

**Summary details of suspected adverse reactions/events
associated with the use of Gardasil
to 31/05/2015**

HPRA ID	Date of first notification to HPRA	Patient Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Reaction Cessation Date	Outcome	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
046961	14/09/2010	12 Years	Female	Prophylaxis	GARDASIL	13/09/2010 -		Injection site erythema Pruritus Hypersensitivity Erythema	13/09/2010 13/09/2010 13/09/2010 13/09/2010		Unknown		Erythema
046962	14/09/2010	13 Years	Female	Prophylaxis	GARDASIL	13/09/2010 -	.5 ml	Ocular hyperaemia Pallor Dizziness Flushing Erythema Feeling hot Hypersensitivity	13/09/2010 13/09/2010 13/09/2010 13/09/2010 13/09/2010 13/09/2010 13/09/2010		Recovered/resolved		
046982	17/09/2010	13 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -	.5 ml	Syncope	15/09/2010	15/09/2010	Recovered/resolved		Syncope
046983	17/09/2010	13 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -	.5 ml	Dizziness Headache	15/09/2010 15/09/2010		Recovered/resolved		
047014	20/09/2010	14 Years	Female	Prophylaxis	GARDASIL	17/09/2010 -	.5 ml	Peripheral coldness Cyanosis	17/09/2010 18/09/2010		Recovered/resolved		
047022	22/09/2010	13 Years	Female	Prophylaxis	GARDASIL	17/09/2010 -	.5 ml	Rash Vomiting Periorbital oedema Dizziness	17/09/2010 17/09/2010 17/09/2010 17/09/2010		Not recovered at time of reporting		
047024	22/09/2010	13 Years	Female	Prophylaxis	GARDASIL	13/09/2010 -	.5 ml	Syncope	13/09/2010		Recovered/resolved		
047025	22/09/2010	13 Years	Female	Prophylaxis	GARDASIL	22/09/2010 -	.5 ml	Syncope	22/09/2010		Recovered/resolved		
047030	22/09/2010	13 Years	Female	Prophylaxis	GARDASIL	20/09/2010 - 20/09/2010	.5 ml	Tremor Dizziness Nausea	20/09/2010 20/09/2010 20/09/2010	26/09/2010 26/09/2010 26/09/2010	Recovered/resolved		
047031	22/09/2010	13 Years	Female	Prophylaxis	GARDASIL	13/09/2010 -	.5 ml	Panic attack Hyperventilation	13/09/2010 13/09/2010		Recovered/resolved		Abdominal pain Vertigo
047039	23/09/2010	12 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -		Pain in extremity Abdominal discomfort Oropharyngeal pain	15/09/2010 15/09/2010 15/09/2010		Unknown		
047052	24/09/2010	13 Years	Female	Prophylaxis	GARDASIL	21/09/2010 -	.5 ml	Urticaria	21/09/2010		Recovered/resolved		
047067	28/09/2010	13 Years	Female	Prophylaxis	GARDASIL	23/09/2010 -	.5 ml	Syncope	23/09/2010		Recovered/resolved		
047068	28/09/2010	13 Years	Female	Prophylaxis	GARDASIL	24/09/2010 -	.5 ml	Syncope	24/09/2010		Recovered/resolved		

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047073	28/09/2010	12 Years	Female	Prophylaxis	GARDASIL	21/09/2010 -	.5 ml	Abdominal discomfort Chest discomfort Throat tightness	21/09/2010 21/09/2010 21/09/2010		Recovered/resolved		
047074	28/09/2010	12 Years	Female	Prophylaxis	GARDASIL	24/09/2010 -	.5 ml	Syncope Bradycardia Hypotension	24/09/2010 24/09/2010 24/09/2010		Recovered/resolved		Syncope
047075	28/09/2010		Female	Prophylaxis	GARDASIL	23/09/2010 -		Cyanosis Peripheral coldness Cold sweat	23/09/2010 23/09/2010 23/09/2010		Recovered/resolved		
047077	28/09/2010	12 Years	Female	Prophylaxis	GARDASIL	21/09/2010 -	.5 ml	Hypoaesthesia Pain in extremity Gait disturbance Chest discomfort Dizziness Myalgia Groin pain	21/09/2010 21/09/2010 21/09/2010 21/09/2010 21/09/2010		Recovered/resolved		
047082	29/09/2010		Female	Prophylaxis	GARDASIL	23/09/2010 -		Paraesthesia Paresis	23/09/2010 23/09/2010		Recovered/resolved		
047096	29/09/2010		Female	Prophylaxis	GARDASIL	22/09/2010 - 22/09/2010		Chronic fatigue syndrome Viral infection Lethargy Somnolence Dysstasia Blood alkaline phosphatase increased Fatigue Dizziness Pallor Headache Joint swelling Rash Arthralgia	22/09/2010 22/09/2010 22/09/2010 22/09/2010 09/2010 22/09/2010 06/2011 06/2011 06/2011		Not recovered at time of reporting		
047097	30/09/2010	12 Years	Female	Prophylaxis	GARDASIL	23/09/2010 - 23/09/2010	.5 ml	Myalgia Lethargy Headache	23/09/2010 23/09/2010 23/09/2010		Recovered/resolved		
047101	30/09/2010	12 Years	Female	Prophylaxis	GARDASIL	30/09/2010 - 30/09/2010	.5 ml	Presyncope Mydriasis Dizziness Fatigue Visual impairment Photopsia	30/09/2010 30/09/2010 30/09/2010 30/09/2010 30/09/2010		Recovered/resolved		

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047103	30/09/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Anaphylactic reaction Swollen tongue	30/09/2010		Unknown	VENTOLIN	Asthma
047104	01/10/2010	14 Years	Female	Prophylaxis	GARDASIL			Hypersensitivity Angioedema	23/09/2010 23/09/2010		Recovered/resolved		
047105	01/10/2010	14 Years	Female	Prophylaxis	GARDASIL	16/09/2010 -		Headache Fatigue			Not recovered at time of reporting		Fatigue
047109	01/10/2010	12 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -	.5 ml	Hyperventilation Syncope Tetany	30/09/2010 30/09/2010 30/09/2010		Recovered/resolved		
047111	04/10/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -	.5 ml	Anaphylactic reaction Hypotension Rash maculo-papular Tachycardia Erythema	30/09/2010 30/09/2010 30/09/2010 30/09/2010		Unknown		
047114	30/09/2010	13 Years	Female	Prophylaxis	GARDASIL		.5 ml	Urticaria Hypersensitivity			Recovered/resolved		
047118	04/10/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Hypoaesthesia Hyperventilation Paraesthesia Tetany Joint stiffness Muscle twitching Anxiety	30/09/2010 30/09/2010 30/09/2010 30/09/2010 30/09/2010 30/09/2010 30/09/2010		Recovered/resolved		
047123	05/10/2010	13 Years	Female	Prophylaxis	GARDASIL	01/10/2010 -		Hypersensitivity Rash erythematous Flushing Headache	01/10/2010 01/10/2010 01/10/2010 01/10/2010		Recovered/resolved		
047127	05/10/2010	12 Years	Female		GARDASIL	20/09/2010 - 20/09/2010	1 Dosage forms	Muscular weakness Chest pain Back pain Dizziness Abdominal pain upper Fatigue Dyspnoea Paraesthesia Muscle tightness Pain in extremity	20/09/2010 20/09/2010 27/09/2010 20/09/2010 20/09/2010 20/09/2010 27/09/2010 21/09/2010 21/09/2010 27/09/2010		Recovering/resolving		

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047133	06/10/2010		Female		GARDASIL			Fatigue Lethargy Somnolence			Unknown		
047134	06/10/2010	12 Years	Female	Prophylaxis	GARDASIL	06/10/2010 -		Syncope	06/10/2010		Recovered/resolved		
047146	08/10/2010	13 Years	Female	Prophylaxis	GARDASIL	05/10/2010 -		Blood glucose increased Ketonuria Asthenia	05/10/2010 05/10/2010 05/10/2010		Recovered/resolved	LANTUS APIDRA ELTROXIN	
047156	11/10/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Vomiting	04/10/2010		Recovered/resolved		
047157	11/10/2010	13 Years	Female	Prophylaxis	GARDASIL		.5 ml	Rash Headache Asthenia Nausea Syncope Anxiety	30/09/2010 30/09/2010 30/09/2010 30/09/2010 30/09/2010		Recovered/resolved		
047159	07/10/2010	13 Years	Female	Prophylaxis	GARDASIL	01/10/2010 -	.5 ml	Polydipsia Thirst	02/10/2010 02/10/2010		Not recovered at time of reporting		
047160	11/10/2010	13 Years	Female	Prophylaxis	GARDASIL		.5 ml	Asthenia	16/09/2010		Recovered/resolved		
047161	11/10/2010	13 Years	Female	Prophylaxis	GARDASIL		.5 ml	Clonus Syncope			Recovered/resolved		
047162	11/10/2010	12 Years	Female	Prophylaxis	GARDASIL	17/09/2010 - 17/09/2010	.5 ml	Dizziness	17/09/2010		Recovered/resolved		
047190	14/10/2010	14 Years	Female	Prophylaxis	GARDASIL	06/10/2010 - 06/10/2010		Livedo reticularis Throat irritation Asthenia Dizziness Hypersensitivity	06/10/2010 06/10/2010 06/10/2010 06/10/2010 06/10/2010		Recovered/resolved		Asthma
047192	14/10/2010	13 Years	Female	Prophylaxis	GARDASIL	12/10/2010 -	.5 ml	Dizziness Nausea Gait disturbance	12/10/2010 12/10/2010 12/10/2010		Not recovered at time of reporting		
047194	14/10/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Convulsion	30/09/2010		Unknown	EPILIM LAMICTAL	Epilepsy
2010-000002	15/10/2010	13 Years	Female	Prophylaxis	GARDASIL	05/10/2010 -		Fatigue Headache Dizziness Pallor Somnolence	06/10/2010 06/10/2010 06/10/2010 06/10/2010 06/10/2010		Not recovered at time of reporting		Atrial septal defect Petit mal epilepsy Asthma Constipation

