

## Details of suspected adverse drug reactions associated with the use of Gardasil to 19<sup>th</sup> November 2010

IMB ID	Date of first notification to IMB	Patient Age	Vaccine name	Indication	Vaccination Date (s) where known	Reaction onset date	Adverse reaction (MedDRA PT)	Concomitant medication	Outcome
037568	22/05/2007	21	Gardasil	Prophylaxis	05/04/2007	05/04/2007	Lymphadenopathy	Not provided	Recovered
039549	05/03/2008	22	Gardasil	Prophylaxis	03/03/2008	03/03/2008	Chest pain Chest discomfort	None reported	Recovered
039639	11/03/2008	14	Gardasil	Prophylaxis	11/01/2008	18/01/2008	Oedema peripheral Vomiting	None reported	Recovered
041253	15/12/2008	41	Gardasil	Prophylaxis	First dose: 01/04/2008 Second dose: 30/04/08 Third Dose: 28/11/2008	28/11/2008	Blepharitis Dry eye Eyelid oedema Eyelids pruritus	Zyprexa, Prothiaden	Unknown
041583	10/02/2009	16	Gardasil	Prophylaxis	29/01/2009	29/01/2009	Dizziness Syncope Pallor Malaise	Not provided	Recovered
042769	04/08/2009	22	Gardasil	Prophylaxis	First dose: 14/01/2009 Second dose: 14/03/2009	February 2009 - April 2009	Abdominal distension Alopecia Constipation Decreased appetite Dizziness Feeling cold Feeling of body temperature change Hypoaesthesia Paraesthesia Weight decreased	Dianette	Not recovered at time of reporting

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043077	28/09/2009	12	Gardasil	Prophylaxis	26/02/2009	06/03/2009	Convulsion Dizziness Heart rate irregular Arrhythmia	None reported	Unknown
045850	31/03/2010	14	Gardasil	Prophylaxis	17/02/2010	22/02/2010	Erythema multiforme	Not provided	Recovered
046029	21/04/2010	15	Gardasil	Prophylaxis	Second dose: 30/03/2010	30/03/2010	Convulsion Muscle rigidity Hypotonia Eye rolling	Not provided	Recovered
046374	10/06/2010	13	Gardasil	Prophylaxis	19/05/2010	21/05/2010	Pruritus Urticaria	Tegretol	Not recovered at time of reporting
046961	14/09/2010	12	Gardasil	Prophylaxis	13/09/2010	13/09/2010	Injection Site Erythema Erythema Pruritus	None reported	Unknown
046962	14/09/2010	13	Gardasil	Prophylaxis	Not provided	13/09/2010	Flushing Feeling Hot Ocular Hyperaemia Pallor Dizziness Erythema	None reported	Recovered
046982	17/09/2010	13	Gardasil	Prophylaxis	15/09/2010	15/09/2010	Syncope	None reported	Recovered
046983	17/09/2010	13	Gardasil	Prophylaxis	15/09/2010	15/09/2010	Dizziness Headache	None reported	Recovered

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047014	20/09/2010	14	Gardasil	Prophylaxis	17/09/2010	18/09/2010	Peripheral coldness Peripheral cyanosis	None reported	Not recovered at time of reporting
047022	22/09/2010	13	Gardasil	Prophylaxis	17/09/2010	17/09/2010	Dizziness Vomiting Rash Periorbital Oedema	None reported	Not recovered at time of reporting
047030	22/09/2010	13	Gardasil	Prophylaxis	20/09/2010	20/09/2010	Dizziness Nausea Tremor	None reported	Recovered
047031	22/09/2010	13	Gardasil	Prophylaxis	13/09/2010	13/09/2010	Hyperventilation Panic attack	None reported	Recovered
047024	22/09/2010	13	Gardasil	Prophylaxis	13/09/2010	13/09/2010	Syncope	None reported	Recovered
047025	22/09/2010	13	Gardasil	Prophylaxis	22/09/2010	22/09/2010	Syncope	None reported	Recovered
047039	23/09/2010	12	Gardasil	Prophylaxis	15/09/2010	15/09/2010	Abdominal discomfort Oropharyngeal pain Pain in extremity	None reported	Unknown
047052	24/09/2010	13	Gardasil	Prophylaxis	21/09/2010	21/09/2010	Urticaria	None reported	Recovered
047067	28/09/2010	13	Gardasil	Prophylaxis	23/09/2010	23/09/2010	Syncope	None reported	Recovered
047068	28/09/2010	13	Gardasil	Prophylaxis	24/09/2010	24/09/2010	Syncope	None reported	Recovered
047073	28/09/2010	12	Gardasil	Prophylaxis	21/09/2010	21/09/2010	Chest discomfort Abdominal discomfort	None reported	Recovered

