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				Heart rate irregular Disability Personality change Trismus Pancreatitis Anxiety
2015-025450	Prophylaxis	GARDASIL	.5 ml .5 ml	Fatigue Headache Myalgia Depression
2015-025474	Prophylaxis	GARDASIL	Not Stated	Seizure
2015-025478	Prophylaxis	GARDASIL	Not Stated	Fatigue Headache Malaise Disturbance in attention Arthralgia Feeling abnormal
2015-025491	Prophylaxis	GARDASIL	.5 ml	Fatigue Syncope Menorrhagia Dizziness Headache Endometriosis
2015-025494	Prophylaxis	GARDASIL	Not Stated	Pain Raynaud's phenomenon Fibromyalgia Fatigue Arthralgia Dizziness Headache
2015-025495	Prophylaxis	GARDASIL	.5 ml	Systemic lupus erythematosus
2015-025496	Prophylaxis	GARDASIL	Not Stated	Decreased appetite Depression Abdominal pain Fatigue
2015-025497	Prophylaxis	GARDASIL	Not Stated	Syncope Seizure like phenomena Dizziness Fatigue
2015-025499	Prophylaxis	GARDASIL BOOSTRIX	Not Stated	Syncope Migraine Irritable bowel syndrome Postural orthostatic tachycardia syndrome
2015-025523	Prophylaxis	GARDASIL	5 ml 5 ml 5 ml	Hypoaesthesia Headache Dizziness Contusion Immune thrombocytopenic purpura
2015-025524	Prophylaxis	GARDASIL	.5 ml	Limb discomfort Influenza like illness Nasopharyngitis Pain Headache Fatigue
2015-025547	Prophylaxis	GARDASIL	Not Stated	Fatigue Asthenia Asthenia Palpitations Chest pain Asthenia
2015-025559	Prophylaxis	GARDASIL	.5 ml .5 ml .5 ml	Lichen sclerosus Dysuria Painful defaecation Tonsillitis

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2015-025574	Prophylaxis	GARDASIL	Not Stated	Headache Nausea Chest pain Dyspnoea Back pain Rash Abdominal pain upper Arthralgia Dizziness Syncope Fatigue Lethargy Feeling abnormal Sleep disorder Gluten sensitivity Irritable bowel syndrome Menstruation irregular Dysmenorrhoea Migraine Depression

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