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2010-000020	19/10/2010	13 Years	Female	Prophylaxis	GARDASIL	08/10/2010 - 08/10/2010	.5 ml	Injection site reaction Contusion Oedema peripheral Nausea Fatigue	08/10/2010 08/10/2010 08/10/2010 08/10/2010		Not recovered at time of reporting		
2010-000034	20/10/2010	14 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -		Urticaria	07/10/2010		Recovered/resolved		
2010-000035	20/10/2010	13 Years	Female	Prophylaxis	GARDASIL	21/09/2010 - 21/09/2010	.5 ml	Headache Fatigue Malaise	23/09/2010 23/09/2010 23/09/2010		Recovered/resolved		
2010-000052	21/10/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 - 27/09/2010		Pruritus Rash erythematous Nausea	02/10/2010 02/10/2010 06/10/2010		Recovered/resolved		
2010-000053	21/10/2010	12 Years	Female	Prophylaxis	GARDASIL	05/10/2010 -	.5 ml	Dizziness Decreased appetite Feeling cold Chills	05/10/2010 05/10/2010 05/10/2010 05/10/2010		Recovered/resolved		
2010-000055	21/10/2010	13 Years	Female	Prophylaxis	GARDASIL PER CENT	21/09/2010 -		Syncope Nausea Asthenia Fatigue Malaise	21/09/2010		Not recovered at time of reporting		
2010-000070	22/10/2010	14 Years	Female	Prophylaxis	GARDASIL	06/10/2010 - 06/10/2010		Dizziness Crying Emotional distress Cough Flushing Stridor Hyperventilation Tetany Malaise	06/10/2010 06/10/2010 06/10/2010 06/10/2010 06/10/2010 06/10/2010 06/10/2010 06/10/2010 06/10/2010		Recovered/resolved	AMOXIL	Asthma Lower respiratory tract infection
2010-000071	22/10/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 - 04/10/2010		Headache Pain in extremity Rash Photophobia Fatigue Feeling hot Pallor	04/10/2010 04/10/2010		Unknown		
2010-000073	22/10/2010	13 Years	Female	Prophylaxis	GARDASIL	22/09/2010 - 19/05/2010 -		Oedema peripheral	22/09/2010		Recovered/resolved		

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2010-000189	03/11/2010	14 Years	Female	Prophylaxis	GARDASIL	05/10/2010 -		Alopecia Visual impairment Vision blurred Abdominal pain upper Diarrhoea	01/11/2010 01/11/2010 01/11/2010 01/11/2010		Not recovered at time of reporting	RISPERDAL EQUASYM XL	Underweight Gastritis Tonsillitis
2010-000531	04/11/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 - 30/09/2010		Syncope Headache	30/09/2010 30/09/2010	30/09/2010	Recovered/resolved		
2010-000578	04/11/2010	13 Years	Female		GARDASIL	04/10/2010 - 04/10/2010		Hypersensitivity Urticaria Pruritus	08/10/2010 05/10/2010 08/10/2010	12/10/2010 07/10/2010 12/10/2010	Recovered/resolved		
2010-000588	05/11/2010		Female	Prophylaxis	GARDASIL	30/09/2010 -	.5 ml	Asthenia Headache Malaise Somnolence Diarrhoea Headache			Not recovered at time of reporting		
2010-000791	15/11/2010	13 Years	Female	Prophylaxis	GARDASIL	15/11/2010 - 15/11/2010	.5 ml	Anaphylactic reaction Throat tightness Dizziness Urticaria Cough Cyanosis central	15/11/2010 15/11/2010 15/11/2010 15/11/2010 15/11/2010		Unknown		
2010-000792	15/11/2010	13 Years	Female	Prophylaxis	GARDASIL	15/11/2010 - 15/11/2010	.5 ml	Migraine Dizziness Depressed level of Nausea Hypoaesthesia Pulse pressure decreased Photophobia Dysarthria	15/11/2010 15/10/2010 15/10/2010 15/10/2010 15/10/2010 15/10/2010 15/10/2010		Recovered/resolved		Headache

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2010-000793	16/11/2010	12 Years	Female	Prophylaxis	GARDASIL	13/09/2010 - 13/09/2010		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			Not recovered at time of reporting		
2010-000837	16/11/2010	12 Years	Female	Prophylaxis	GARDASIL	27/09/2010 - 27/09/2010		Lip swelling Malaise Hypersensitivity	27/09/2010 27/09/2010 27/09/2010	28/09/2010 28/09/2010 28/09/2010	Recovered/resolved		
2010-000852	16/11/2010	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Anaphylactic reaction Dizziness Pallor Tachycardia Tachypnoea Anxiety Wheezing Pulse pressure decreased Stridor	16/11/2010 16/11/2010 16/11/2010 16/11/2010 16/11/2010 16/11/2010 16/11/2010 16/11/2010 16/11/2010		Recovered/resolved		
2010-000884	17/11/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Syncope Headache	04/10/2010 04/10/2010		Recovered/resolved		
2010-000927	18/11/2010		Female	Prophylaxis	GARDASIL	17/11/2010 -	.5 ml	Dizziness	17/11/2010	17/11/2010	Recovered/resolved		
2010-000929	18/11/2010	12 Years	Female	Prophylaxis	GARDASIL	17/11/2010 - 17/11/2010	.5 ml	Dizziness	17/11/2010	17/11/2010	Recovered/resolved		
2010-000931	18/11/2010	12 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -		Paraesthesia Pyrexia	28/09/2010 28/09/2010		Recovered/resolved		
2010-000940	18/11/2010	12 Years	Female	Prophylaxis	GARDASIL	17/11/2010 - 17/11/2010		Headache Dizziness Urticaria	17/11/2010 17/11/2010 17/11/2010		Recovered/resolved		Hypersensitivity
2010-000962	18/11/2010	13 Years	Female	Prophylaxis	GARDASIL	17/11/2010 -		Headache Flushing	17/11/2010 17/11/2010	17/11/2010 17/11/2010	Recovered/resolved		Migraine
2010-000968	19/11/2010	13 Years	Female	Prophylaxis	GARDASIL	17/11/2010 - 17/11/2010		Abdominal discomfort	17/11/2010	17/11/2010	Recovered/resolved		

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2010-000969	19/11/2010	14 Years	Female	Prophylaxis	GARDASIL	17/11/2010 - 17/11/2010	.5 ml	Dizziness	17/11/2010	17/11/2010	Recovered/resolved		
2010-000971	19/11/2010	12 Years	Female	Prophylaxis	GARDASIL	17/11/2010 - 17/11/2010	.5 ml	Pain in extremity	17/11/2010	17/11/2010	Recovered/resolved		
2010-000972	17/11/2010	12 Years	Female	Prophylaxis	GARDASIL	17/11/2010 - 17/11/2010		Headache Abdominal discomfort	17/11/2010 17/11/2010	17/11/2010 17/11/2010	Recovered/resolved		
2010-000975	19/11/2010	13 Years	Female	Prophylaxis	GARDASIL	19/11/2010 - 19/11/2010	.5 ml	Cyanosis Feeling cold	19/11/2010 19/11/2010		Recovered/resolved		
2010-000992	22/11/2010	14 Years	Female	Prophylaxis	GARDASIL	15/11/2010 -	.1 ml	Urticaria	16/11/2010		Not recovered at time of reporting		
2010-001014	22/11/2010	15 Years	Female		GARDASIL	03/11/2010 - 03/11/2010	.5 ml	Tonsillitis Oropharyngeal pain Dysphagia Dizziness Abdominal pain upper Paraesthesia Headache Myalgia Neck pain Musculoskeletal stiffness	04/11/2010 04/11/2010 04/11/2010 03/11/2010 04/11/2010 04/11/2010 03/11/2010 03/11/2010 05/11/2010 05/11/2010 05/11/2010	10/11/2010 06/11/2010 06/11/2010 05/11/2010 06/11/2010 06/11/2010 05/11/2010 05/11/2010 06/11/2010 06/11/2010	Recovered/resolved		Tonsillitis
2010-001050	23/11/2010	13 Years	Female	Prophylaxis	GARDASIL	17/11/2010 - 17/11/2010	.5 ml	Feeling abnormal Thirst	17/11/2010 17/11/2010	17/11/2010 17/11/2010	Recovered/resolved		
2010-001054	23/11/2010	13 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -		Injection site swelling Injection site pain Injection site erythema	29/09/2010 29/09/2010 29/09/2010		Recovered/resolved		
2010-001068	17/11/2010	16	Female	Prophylaxis	GARDASIL	24/09/2010 -		Visual impairment Headache Eye swelling Malaise Myalgia Muscular weakness Syncope Fatigue	24/09/2010 24/09/2010 24/09/2010 25/09/2010 25/09/2010 25/09/2010 25/09/2010 28/09/2010		Recovered/resolved		
2010-001087	24/11/2010	12 Years	Female	Prophylaxis	GARDASIL	22/11/2010 - 22/11/2010	.5 ml	Dizziness	22/11/2010	22/11/2010	Recovered/resolved		
2010-001088	24/11/2010	13 Years	Female	Prophylaxis	GARDASIL	23/11/2010 - 23/11/2010	.5 ml	Dizziness Headache	23/11/2010 23/11/2010		Recovered/resolved		
2010-001089	24/11/2010	12 Years	Female	Prophylaxis	GARDASIL	22/11/2010 - 22/11/2010	.5 ml	Dizziness	22/11/2010	22/11/2010	Recovered/resolved		