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047074	28/09/2010	12	Gardasil	Prophylaxis	24/09/2010	24/09/2010	Throat tightness Bradycardia Hypotension Syncope	None reported	Recovered
047075	28/09/2010	Not provided	Gardasil	Prophylaxis	23/09/2010	23/09/2010	Peripheral coldness Peripheral cyanosis Cold Sweat	None reported	Recovered
047077	28/09/2010	12	Gardasil	Prophylaxis	21/09/2010	21/09/2010	Dizziness Gait disturbance Hypoaesthesia Chest discomfort Pain in extremity Myalgia Groin Pain	None reported	Recovered
047082	29/09/2010	14	Gardasil	Prophylaxis	23/09/2010	23/09/2010	Paraesthesia Paresis	None reported	Recovered
047096	29/09/2010	13	Gardasil	Prophylaxis	22/09/2010	22/09/2010	Somnolence Fatigue extreme Lethargy Viral Infection NOS Alkaline Phosphatase Increased	None reported	Not recovered at time of reporting
047097	30/09/2010	12	Gardasil	Prophylaxis	23/09/2010	23/09/2010	Myalgia Headache Lethargy	None reported	Recovered

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047101	30/09/2010	12	Gardasil	Prophylaxis	30/09/2010	30/09/2010	Dizziness Presyncope Mydriasis Visual impairment Fatigue extreme Photopsia	None reported	Recovered
047103	30/09/2010	13	Gardasil	Prophylaxis	30/09/2010	30/09/2010	Anaphylactic Reaction Swollen tongue Throat tightness Chest tightness Respiratory distress Tachypnoea	Ventolin Inhaler	Recovered
047104	01/10/2010	14	Gardasil	Prophylaxis	Not provided	23/09/2010	Angiodema	None reported	Recovered
047105	01/10/2010	14	Gardasil	Prophylaxis	16/09/2010	16/09/2010	Headache Fatigue	None reported	Not recovered at time of reporting
047111	01/10/2010	13	Gardasil	Prophylaxis	30/09/2010	30/09/2010	Rash maculopapular Hypotension Tachycardia Anaphylactic reaction Erythema	None reported	Recovered
047109	01/10/2010	12	Gardasil	Prophylaxis	30/09/2010	30/09/2010	Tetany Syncope Hyperventilation	None reported	Recovered
047118	04/10/2010	13	Gardasil	Prophylaxis	30/09/2010	30/09/2010	Hypoaesthesia Paraesthesia Tetany	None reported	Recovered

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IMB ID	Date of first notification to IMB	Patient Age	Vaccine name	Indication	Vaccination Date (s) where known	Reaction onset date	Adverse reaction (MedDRA PT)	Concomitant medication	Outcome
							Joint stiffness Muscle twitching Anxiety Hyperventilation		
047114	30/09/2010	13	Gardasil	Prophylaxis	Not provided	Not provided	Urticaria	None reported	Recovered
047123	05/10/2010	13	Gardasil	Prophylaxis	01/10/2010	01/10/2010	Rash erythematous Headache Flushing Pruritus	None reported	Recovered
047127	05/10/2010	12	Gardasil	Prophylaxis	20/09/2010	20/09/2010	Muscular weakness Fatigue Dizziness Muscle tightness Paraesthesia Abdominal Pain Upper Dyspnoea Asthenia Back Pain Chest pain Pain in extremity Fatigue	None reported	Not recovered at time of reporting
047133	06/10/2010	Not provided	Gardasil	Prophylaxis	Not provided	Not provided	Somnolence Lethargy Fatigue	Not reported	Unknown
047134	06/10/2010	12	Gardasil	Prophylaxis	06/10/2010	06/10/2010	Syncope	None reported	Recovered