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2010-001090	24/11/2010	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 - 22/11/2010		Headache	22/11/2010	22/11/2010	Not recovered at time of reporting	EPILIM	
2010-001091	24/11/2010	13 Years	Female	Prophylaxis	GARDASIL	22/11/2010 - 22/11/2010	.5 Milligram	Headache	22/11/2010		Unknown		
2010-001092	24/11/2010	12 Years	Female	Prophylaxis	GARDASIL	22/11/2010 - 22/11/2010	.5 ml	Abdominal pain upper	22/11/2010	22/11/2010	Recovered/resolved		
2010-001093	24/11/2010	15 Years	Female	Prophylaxis	GARDASIL	22/11/2010 - 22/11/2010	.5 ml	Epigastric discomfort	22/11/2010	22/11/2010	Recovered/resolved		
2010-001094	24/11/2010	13 Years	Female	Prophylaxis	GARDASIL	22/11/2010 - 22/11/2010	.5 ml	Pain in extremity	22/11/2010		Recovered/resolved		
2010-001095	24/11/2010	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 - 22/11/2010	.5 ml	Headache Asthenia	22/11/2010 22/11/2010	22/11/2010 22/11/2010	Recovered/resolved	NOVORAPID LANTUS	Type 1 diabetes mellitus
2010-001097	24/11/2010	12 Years	Female	Prophylaxis	GARDASIL	22/11/2010 - 22/11/2010	.5 ml	Headache	22/11/2010	22/11/2010	Recovered/resolved		
2010-001100	24/11/2010	13 Years	Female	Prophylaxis	GARDASIL	23/11/2010 - 23/11/2010	.5 ml	Dizziness	23/11/2010	23/11/2010	Recovered/resolved		
2010-001104	24/11/2010	13 Years	Unknown	Prophylaxis	GARDASIL	22/11/2010 - 22/11/2010	.5 ml	Dizziness	22/11/2010	22/11/2010	Recovered/resolved		
2010-001132	25/11/2010	14	Female		GARDASIL	23/11/2010 -		Urticaria Rash pruritic	24/11/2010		Not recovered at time of reporting	CLONAMOX	Tonsillitis Premature baby Rash
2010-001133	25/11/2010	12 Years	Female	Prophylaxis	GARDASIL	13/09/2010 - 13/09/2010	.5 ml	Urticaria	13/09/2010		Recovered/resolved		
2010-001152	25/11/2010	12.5 Years	Female	Prophylaxis	GARDASIL	22/11/2010 - 22/11/2010		Limb discomfort Myalgia Sensation of heaviness	23/11/2010 24/11/2010 24/11/2010		Recovered/resolved		
2010-001195	29/11/2010	13 Years	Female	Prophylaxis	GARDASIL	21/09/2010 -	.5 ml	Urticaria Pruritus	22/09/2010 22/09/2010		Recovered/resolved		
2010-001211	30/11/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dermatitis allergic Urticaria Pruritus	29/09/2010 29/09/2010 29/09/2010	06/10/2010 06/10/2010 06/10/2010	Recovered/resolved		
2010-001212	01/12/2010	13 Years	Female	Prophylaxis	GARDASIL	26/11/2010 - 26/11/2010	.5 ml	Headache	26/11/2010	26/11/2010	Recovered/resolved		
2010-001213	01/12/2010	13 Years	Female	Prophylaxis	GARDASIL	26/11/2010 - 26/11/2010	.5 ml	Headache Flushing	26/11/2010 26/11/2010	26/11/2010 26/11/2010	Recovered/resolved		
2010-001216	01/12/2010	12 Years	Female	Prophylaxis	GARDASIL	26/11/2010 - 26/11/2010	.5 ml	Malaise	26/11/2010	26/11/2010	Recovered/resolved		
2010-001217	01/12/2010	12 Years	Female	Prophylaxis	GARDASIL	26/11/2010 - 26/11/2010	.5 ml	Asthenia	26/11/2010		Recovered/resolved		

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2010-001219	01/12/2010	13 Years	Female	Prophylaxis	GARDASIL	22/09/2010 - 22/09/2010		Lethargy Headache Local reaction	22/09/2010 22/09/2010 22/09/2010	23/09/2010 27/09/2010	Recovered/resolved		
2010-001220	01/12/2010	13 Years	Female	Prophylaxis	GARDASIL	26/11/2010 - 26/11/2010	.5 ml	Limb discomfort	26/11/2010		Recovered/resolved		
2010-001304	26/11/2010	13 Years	Female	Prophylaxis	GARDASIL	24/11/2010 - 24/11/2010		Pyrexia Oropharyngeal pain Lymphadenopathy	24/11/2010 24/11/2010 24/11/2010		Unknown		Adverse event following Prophylaxis
2010-001310	03/12/2010	13 Years	Female	Prophylaxis	GARDASIL	25/11/2010 - 25/11/2010	.5 ml	Epigastric discomfort	25/11/2010	25/11/2010	Recovered/resolved		
2010-001313	03/12/2010	12 Years	Female	Prophylaxis	GARDASIL	25/11/2010 - 25/11/2010	.5 ml	Injection site pain	25/11/2010	25/11/2010	Recovered/resolved		
2010-001314	03/12/2010		Female	Prophylaxis	GARDASIL	24/11/2010 - 24/11/2010	.5 ml	Injection site swelling	27/11/2010	30/11/2010	Not recovered at time of reporting		
2010-001315	03/12/2010	13 Years	Female	Prophylaxis	GARDASIL	25/11/2010 - 25/11/2010	.5 ml	Headache	25/11/2010		Recovered/resolved		
2010-001316	03/12/2010	12 Years	Female	Prophylaxis	GARDASIL	25/11/2010 - 25/11/2010	.5 ml	Injection site pain	25/11/2010	25/11/2010	Recovered/resolved		
2010-001362	07/12/2010	13 Years	Female	Prophylaxis	GARDASIL	06/12/2010 -	.5 ml	Oropharyngeal pain Swollen tongue	06/12/2010 06/12/2010	06/12/2010 06/12/2010	Recovered/resolved		
2010-001387	07/12/2010	13 Years	Female	Prophylaxis	GARDASIL	05/10/2010 - 05/10/2010	.5 ml	Deep vein thrombosis Pulmonary embolism	18/10/2010 18/10/2010		Recovering/resolving	WARFARIN	
2010-001389	08/12/2010	14 Years	Female	Prophylaxis	GARDASIL	05/10/2010 - 05/10/2010	.5 ml	Cellulitis Injection site mass Pyrexia	19/10/2010 19/10/2010 19/10/2010		Recovered/resolved		
2010-001390	09/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 - 29/09/2010		Skin reaction Urticaria	30/09/2010 30/09/2010	02/10/2010 02/10/2010	Recovered/resolved		
2010-001391	09/12/2010	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Local reaction Injection site induration Pain in extremity Rash macular Urticaria	16/11/2010 16/11/2010 16/11/2010 16/11/2010 16/11/2010		Unknown		
2010-001402	10/12/2010	13 Years	Female	Prophylaxis	GARDASIL	23/09/2010 - 23/09/2010	.5 ml	Pallor Dizziness Limb discomfort Eye pruritus	23/09/2010 23/09/2010 23/09/2010 23/09/2010	23/09/2010 23/09/2010 23/09/2010 23/09/2010	Recovered/resolved		
2010-001420	13/12/2010	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Urticaria	22/11/2010		Recovered/resolved		

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2010-001421	13/12/2010	12 Years	Female	Prophylaxis	GARDASIL	21/09/2010 - 21/09/2010	.5 ml	Urticaria	21/09/2010		Unknown		
2010-001422	13/12/2010	12 Years	Female	Prophylaxis	GARDASIL	12/10/2010 - 12/10/2010	.5 ml	Nausea Vomiting Lethargy	12/10/2010 12/10/2010 12/10/2010		Recovered/resolved		
2010-001423	13/12/2010	13 Years	Female	Prophylaxis	GARDASIL	22/11/2010 - 22/11/2010	.5 ml	Nausea	22/11/2010	27/11/2010	Recovered/resolved		Vaccination complication
2010-001435	14/12/2010		Female	Prophylaxis	GARDASIL	17/11/2010 -		Chest pain	17/11/2010		Recovered/resolved		
2010-001436	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Dizziness Vision blurred Pallor			Recovered/resolved		
2010-001437	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL			Headache Hyperhidrosis			Not recovered at time of		
2010-001439	14/12/2010		Female		GARDASIL	15/09/2010 -		Syncope	15/09/2010		Recovered/resolved		
2010-001440	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	05/10/2010 -		Dizziness Flushing	05/10/2010 05/10/2010		Recovered/resolved		
2010-001441	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	19/05/2010 -		Syncope	19/05/2010		Recovered/resolved		
2010-001442	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Feeling hot Dizziness Asthenia	05/10/2010 05/10/2010 05/10/2010		Recovered/resolved		
2010-001443	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL			Pain in extremity Headache	05/10/2010 05/10/2010		Recovered/resolved		
2010-001444	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	05/10/2010 -		Nausea Malaise	05/10/2010		Recovered/resolved		
2010-001445	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Presyncope			Recovered/resolved		
2010-001446	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Nausea	05/10/2010		Recovered/resolved		
2010-001447	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL			Dizziness Pallor	05/10/2010 05/10/2010		Recovered/resolved		
2010-001448	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	05/10/2010 -		Dizziness	05/10/2010		Recovered/resolved		
2010-001449	14/12/2010	12 Years	Female		GARDASIL	04/10/2010 -		Headache	04/10/2010		Recovered/resolved		

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2010-001450	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL			Headache Pallor	15/09/2010 15/09/2010		Recovered/resolved		
2010-001451	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -		Abdominal pain upper Dizziness	15/09/2010 15/09/2010		Recovered/resolved		
2010-001452	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -		Dizziness	15/09/2010		Recovered/resolved		
2010-001453	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -		Pain in extremity Back pain	15/09/2010 15/09/2010		Recovered/resolved		
2010-001454	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	24/11/2010 -		Chills			Not recovered at time of reporting	ACICLOVIR MONTELUKAST SERETIDE GRAZAX SALAMOL	Food allergy Eczema Asthma Herpes simplex
2010-001456	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Dizziness	15/09/2010		Recovered/resolved		
2010-001457	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -		Abdominal pain upper	15/09/2010		Recovered/resolved		
2010-001458	14/12/2010		Female	Prophylaxis	GARDASIL	05/10/2010 -		Nausea	05/10/2010		Recovered/resolved		
2010-001459	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Abdominal pain	15/09/2010		Recovered/resolved		
2010-001460	14/12/2010	12 Years	Male	Prophylaxis	GARDASIL	21/09/2010 -		Dizziness	21/09/2010		Recovered/resolved		
2010-001461	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL			Nausea Headache			Recovered/resolved		
2010-001464	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	06/10/2010 -		Dizziness	06/10/2010		Recovered/resolved		
2010-001465	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL			Dizziness Asthenia	07/10/2010 07/10/2010		Recovered/resolved		
2010-001470	13/12/2010	19 Years	Female	Prophylaxis	GARDASIL	06/2010 -		Panic attack Anxiety Chest pain Dizziness Limb discomfort	07/2010 07/2010 07/2010 07/2010		Not recovered at time of reporting		
2010-001475	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL			Nausea Vomiting			Recovered/resolved		
2010-001476	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Dizziness Headache			Recovered/resolved		

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2010-001477	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	21/09/2010 -		Headache Dizziness Asthenia	21/09/2010 21/09/2010 21/09/2010		Recovered/resolved		
2010-001478	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	17/11/2010 -		Feeling hot Hyperhidrosis	17/11/2010 17/11/2010		Recovered/resolved		
2010-001479	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	03/11/2010 -		Dizziness	03/11/2010		Recovered/resolved		
2010-001480	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	03/11/2010 -	.5 ml	Malaise Headache	03/11/2010 03/11/2010		Recovered/resolved		
2010-001483	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Anxiety Feeling of body temperature change	30/09/2010 30/09/2010	30/09/2010 30/09/2010	Recovered/resolved		
2010-001484	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Dizziness Abdominal discomfort	30/09/2010 30/09/2010		Recovered/resolved		
2010-001486	15/12/2010	12 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Urticaria Lethargy Fatigue Rash vesicular Pruritus Hypersensitivity	27/09/2010 27/09/2010 27/09/2010 27/09/2010 27/09/2010 27/09/2010		Not recovered at time of reporting		
2010-001487	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Abdominal discomfort Dizziness	30/09/2010 30/09/2010	30/09/2010 30/09/2010	Recovered/resolved		
2010-001488	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Pain in extremity Headache Nausea	30/09/2010 30/09/2010 30/09/2010		Recovered/resolved		
2010-001490	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Headache Nausea	30/09/2010 30/09/2010		Recovered/resolved		
2010-001492	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Nausea Dizziness	30/09/2010 30/09/2010		Recovered/resolved		
2010-001493	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Dizziness Asthenia	30/09/2010 30/09/2010		Recovered/resolved		
2010-001494	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -		Nausea Dizziness	29/09/2010 29/09/2010	29/09/2010 29/09/2010	Recovered/resolved		
2010-001495	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -		Dizziness Pallor	29/09/2010 29/09/2010	29/09/2010 29/09/2010	Recovered/resolved		
2010-001496	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Headache Abdominal discomfort	30/09/2010 30/09/2010	30/09/2010 30/09/2010	Recovered/resolved		

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2010-001497	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Headache Dizziness	30/09/2010 30/09/2010		Recovered/resolved		
2010-001498	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Dizziness Abdominal discomfort	30/09/2010 30/09/2010	30/09/2010 30/09/2010	Recovered/resolved		
2010-001499	14/12/2010	13 Weeks	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness	11/10/2010		Recovered/resolved		
2010-001500	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Dizziness Nausea	30/09/2010 30/09/2010	30/09/2010 30/09/2010	Recovered/resolved		
2010-001501	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness Pallor	11/10/2010 11/10/2010		Recovered/resolved		
2010-001502	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Asthenia Dizziness	30/09/2010 30/09/2010	30/09/2010 30/09/2010	Recovered/resolved		
2010-001503	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness Pallor	11/10/2010 11/10/2010		Recovered/resolved		
2010-001504	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Syncope Dizziness	30/09/2010 30/09/2010	30/09/2010 30/09/2010	Recovered/resolved		
2010-001505	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness Asthenia	11/10/2010 11/10/2010		Recovered/resolved		
2010-001506	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Dizziness			Recovered/resolved		
2010-001507	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -	.5 ml	Dizziness	29/09/2010		Recovered/resolved		
2010-001508	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Asthenia Dizziness Pain in extremity	11/10/2010 11/10/2010 11/10/2010		Recovered/resolved		
2010-001509	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL			Oropharyngeal pain			Recovered/resolved		
2010-001510	14/12/2010	15 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -	.5 ml	Dizziness Emotional distress Headache Nausea	29/09/2010 29/09/2010 29/09/2010 29/09/2010		Recovered/resolved		
2010-001511	14/12/2010	12 Years	Female		GARDASIL	29/09/2010 -	.5 ml	Pallor	29/09/2010		Recovered/resolved		
2010-001512	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -	.5 ml	Dizziness Headache	29/09/2010 29/09/2010		Recovered/resolved		
2010-001513	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -	.5 ml	Nausea Headache Malaise	29/09/2010 29/09/2010 29/09/2010		Recovered/resolved	METHOTREXATE LOSAMEL NAPROSYN	Rheumatoid arthritis

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2010-001514	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	29/09/2010 - 29/09/2010	.5 ml	Syncope	29/09/2010		Recovered/resolved		
2010-001515	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	29/09/2010 - 29/09/2010	.5 ml	Feeling hot Cold sweat	29/09/2010 29/09/2010		Recovered/resolved		
2010-001516	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -	.5 ml	Dizziness Nausea	29/09/2010 29/09/2010		Recovered/resolved		
2010-001517	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Dizziness	04/10/2010		Recovered/resolved		
2010-001518	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	04/04/2010 -	.5 ml	Dizziness	04/04/2010		Recovered/resolved		
2010-001519	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Dizziness	04/10/2010		Recovered/resolved		
2010-001520	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Dizziness Nausea	04/10/2010 04/10/2010	04/10/2010 04/10/2010	Recovered/resolved		
2010-001521	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Dizziness	04/10/2010	04/10/2010	Recovered/resolved		
2010-001522	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness Somnolence	28/09/2010 28/09/2010		Recovered/resolved		
2010-001523	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Dizziness Headache Emotional distress	04/10/2010 04/10/2010 04/10/2010	04/10/2010 04/10/2010 04/10/2010	Recovered/resolved		
2010-001524	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness	28/09/2010		Recovered/resolved		
2010-001525	16/12/2010	13 Years	Female	Prophylaxis	GARDASIL	29/11/2010 -	.5 ml	Grand mal convulsion	03/12/2010		Recovered/resolved		
2010-001526	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness Pallor	28/09/2010 28/09/2010	28/09/2010 28/09/2010	Recovered/resolved		
2010-001527	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Malaise	28/09/2010		Recovered/resolved		
2010-001528	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	13/10/2010 - 13/10/2010	.5 ml	Dizziness	13/10/2010	13/10/2010	Recovered/resolved		
2010-001529	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness Pallor	28/09/2010 28/09/2010		Recovered/resolved		
2010-001531	16/12/2010	13 Years	Female	Prophylaxis	GARDASIL	14/12/2010 -	.5 ml	Headache Nausea	14/12/2010 14/12/2010	14/12/2010 14/12/2010	Recovered/resolved		
2010-001532	16/12/2010	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -		Malaise Hypoaesthesia Pyrexia Vomiting Lethargy	16/11/2010 16/11/2010 16/11/2010 16/11/2010		Unknown		

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2010-001533	16/12/2010	14 Years	Female	Prophylaxis	GARDASIL	14/12/2010 -	.5 ml	Malaise	14/12/2010	14/12/2010	Recovered/resolved		
2010-001534	16/12/2010	14 Years	Female	Prophylaxis	GARDASIL	14/12/2010 -	.5 ml	Headache Dizziness	14/12/2010 14/12/2010		Recovered/resolved		
2010-001535	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	13/10/2010 -	.5 ml	Dizziness	13/10/2010	13/10/2010	Recovered/resolved		
2010-001536	16/12/2010	14 Years	Female	Prophylaxis	GARDASIL	24/09/2010 -	.5 ml	Nausea	24/09/2010		Recovered/resolved		
2010-001537	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Abdominal discomfort Headache Nausea	28/09/2010 28/09/2010 28/09/2010	28/09/2010 28/09/2010 28/09/2010	Recovered/resolved		
2010-001538	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 - 28/09/2010	.5 ml	Dizziness	28/09/2010		Recovered/resolved		
2010-001539	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Abdominal discomfort	28/09/2010		Recovered/resolved		
2010-001540	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Abdominal discomfort	28/09/2010		Recovered/resolved		
2010-001541	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness	28/09/2010		Recovered/resolved		
2010-001542	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 - 28/09/2010	.5 ml	Dizziness Abdominal discomfort Headache	28/09/2010 28/09/2010 28/09/2010	28/09/2010 28/09/2010 28/09/2010	Recovered/resolved		
2010-001543	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness	28/09/2010		Recovered/resolved		
2010-001544	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Presyncope Pallor Hyperhidrosis	28/09/2010 28/09/2010 28/09/2010	28/09/2010 28/09/2010 28/09/2010	Recovered/resolved		
2010-001545	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL		.5 ml	Nausea Dizziness	11/10/2010 11/10/2010		Unknown		
2010-001547	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness	11/10/2010		Recovered/resolved		
2010-001548	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness Chills	01/10/2010 11/10/2010		Recovered/resolved		
2010-001549	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Presyncope Headache	27/09/2010 27/09/2010	27/09/2010 27/09/2010	Recovered/resolved		
2010-001550	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Headache	28/09/2010	28/09/2010	Recovered/resolved		
2010-001551	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -		Dizziness Nausea	29/09/2010 29/09/2010		Recovered/resolved		
2010-001552	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Dizziness			Recovered/resolved		