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047146	08/10/2010	13	Gardasil	Prophylaxis	05/10/2010	05/10/2010	Blood glucose increased Asthenia Ketonuria	Lantus, Apidra, Eltroxin	Recovered
047161	11/10/2010	13	Gardasil	Prophylaxis	Not provided	Not provided	Syncope Tonic clonic movements	None reported	Recovered
047156	11/10/2010	13	Gardasil	Prophylaxis	04/10/2010	04/10/2010	Vomiting	None reported	Recovered
047162	11/10/2010	12	Gardasil	Prophylaxis	17/09/2010	17/09/2010	Dizziness	None reported	Recovered
047160	11/10/2010	13	Gardasil	Prophylaxis	16/09/2010	16/09/2010	Asthenia	None reported	Recovered
047157	11/10/2010	13	Gardasil	Prophylaxis	30/09/2010	30/09/2010	Rash Headache Anxiety Syncope Nausea Asthenia	None reported	Recovered
047159	07/10/2010	13	Gardasil	Prophylaxis	01/10/2010	02/10/2010	Polydipsia Thirst	None reported	Not recovered at time of reporting
047190	14/10/2010	14	Gardasil	Prophylaxis	06/10/2010	06/10/2010	Dizziness Throat irritation Asthenia Livedo reticularis		Recovered

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047192	14/10/2010	13	Gardasil	Prophylaxis	12/10/2010	12/10/2010	Dizziness Nausea Gait disturbance	None reported	Not recovered at time of reporting
047194	14/10/2010	13	Gardasil	Prophylaxis	30/09/2010	30/09/2010	Convulsion	None reported	Not recovered at time of reporting
2010-000053	21/10/2010	12	Gardasil	Prophylaxis	05/10/2010	05/10/2010	Dizziness Decreased appetite Feeling cold Chills	None reported	Recovered
2010-000055	21/10/2010	13		Prophylaxis	21/09/2010	21/09/2010	Syncope Nausea Asthenia Fatigue Malaise	None reported	Not recovered at time of reporting
2010-000052	21/10/2010	13	Gardasil	Prophylaxis	27/09/2010	02/10/2010	Nausea Rash erythematous Pruritus	None reported	Recovered
2010-000035	20/10/2010	13	Gardasil	Prophylaxis	21/09/2010	24/09/2010	Headache Fatigue Malaise	None reported	Recovered
2010-000020	19/10/2010	13	Gardasil	Prophylaxis	08/10/2010	08/10/2010	Injection site reaction Contusion Oedema peripheral Nausea Fatigue	None reported	Recovered

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2010-000034	20/10/2010	14	Gardasil	Prophylaxis	04/10/2010	07/10/2010	Urticaria	None reported	Recovered
2010-000071	22/10/2010	13	Gardasil	Prophylaxis	04/10/2010	04/10/2010	Headache Pain in extremity Rash Photophobia Fatigue	None reported	Unknown
2010-000070	22/10/2010	14	Gardasil	Prophylaxis	06/10/2010	06/10/2010	Dizziness Crying Emotional distress Cough Flushing Stridor Hyperventilation Tetany Malaise	Amoxil	Recovered
2010-000073	22/10/2010	13	Gardasil	Prophylaxis	First dose: 19/05/2010 Second dose: 22/09/2010	22/09/2010	Oedema peripheral	None reported	Recovered
2010-000002	15/10/2010	13	Gardasil	Prophylaxis	05/10/2010	06/10/2010	Fatigue Headache Dizziness Pallor Somnolence	None reported	Not recovered at time of reporting
2010-000531	04/11/2010	13	Gardasil	Prophylaxis	30/09/2010	30/09/2010	Syncope Headache	None reported	Recovered