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2010-001556	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -		Dizziness Pallor	29/09/2010 29/09/2010		Recovered/resolved		
2010-001557	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness	28/09/2010		Recovered/resolved		
2010-001558	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Headache Nausea	28/09/2010 28/09/2010		Recovered/resolved		
2010-001559	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -		Dizziness Headache	29/09/2010 29/09/2010		Recovered/resolved		
2010-001560	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Dizziness	04/10/2010		Recovered/resolved		
2010-001561	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Nausea	28/09/2010		Recovered/resolved		
2010-001562	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Abdominal pain Dizziness Feeling of body temperature change	28/09/2010 28/09/2010 28/09/2010		Recovered/resolved		
2010-001563	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL			Dizziness Panic attack			Unknown		
2010-001564	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness Feeling of body temperature change	28/09/2010 28/09/2010		Recovered/resolved		
2010-001565	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Dizziness Pallor			Unknown		
2010-001566	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Dizziness Asthenia	27/09/2010 27/09/2010	27/09/2010 27/09/2010	Recovered/resolved		
2010-001567	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Headache Pain in extremity			Unknown		
2010-001568	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Dizziness	27/09/2010		Recovered/resolved		
2010-001569	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness Hypoaesthesia	11/10/2010 11/10/2010		Recovered/resolved		
2010-001570	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Presyncope	27/09/2010	27/09/2010	Recovered/resolved		
2010-001571	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Dizziness	27/09/2010		Recovered/resolved		
2010-001572	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Abdominal pain Headache	27/09/2010 27/09/2010	27/09/2010 27/09/2010	Recovered/resolved		
2010-001573	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Presyncope	27/09/2010		Recovered/resolved		

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2010-001574	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Dizziness Headache	27/09/2010 27/09/2010		Recovered/resolved		
2010-001575	15/12/2010	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Malaise	22/11/2010	22/11/2010	Recovered/resolved		
2010-001576	15/12/2010	13 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Malaise Fatigue	22/11/2010 22/11/2010	22/11/2010 22/11/2010	Recovered/resolved		
2010-001577	15/12/2010	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Fatigue	22/11/2010	22/11/2010	Recovered/resolved		Asthenia
2010-001578	15/12/2010	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Malaise Dizziness	22/11/2010 22/11/2010	22/11/2010 22/11/2010	Recovered/resolved		
2010-001579	15/12/2010	13 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Malaise Headache	22/11/2010 22/11/2010	22/11/2010 22/11/2010	Recovered/resolved		
2010-001580	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Headache	27/09/2010		Recovered/resolved		
2010-001581	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Abdominal pain	27/09/2010		Recovered/resolved		
2010-001584	14/12/2010	12 Years	Female		GARDASIL	27/09/2010 -	.5 ml	Presyncope Nausea	27/09/2010 27/09/2010		Recovered/resolved		
2010-001590	17/12/2010		Female		GARDASIL			Cyanosis			Unknown		
2010-001591	17/12/2010		Female		GARDASIL			Cyanosis			Recovered/resolved		
2010-001595	17/12/2010		Female		GARDASIL			Urticaria					
2010-001607	20/12/2010	14 Years	Female	Prophylaxis	GARDASIL	15/12/2010 -		Convulsion	15/12/2010		Recovered/resolved	LAMICTAL	Epilepsy
2010-001608	20/12/2010	13 Years	Female	Prophylaxis	GARDASIL	15/12/2010 - 15/12/2010	.5 ml	Abdominal discomfort Headache	15/12/2010 15/12/2010		Recovered/resolved		
2010-001610	20/12/2010	13 Years	Female	Prophylaxis	GARDASIL	15/12/2010 - 15/12/2010	.5 ml	Dermatitis allergic Pruritus Rash erythematous	15/12/2010 15/12/2010 15/12/2010		Recovered/resolved		
2010-001616	20/12/2010	12 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -		Nausea Vomiting	04/10/2010 04/10/2010		Recovered/resolved		
2010-001617	20/12/2010	13 Years	Female	Prophylaxis	GARDASIL	10/2010 -	.5 ml	Rash Headache Urticaria	22/11/2010		Recovered/resolved		
2010-001671	23/12/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Headache	04/10/2010		Recovered/resolved		

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2010-001675	23/12/2010	14 Years	Female	Prophylaxis	GARDASIL	20/10/2010 - 20/10/2010		Rash pruritic Sleep disorder			Recovered/resolved	PREDNISOLONE AZATHIOPRINE	Myasthenia gravis
2011-001706	04/01/2011	12 Years	Female	Prophylaxis	GARDASIL	19/09/2010 -	.5 ml	Headache Dizziness Presyncope Tonsillitis	19/09/2010 10/2010		Unknown		
2011-001712	04/01/2011	12 Years	Female	Prophylaxis	GARDASIL	09/2010 -	.5 ml	Headache			Not recovered at time of reporting		
2011-001714	04/01/2011	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 - 27/09/2010	.5 ml	Headache Influenza like illness Asthenia	27/09/2010 27/09/2010 27/09/2010		Not recovered at time of reporting		
2011-001729	05/01/2011	13 Years	Female	Prophylaxis	GARDASIL	17/12/2010 -		Abdominal pain Vomiting	21/12/2010 21/12/2010		Not recovered at time of reporting		
2011-001754	15/12/2010	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Asthenia	22/11/2010		Recovered/resolved		
2011-001755	05/01/2011	13 Years	Female	Prophylaxis	GARDASIL	27/10/2010 -		Abdominal pain Vomiting	10/2010 10/2010		Unknown		
2011-001791	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Nausea Dizziness Chest discomfort	22/11/2010 22/11/2010 22/11/2010		Recovered/resolved		Asthma
2011-001792	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	15/11/2010 -		Dizziness Anxiety Dyspnoea	15/11/2010 15/11/2010 15/11/2010		Recovered/resolved		Asthma
2011-001793	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	09/12/2010 -	.5 ml	Eye irritation Rash Pruritus	09/12/2010 09/12/2010 09/12/2010		Recovered/resolved		
2011-001800	13/01/2011	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Dizziness	22/11/2010	22/11/2010	Recovered/resolved		
2011-001801	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Nausea Dizziness	22/11/2010 22/11/2010		Recovered/resolved		
2011-001802	13/01/2011	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Dizziness Injection site pain	22/11/2010 22/11/2010		Recovered/resolved		
2011-001803	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Nausea Headache	22/11/2010 22/11/2010	22/11/2010 22/11/2010	Recovered/resolved		

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2011-001804	13/01/2011	14 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Malaise Headache	16/11/2010 16/11/2010		Recovered/resolved		
2011-001805	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -		Headache Dizziness Nausea	28/09/2010 28/09/2010 28/09/2010		Recovered/resolved		
2011-001806	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -		Abdominal pain upper Feeling hot Dysgeusia Headache Cold sweat	16/11/2010 16/11/2010 16/11/2010 16/11/2010 16/11/2010		Recovered/resolved		
2011-001807	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Chills Fatigue Dizziness	16/11/2010 16/11/2010 16/11/2010		Recovered/resolved		
2011-001809	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Malaise	16/11/2010		Recovered/resolved		
2011-001818	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -		Dizziness Headache	16/11/2010 16/11/2010		Recovered/resolved		
2011-001819	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Headache	16/11/2010		Recovered/resolved		
2011-001824	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Headache Nausea	16/11/2010 16/11/2010		Recovered/resolved		
2011-001826	13/01/2011	14 Years	Female	Prophylaxis	GARDASIL	16/11/2010 - 16/11/2010	.5 ml	Headache	16/11/2010		Recovered/resolved		
2011-001827	13/01/2011	12 Years	Female		GARDASIL	16/11/2010 - 16/11/2010	.5 ml	Dizziness	16/11/2010		Recovered/resolved		
2011-001828	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	09/12/2010 -	.5 ml	Dizziness Nausea	09/12/2010 09/12/2010		Recovered/resolved		
2011-001829	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	09/12/2010 - 19/12/2010	.5 ml	Dizziness Nausea	09/12/2010 09/12/2010		Recovered/resolved		
2011-001830	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -		Dizziness Visual impairment Headache	16/11/2010 16/11/2010 16/11/2010		Recovered/resolved		
2011-001831	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Chills Feeling cold Abdominal discomfort	16/11/2010 16/11/2010 16/11/2010		Recovered/resolved		
2011-001832	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Headache Dizziness	16/11/2010 16/11/2010		Recovered/resolved		

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2011-001849	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	15/11/2010 -	.5 ml	Feeling hot Dizziness	15/11/2010 15/11/2010		Recovered/resolved		
2011-001854	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL			Dizziness Nausea			Not recovered at time of reporting		
2011-001856	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	15/11/2010 -		Nausea Headache Dizziness Abdominal pain	15/11/2010 15/11/2010 15/11/2010 15/11/2010		Not recovered at time of reporting		
2011-001857	13/01/2011	14 Years	Female	Prophylaxis	GARDASIL	15/11/2010 -		Dizziness	15/11/2010		Recovering/resolving		
2011-001859	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	15/11/2010 -		Pain	15/11/2010		Not recovered at time of reporting		
2011-001863	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL			Dizziness			Recovered/resolved		
2011-001864	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	15/11/2010 -		Nausea Dizziness	15/11/2010 15/11/2010		Recovered/resolved		
2011-001866	13/01/2011	14 Years	Female	Prophylaxis	GARDASIL	15/11/2010 -		Dizziness	15/11/2010		Recovered/resolved		
2011-001869	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL			Asthenia Dizziness Pallor			Recovered/resolved		
2011-001870	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL			Dizziness Headache			Recovered/resolved		
2011-001872	13/01/2011	14 Years	Female	Prophylaxis	GARDASIL			Headache			Recovered/resolved		
2011-001873	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL			Syncope Dizziness	10/12/2010 10/12/2010		Recovered/resolved		
2011-001874	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	13/10/2010 -	.5 ml	Dizziness	13/10/2010		Recovered/resolved		
2011-001875	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL		.5 ml	Dizziness Headache Nausea			Recovered/resolved		