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2010-000189	03/11/2010	14	Gardasil	Prophylaxis	05/10/2010	01/11/2010	Alopecia Visual impairment Vision blurred Abdominal pain upper Diarrhoea	None reported	Not recovered at time of reporting
2010-000588	05/11/2010	12	Gardasil	Prophylaxis	30/09/2010	07/10/2010	Asthenia Headache Malaise Somnolence Diarrhoea	None reported	Not recovered at time of reporting
2010-000792	15/11/2010	13	Gardasil	Prophylaxis	Second dose: 15/11/2010	15/11/2010	Migraine Dizziness Consciousness decreased Nausea Hypoaesthesia Pulse pressure decreased Photophobia	None reported	Recovered
2010-000791	15/11/2010	13	Gardasil	Prophylaxis	First dose: 13/09/2010 Second dose: 15/11/2010	15/11/2010	Anaphylactic Reaction Throat tightness Dizziness Urticaria Cough Cyanosis central	None reported	Unknown
2010-000793	16/11/2010	12	Gardasil	Prophylaxis	13/09/2010	17/09/2010	Syncope Loss of consciousness Incontinence Asthenia Disorientation Abdominal Pain Upper	None reported	Not recovered at time of reporting

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							Nausea Pyrexia Headache Influenza Like Illness Dizziness Limb weakness Cyanosis Dyspnoea Back pain Pain in extremity Myalgia		
2010-000852	16/11/2010	13	Gardasil	Prophylaxis	First dose: 14/09/2010 Second dose 16/11/2010	16/11/2010	Anaphylactic Reaction Dizziness Pallor Tachycardia Tachypnoea Anxiety Wheezing Pulse pressure decreased Stridor	None reported	Recovered
2010-000837	16/11/2010	12	Gardasil	Prophylaxis	27/09/2010	27/09/2010	Lip Swelling Malaise Anaphylactoid Reaction	None reported	Recovered
2010-000884	17/11/2010	13	Gardasil	Prophylaxis	04/10/2010	04/10/2010	Syncope Headache	None reported	Unknown
2010-000927	18/11/2010		Gardasil	Prophylaxis	17/11/2010	17/11/2010	Dizziness	None reported	Recovered

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2010-000931	18/11/2010	12	Gardasil	Prophylaxis	28/09/2010	28/09/2010	Paraesthesia Pyrexia		Recovered
2010-000962	18/11/2010	13	Gardasil	Prophylaxis	Second dose: 17/11/2010	17/11/2010	Headache Flushing	None reported	Recovered
2010-000972	17/11/2010	12	Gardasil	Prophylaxis	17/11/2010	17/11/2010	Headache Abdominal discomfort	None reported	Recovered
2010-000929	18/11/2010	12	Gardasil	Prophylaxis	17/11/2010	17/11/2010	Dizziness	None reported	Recovered
2010-000969	19/11/2010	14	Gardasil	Prophylaxis	17/11/2010	17/11/2010	Dizziness	None reported	Recovered
2010-000968	19/11/2010	13	Gardasil	Prophylaxis	17/11/2010	17/11/2010	Abdominal discomfort	None reported	Recovered
2010-000940	18/11/2010	12	Gardasil	Prophylaxis	17/11/2010	17/11/2010	Erythema Urticaria Headache Dizziness	None reported	Not recovered at time of reporting
2010-000975	19/11/2010	13	Gardasil	Prophylaxis	19/11/2010	19/11/2010	Peripheral cyanosis Feeling cold	None reported	Not recovered at time of reporting
2010-000971	19/11/2010	12	Gardasil	Prophylaxis	17/11/2010	17/11/2010	Pain in extremity	None reported	Recovered
2010-001068	17/11/2010	16	Gardasil	Prophylaxis	24/09/2010	24/09/2010	Visual impairment Syncope Headache	None reported	Not recovered at time of

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