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2011-001924	20/01/2011	14 Years	Female	Prophylaxis	GARDASIL	29/11/2010 - 29/11/2010	.5 ml	Vertigo Syncope Emotional distress Pallor Nausea Anxiety Pain in extremity Burning sensation Insomnia Local reaction	01/12/2010 01/12/2010 01/12/2010 01/12/2010	22/12/2010 22/12/2010 22/12/2010 22/12/2010	Recovered/resolved		
2011-001944	21/01/2011	12 Years	Female	Prophylaxis	GARDASIL	17/01/2011 -	.5 ml	Pain in extremity	17/01/2011		Not recovered at time of reporting		
2011-001977	25/01/2011	13 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -	.5 ml	Pyrexia Pain in extremity	29/09/2010 29/09/2010		Recovered/resolved		
2011-001982	25/01/2011	13 Years	Female	Prophylaxis	GARDASIL	01/10/2010 -	.5 ml	Limb discomfort Erythema	01/10/2010 01/10/2010		Recovered/resolved		
2011-002012	26/01/2011	15 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Body temperature increased Pain Lymphadenopathy Asthenia Decreased appetite	16/11/2010 16/11/2010 16/11/2010 16/11/2010		Not recovered at time of reporting		
2011-002013	26/01/2011		Female	Prophylaxis	GARDASIL	13/12/2010 -	.5 ml	Syncope	13/12/2010		Recovered/resolved		Syncope
2011-002014	26/01/2011	15 Years	Female	Prophylaxis	GARDASIL	07/12/2010 -	.5 ml	Asthenia Nausea Pain in extremity	07/12/2010 07/12/2010 07/12/2010		Recovered/resolved		Asthma
2011-002015	26/01/2011	16 Years	Female	Prophylaxis	GARDASIL	13/12/2010 -	.5 Milligram	Syncope Muscle twitching Headache Dizziness	13/12/2010 13/12/2010 13/12/2010 13/12/2010		Recovered/resolved		Phobia
2011-002037	28/01/2011	14 Years	Female	Prophylaxis	GARDASIL	25/01/2011 -		Arthralgia	25/01/2011		Recovered/resolved		
2011-002222	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	21/09/2010 - 21/09/2010		Dizziness	21/09/2010		Recovered/resolved		

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HPRA ID	Date of first notification to HPRA	Patient Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Reaction Cessation Date	Outcome	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
2011-002370	16/02/2011	14 Years	Female		GARDASIL	04/02/2011 - 04/02/2011		Trance Transient memory impairment Anxiety Somnolence Eye movement disorder Fatigue Headache			Not recovered at time of reporting		
2011-002757	14/03/2011	13 Years	Female	Prophylaxis	GARDASIL	10/03/2011 -	.5 ml	Dizziness	10/03/2011		Recovered/resolved		
2011-002758	14/03/2011	14 Years	Female	Prophylaxis	GARDASIL	09/03/2011 -	.5 ml	Pallor	09/03/2011	09/03/2011	Recovered/resolved		
2011-002759	14/03/2011	13 Years	Female	Prophylaxis	GARDASIL	10/03/2011 -	.5 ml	Injection site pain	10/03/2011		Unknown		
2011-002761	14/03/2011	14 Years	Female	Prophylaxis	GARDASIL	09/03/2011 -	.5 ml	Headache	09/03/2011		Recovered/resolved		
2011-002763	14/03/2011	13 Years	Female	Prophylaxis	GARDASIL	10/03/2011 -	.5 ml	Malaise	10/03/2011		Recovered/resolved		Coeliac disease
2011-002765	14/03/2011	13 Years	Female	Prophylaxis	GARDASIL	10/03/2011 -	.5 ml	Dizziness Malaise			Recovered/resolved		
2011-002766	14/03/2011	14 Years	Female	Prophylaxis	GARDASIL	09/03/2011 - 09/03/2011	.5 ml	Headache	09/03/2011		Recovered/resolved		
2011-002767	14/03/2011	13 Years	Female	Prophylaxis	GARDASIL	09/03/2011 -	.5 ml	Asthenia	09/03/2011		Recovered/resolved		
2011-002768	14/03/2011	14 Years	Female	Prophylaxis	GARDASIL	09/03/2011 - 09/03/2011	.5 ml	Headache	09/03/2011		Recovered/resolved		
2011-002769	14/03/2011		Female	Prophylaxis	GARDASIL DITEBOOSTER	09/03/2011 - 09/03/2011 09/03/2011 - 09/03/2011	.5 ml .5 ml	Dizziness	09/03/2011		Recovered/resolved		
2011-002883	21/03/2011	14 Years	Female	Prophylaxis	GARDASIL	09/2010 - 11/2010 -		Vision blurred Syncope Dermal cyst Fatigue Tremor			Not recovered at time of reporting	PHARMATON	
2011-002901	22/03/2011	13 Years	Female	Prophylaxis	GARDASIL	14/03/2011 - 14/03/2011		Pain in extremity Swelling Peripheral coldness Skin discolouration Complex regional pain syndrome	15/03/2011 15/03/2011 15/03/2011 15/03/2011 15/03/2011		Not recovered at time of reporting		
2011-002919	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	14/03/2011 - 14/03/2011	.05 ml	Chills Vomiting Decreased appetite	15/03/2011 15/03/2011 15/03/2011		Not recovered at time of reporting		
2011-002929	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	24/11/2010 -	.5 ml	Dizziness Nausea	24/11/2010 24/11/2010		Unknown		

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2011-002930	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	29/11/2010 -	.5 ml	Dizziness Tremor	29/11/2010 29/11/2010		Unknown		
2011-002934	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	29/11/2010 -	.5 ml	Dizziness	29/11/2010		Recovered/resolved		
2011-002935	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	24/11/2010 -	.5 ml	Dizziness Feeling hot	24/11/2010 24/11/2010		Unknown		
2011-002936	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	24/11/2010 -	.5 ml	Dizziness	24/11/2010		Unknown		
2011-002937	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	13/10/2010 -	.5 ml	Dizziness Headache	13/10/2010 13/10/2010		Unknown		
2011-002941	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL		.5 ml	Headache Dizziness Abdominal discomfort			Unknown		
2011-002942	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL		.5 ml	Dizziness			Unknown		
2011-002943	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL	13/12/2010 -	.5 ml	Dizziness	13/12/2010		Unknown		
2011-002944	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	24/11/2010 -	.5 ml	Dizziness	24/11/2010		Unknown		
2011-002945	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	23/11/2010 -	.5 ml	Feeling abnormal Pallor	23/11/2010 23/11/2010		Unknown		
2011-002946	24/03/2011	14 Years	Not specified	Prophylaxis	GARDASIL	24/11/2010 -	.5 ml	Feeling of body temperature change Tachycardia	24/11/2010 24/11/2010		Unknown		
2011-002947	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL	23/11/2010 -	.5 ml	Dizziness Headache Tremor Feeling hot	23/11/2010 23/11/2010 23/11/2010 23/11/2010		Unknown		
2011-002948	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	23/11/2010 -	.5 ml	Headache	23/11/2010		Unknown		
2011-002952	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	23/11/2010 -	.5 ml	Dizziness Abdominal discomfort	23/11/2010 23/11/2010		Unknown		
2011-002953	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL	23/11/2010 -	.5 ml	Dizziness	23/11/2010		Unknown		
2011-002954	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	23/11/2010 -	.5 ml	Dizziness Cold sweat	23/11/2010 23/11/2010		Unknown		

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2011-002955	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	23/11/2010 -	.5 ml	Oropharyngeal pain Pain in extremity Headache Cough	23/11/2010 23/11/2010 23/11/2010 23/11/2010		Unknown		
2011-002956	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL		.5 ml	Abdominal pain Muscle spasms			Unknown		
2011-002957	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL	23/11/2010 -	.5 ml	Headache	23/11/2010		Unknown		
2011-002958	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL		.5 ml	Dizziness Headache			Unknown		
2011-002959	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL		.5 ml	Dizziness			Unknown		
2011-002960	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL	29/11/2010 -	.5 ml	Dizziness Chest discomfort	29/11/2010 29/11/2010		Unknown		
2011-002961	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	25/11/2010 -	.5 ml	Dizziness Abdominal pain lower Headache	25/11/2010 25/11/2010 25/11/2010		Unknown		
2011-002962	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	13/12/2010 -	.5 ml	Dizziness	13/12/2010		Not recovered at time of reporting		
2011-002963	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	24/11/2010 -	.5 ml	Dizziness	24/11/2010		Unknown		
2011-002964	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	13/12/2010 -	.5 ml	Nausea	13/12/2010		Unknown		
2011-002965	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL	29/11/2010 -	.5 ml	Dizziness Headache	29/11/2010 29/11/2010		Not recovered at time of reporting		Asthma
2011-002966	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL		.5 ml	Dizziness			Unknown		Diabetes mellitus
2011-002967	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	29/11/2010 -	.5 ml	Dizziness Ear discomfort	29/11/2010 29/11/2010		Unknown		
2011-002968	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL	13/12/2010 -	.5 ml	Dizziness Headache Feeling cold	13/12/2010 13/12/2010 13/12/2010		Unknown		
2011-002970	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	22/03/2011 -	.5 ml	Nausea Pain in extremity Rash macular	22/03/2011 22/03/2011 22/03/2011		Recovered/resolved		

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2011-002971	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	22/03/2011 -	.5 ml	Dizziness	22/03/2011		Recovered/resolved		
2011-002972	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	22/03/2011 -	.5 ml	Nausea Headache	22/03/2011 22/03/2011		Recovered/resolved		
2011-002973	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	22/03/2011 -	.5 ml	Dizziness	22/03/2011		Recovered/resolved		Anaemia
2011-002983	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	22/03/2010 -	.5 ml	Dizziness	22/03/2011		Recovered/resolved		
2011-002985	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	22/03/2011 -	.5 ml	Dizziness Headache Nausea	22/03/2011 22/03/2011 22/03/2011		Recovered/resolved		
2011-002991	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	24/11/2010 -	.5 ml	Pain in extremity Injection site pain	24/11/2010 24/11/2010		Not recovered at time of		
2011-002992	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL	23/11/2010 -	.5 ml	Nausea Paraesthesia	23/11/2010 23/11/2010		Not recovered at time of reporting		
2011-003081	29/03/2011	13 Years	Female	Prophylaxis	GARDASIL			Lymphadenopathy Oropharyngeal pain Chills			Not recovered at time of reporting		
2011-003104	31/03/2011		Female	Prophylaxis	GARDASIL	28/03/2011 -	.5 ml	Anaphylactoid reaction Hypotension Tachycardia Nausea Asthenia Dyspnoea Throat tightness	28/03/2011 28/03/2011 28/03/2011 28/03/2011 28/03/2011 28/03/2011		Recovered/resolved		Asthma Anaphylactic reaction
2011-003108	31/03/2011	13 Years	Female	Prophylaxis	GARDASIL	30/03/2011 - 30/03/2011	.5 ml	Dizziness Asthenia Syncope	30/03/2011 30/03/2011 30/03/2011		Not recovered at time of reporting		
2011-003122	01/04/2011	13 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -	.5 ml	Chest pain Dyspnoea			Recovered/resolved		
2011-003148	04/04/2011	13 Years	Female	Prophylaxis	GARDASIL	22/03/2011 -	.5 ml	Erythema Pain in extremity	22/03/2011 22/03/2011		Recovered/resolved		
2011-003154	04/04/2011	12 Years	Female	Prophylaxis	GARDASIL	28/03/2011 - 18/11/2010 - 20/09/2010 -	.5 ml	Headache Dizziness Vomiting	28/03/2011 28/03/2011 28/03/2011	29/03/2011 29/03/2011 29/03/2011	Recovered/resolved		

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2011-003160	04/04/2011	14 Years	Female	Prophylaxis	GARDASIL	10/10/2010 - 14/12/2010 14/12/2010 -	.5 ml .5 ml	Headache Abdominal discomfort Asthenia Decreased appetite Weight decreased	10/10/2010 10/10/2010 10/10/2010 10/10/2010		Not recovered at time of reporting		
2011-003161	04/04/2011	12 Years	Female	Prophylaxis	GARDASIL	18/11/2010 -		Malaise Headache Dizziness	28/03/2011		Recovered/resolved		
2011-003167	05/04/2011	13 Years	Female	Prophylaxis	GARDASIL	30/11/2010 -		Fatigue Nausea Headache Vomiting Sleep disorder Fatigue	12/2010 12/2010 12/2010 12/2010		Not recovered at time of reporting		Abdominal pain upper
2011-003255	08/04/2011	13 Years	Female	Prophylaxis	GARDASIL	04/04/2011 -		Urticaria Pruritus	05/04/2011 05/04/2011		Not recovered at time of reporting		
2011-003276	08/04/2011	13 Years	Female	Prophylaxis	GARDASIL	31/03/2011 -	.5 ml	Dizziness Pyrexia Chills Nausea Headache Rash generalised	31/03/2011 01/04/2011 01/04/2011 01/04/2011 01/04/2011 03/04/2011		Recovered/resolved		
2011-003281	11/04/2011	13 Years	Female	Prophylaxis	GARDASIL	15/12/2010 -	.5 ml	Vomiting	15/12/2010		Recovered/resolved		
2011-003319	12/04/2011	14 Years	Female	Prophylaxis	GARDASIL	15/12/2010 -		Injection site swelling Injection site induration Swelling face Erythema	15/12/2010 15/12/2010 15/12/2010 15/12/2010		Recovered/resolved		
2011-003324	12/04/2011	14 Years	Female	Prophylaxis	GARDASIL	01/04/2011 - 01/04/2011		Pain in extremity Injection site pain	01/04/2011 01/04/2011		Recovered/resolved		
2011-003347	13/04/2011	12.5 Years	Female	Prophylaxis	GARDASIL	14/03/2011 - 14/03/2011		Nausea	14/03/2011		Recovered/resolved		
2011-003351	13/04/2011	14 Years	Female	Prophylaxis	GARDASIL	06/04/2011 -	.5 ml	Epistaxis	06/04/2011		Recovered/resolved		
2011-003353	13/04/2011	12 Years	Female	Prophylaxis	GARDASIL	14/03/2011 -		Dizziness Nausea	14/03/2011 14/03/2011		Recovered/resolved		
2011-003354	13/04/2011	14 Years	Female		GARDASIL	14/03/2011 -		Dizziness Dyspnoea	14/03/2011 14/03/2011		Recovered/resolved		Asthma

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2011-003355	13/04/2011	13 Years	Female	Prophylaxis	GARDASIL	14/03/2011 -		Dizziness Dyspnoea	14/03/2011 14/03/2011		Recovered/resolved	VENTOLIN	Asthma
2011-003357	13/04/2011	12 Years	Female	Prophylaxis	GARDASIL	14/03/2011 -		Dizziness Pallor	14/03/2011 14/03/2011		Not recovered at time of reporting		
2011-003358	13/04/2011	13 Years	Female	Prophylaxis	GARDASIL	06/04/2011 -	.5 ml	Pain in extremity	06/04/2011	08/04/2011	Recovered/resolved		
2011-003360	13/04/2011	13 Years	Female	Prophylaxis	GARDASIL	14/03/2011 -		Nausea Dizziness	14/03/2011 14/03/2011		Recovered/resolved		
2011-003362	13/04/2011	14 Years	Female	Prophylaxis	GARDASIL	14/03/2011 - 14/03/2011		Pallor Dizziness	14/03/2011 14/03/2011		Recovered/resolved		
2011-003384	14/04/2011	14 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Asthenia Lethargy			Unknown		
2011-003385	14/04/2011	14 Years	Female	Prophylaxis	GARDASIL	15/12/2010 -	.5 ml	Asthenia Lethargy			Unknown		
2011-003423	15/04/2011	14 Years	Female	Prophylaxis	GARDASIL	14/01/2011 - 14/01/2011	.5 ml	Headache Pyrexia Myalgia	14/01/2011 14/01/2011 14/01/2011		Unknown		Vitamin B12 deficiency
2011-003425	15/04/2011	14 Years	Female	Prophylaxis	GARDASIL	14/04/2011 - 14/04/2011	.5 ml	Headache Pyrexia Myalgia	14/04/2011 14/04/2011 14/04/2011		Not recovered at time of reporting		Vitamin B12 deficiency
2011-003448	19/04/2011		Female	Prophylaxis	GARDASIL	29/11/2010 -	.5 ml	Headache Pyrexia Myalgia Lethargy Hypotension Vomiting	29/11/2010 29/11/2010 29/11/2010 29/11/2010 29/11/2010 29/11/2010		Recovered/resolved		
2011-003450	19/04/2011	13 Years	Female		GARDASIL	12/04/2011 - 12/04/2011	.5 ml	Oedema mouth Rash Malaise Pyrexia Chills	12/04/2011 12/04/2011 12/04/2011 12/04/2011 12/04/2011	13/04/2011 14/04/2011 14/04/2011 14/04/2011 13/04/2011	Recovered/resolved		
2011-003509	21/04/2011	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 - 11/01/2011 -	.5 ml .5 ml	Influenza like illness	30/09/2010		Recovered/resolved		
2011-003708	06/05/2011	13 Years	Female	Prophylaxis	GARDASIL	03/05/2011 -		Cellulitis	04/05/2011		Not recovered at time of reporting		

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2011-003711	06/05/2011	14 Years	Female	Prophylaxis	GARDASIL	04/05/2011 -	.5 ml	Syncope Pulse absent Pallor Anaphylactic reaction	04/05/2011 04/05/2011 04/05/2011 04/05/2011		Recovered/resolved		
2011-003712	06/05/2011	13 Years	Female	Prophylaxis	GARDASIL	03/05/2011 - 03/05/2011	.5 ml	Hypoaesthesia Peripheral coldness	03/05/2011 03/05/2011		Recovered/resolved		
2011-003825	11/05/2011	13 Years	Female		GARDASIL	03/05/2011 - 03/05/2011		Pyrexia Malaise Asthenia	04/05/2011 04/05/2011		Recovered/resolved		
2011-003901	13/05/2011	14 Years	Female	Prophylaxis	GARDASIL	03/05/2011 -	.5 ml	Influenza like illness	05/05/2011		Recovered/resolved		
2011-003902	13/05/2011	13 Years	Female	Prophylaxis	GARDASIL	10/05/2011 -	.5 ml	Presyncope	10/05/2011		Recovered/resolved		
2011-004036	19/05/2011	13 Years	Female	Prophylaxis	GARDASIL	03/05/2011 -	.5 ml	Injection site pain	04/05/2011		Recovered/resolved		
2011-004131	25/05/2011	13 Years	Female	Prophylaxis	GARDASIL	09/02/2011 - 09/02/2011	.5 ml	Hypersensitivity Swelling face Rash	09/02/2011 09/02/2011 09/02/2011		Recovered/resolved		
2011-004196	27/05/2011	13 Years	Female	Prophylaxis	GARDASIL	06/10/2010 - 29/03/2011 17/12/2010 - 29/03/2011 -		Headache Abdominal pain Alopecia Pollakiuria	12/04/2011 12/04/2011 12/04/2011 12/04/2011		Not recovered at time of reporting		Tonsillectomy
2011-004222	26/05/2011	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 - 06/12/2010 - 28/03/2011 -		Lower respiratory tract infection Tonsillitis Herpes zoster Tooth infection Candidiasis Fatigue Lethargy	11/2010 11/2010 02/2011 03/2011		Unknown		
2011-004420	08/06/2011	13 Years	Female	Prophylaxis	GARDASIL	01/12/2010 -	.5 ml	Eye swelling Eye pruritus Rash pruritic	01/12/2010 01/12/2010		Recovered/resolved		
2011-004460	13/06/2011	14 Years	Female	Prophylaxis	GARDASIL	16/09/2010 - 18/11/2010 -		Fatigue Headache	16/09/2010 16/09/2010		Not recovered at time of reporting		
2011-004480	14/06/2011	12 Years	Female	Prophylaxis	GARDASIL	23/09/2010 - 13/12/2010 -	.5 ml .5 ml	Erythema Pain in extremity Injection site pruritus	23/09/2010 23/09/2010 23/09/2010		Recovered/resolved		
2011-004491	14/06/2011	12 Years	Female	Prophylaxis	GARDASIL	15/09/2010 - 16/12/2010 -	.5 ml .5 ml	Erythema Pruritus Eczema	15/09/2010 15/09/2010 15/09/2010		Not recovered at time of reporting		Dry skin

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HPRA ID	Date of first notification to HPRA	Patient Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Reaction Cessation Date	Outcome	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
2011-004591	17/06/2011	14 Years	Female	Prophylaxis	GARDASIL	13/12/2010 -		Henoch-Schonlein purpura Joint swelling	21/02/2011 21/02/2011		Not recovered at time of		Osteochondrosis
2011-004740	22/06/2011	13 Years	Female	Prophylaxis	GARDASIL	06/06/2010 - 17/12/2010 -		maternal exposure during pregnancy No adverse event			Recovered/resolved		
2011-005120	07/07/2011	14 Years	Female	Prophylaxis	GARDASIL	31/03/2011 -	.5 ml	Dizziness Dizziness Headache	31/03/2011 31/03/2011 31/03/2011		Unknown	IRON	
2011-005128	07/07/2011	13 Years	Female	Prophylaxis	GARDASIL	31/03/2011 -	.5 ml	Dizziness	31/03/2011		Recovered/resolved		
2011-005129	07/07/2011	13 Years	Female	Prophylaxis	GARDASIL	31/03/2011 -	.5 ml	Dizziness	31/03/2011		Unknown		
2011-005130	07/07/2011	13 Years	Female	Prophylaxis	GARDASIL	31/03/2011 -	.5 ml	Dizziness	31/03/2011		Recovered/resolved		
2011-005131	07/07/2011	13 Years	Female	Prophylaxis	GARDASIL	29/03/2011 -	.5 ml	Feeling of body temperature change Malaise Abdominal discomfort	29/03/2011 29/03/2011		Unknown		
2011-005132	07/07/2011	13 Years	Female	Prophylaxis	GARDASIL	31/03/2011 -	.5 ml	Dizziness Nausea	31/03/2011 31/03/2011		Recovered/resolved		
2011-005133	07/07/2011	14 Years	Female	Prophylaxis	GARDASIL	31/03/2011 -	.5 ml	Headache	31/03/2011		Recovered/resolved		
2011-005134	07/07/2011	13 Years	Female	Prophylaxis	GARDASIL	29/03/2011 -	.5 ml	Headache	29/03/2011		Unknown		
2011-005135	07/07/2011	14 Years	Female	Prophylaxis	GARDASIL	31/03/2011 -	.5 ml	Dizziness Nausea	31/03/2011 31/03/2011		Recovered/resolved		
2011-005137	07/07/2011	13 Years	Female	Prophylaxis	GARDASIL	28/03/2011 -	.5 ml	Dizziness	28/03/2011		Recovered/resolved		
2011-005138	07/07/2011	14 Years	Female	Prophylaxis	GARDASIL	31/03/2011 -	.5 ml	Dizziness	31/03/2011		Recovered/resolved		
2011-005161	08/07/2011	14 Years	Female	Prophylaxis	GARDASIL	19/11/2010 -		Headache Vomiting Lethargy	20/11/2010 20/11/2010 20/11/2010		Recovered/resolved		
2011-005169	08/07/2011	13 Years	Female	Prophylaxis	GARDASIL NAPROXEN VALOID TABLETS 50 MG.	16/11/2010 -		Headache Photophobia Vertigo Nausea	17/11/2010 17/11/2010 17/11/2010 17/11/2010		Recovered/resolved		
2011-005412	19/07/2011	16 Years	Female	Prophylaxis	GARDASIL	18/01/2011 - 18/01/2011 17/02/2011 - 17/02/2011		Abortion spontaneous maternal exposure during pregnancy	06/2011		Unknown		Cervix carcinoma

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2011-006753	12/09/2011	16 Years	Female	Prophylaxis	GARDASIL	12/09/2011 -	.5 ml	Abdominal pain Nausea Hyperhidrosis Hypotension Erythema Heart rate increased Tachycardia	12/09/2011 12/09/2011 12/09/2011 12/09/2011 12/09/2011 12/09/2011		Recovered/resolved		
2011-006780	14/09/2011	12 Years	Female	Prophylaxis	GARDASIL	13/09/2011 - 13/09/2011	.5 ml	Headache Abdominal pain Urticaria	13/09/2011 13/09/2011 13/09/2011		Recovered/resolved		
2011-006840	16/09/2011	12 Years	Female	Prophylaxis	GARDASIL	13/09/2011 -	.5 ml	Angioedema Eye oedema Nausea Pain Abdominal pain upper	13/09/2011 13/09/2011 13/09/2011 13/09/2011 13/09/2011		Recovered/resolved		
2011-006847	17/09/2011	14 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -		Petit mal epilepsy Complex partial seizures Myoclonic epilepsy Epilepsy	19/10/2011 19/10/2011 19/10/2011 19/10/2011		Unknown	SERETIDE SINGULAIR SALBUTAMOL	Asthma Seasonal allergy Comment-Investigations are on-going
2011-006869	19/09/2011	13 Years	Female	Prophylaxis	GARDASIL	19/09/2011 -		Dizziness	19/09/2011		Recovered/resolved		
2011-006874	19/09/2011	13 Years	Female	Prophylaxis	GARDASIL	21/09/2010 -	.5 ml	Headache Dizziness	22/09/2010 22/09/2010		Recovered/resolved		Migraine
2011-006876	19/09/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Headache Dizziness	17/11/2010 17/11/2010		Recovered/resolved		Migraine
2011-006893	20/09/2011	13 Years	Female	Prophylaxis	GARDASIL	13/09/2011 - 13/09/2011	.5 ml	Urticaria	14/09/2011		Not recovered at time of reporting		
2011-006898	20/09/2011		Female	Prophylaxis	GARDASIL	20/09/2011 - 20/09/2011		Syncope Malaise	20/09/2011 20/09/2011		Recovered/resolved		Syncope
2011-006916	21/09/2011	16 Years	Female	Prophylaxis	GARDASIL	13/09/2011 -	.5 ml	Urticaria Periorbital oedema	14/09/2011 14/09/2011		Recovered/resolved		
2011-006924	21/09/2011	13 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -		Cough Throat tightness	21/09/2011 21/09/2011		Not recovered at time of reporting		Cough Nasopharyngitis
2011-006925	21/09/2011	12 Years	Female	Prophylaxis	GARDASIL	20/09/2011 - 20/09/2011		Cough Throat tightness	20/09/2011 20/09/2011		Recovered/resolved		

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2011-006940	22/09/2011	12 Years	Female	Prophylaxis	GARDASIL	19/09/2011 -	1 ml	Urticaria	19/09/2011		Not recovered at time of reporting		
2011-006957	22/09/2011	12 Years	Female	Prophylaxis	GARDASIL	22/09/2011 -		Vomiting Dizziness	22/09/2011 22/09/2011		Recovered/resolved		
2011-006982	23/09/2011	17 Years	Female	Prophylaxis	GARDASIL	08/09/2011 -		Malaise Pyrexia Vomiting	08/09/2011 08/09/2011 08/09/2011		Recovered/resolved		
2011-006985	23/09/2011	16 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -	.5 ml	Vomiting	21/09/2011		Recovered/resolved		
2011-006988	23/09/2011	12 Years	Female	Prophylaxis	GARDASIL	15/09/2011 -	.5 ml	Hypopnoea Respiratory rate increased Pain in extremity Muscle spasms Headache Hyperventilation Tetany	15/09/2011 15/09/2011 15/09/2011 15/09/2011 15/09/2011 15/09/2011		Recovered/resolved		
2011-006995	22/09/2011	16 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -	.5 ml	Headache Nausea	21/09/2011 21/09/2011		Recovered/resolved		
2011-007028	26/09/2011	17 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -	.5 ml	Influenza like illness Musculoskeletal stiffness Fatigue Pharyngeal oedema Swollen tongue Oedema Headache Limb discomfort	21/09/2011 22/09/2011 22/09/2011 23/09/2011 23/09/2011 23/09/2011 21/09/2011 21/09/2011		Not recovered at time of reporting		
2011-007029	26/09/2011	12 Years	Female	Prophylaxis	GARDASIL	20/09/2011 -	.5 ml	Syncope Malaise	20/09/2011 20/09/2011		Recovered/resolved		Syncope
2011-007058	27/09/2011	12 Years	Female	Prophylaxis	GARDASIL	27/09/2010 - 03/05/2011		Post viral fatigue syndrome	2010		Not recovered at time of reporting		
2011-007094	28/09/2011	12 Years	Female	Prophylaxis	GARDASIL	27/09/2011 -	.5 ml	Syncope	27/09/2011		Recovered/resolved		Syncope
2011-007095	28/09/2011	12 Years	Female	Prophylaxis	GARDASIL	22/09/2011 -	.5 ml	Headache Nausea	22/09/2011 22/09/2011		Recovered/resolved		
2011-007096	28/09/2011	12 Years	Female	Prophylaxis	GARDASIL	22/09/2011 -	.5 ml	Vomiting	22/09/2011		Recovered/resolved		
2011-007097	28/09/2011	12 Years	Female	Prophylaxis	GARDASIL	27/09/2011 -	.5 ml	Panic attack	27/09/2011		Recovered/resolved		Panic attack

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2011-007099	28/09/2011	12 Years	Female	Prophylaxis	GARDASIL	23/09/2011 -	.5 ml	Urticaria	23/09/2011		Recovered/resolved		
2011-007123	29/09/2011	12 Years	Female	Prophylaxis	GARDASIL	16/09/2011 - 16/09/2011		Asthenia	18/09/2011		Recovered/resolved		
2011-007124	29/09/2011	12 Years	Female	Prophylaxis	GARDASIL	29/09/2011 -	.5 ml	Dizziness Flushing Hypotension Tachycardia Cough	29/09/2011 29/09/2011 29/09/2011 29/09/2011		Unknown	FLORINEF	Syncope
2011-007163	30/09/2011	13 Years	Female	Prophylaxis	GARDASIL	16/09/2011 -	.5 ml	Rash erythematous Asthenia Headache Nasal congestion Pyrexia	16/09/2011 16/09/2011 16/09/2011 16/09/2011		Recovered/resolved		
2011-007184	03/10/2011	13 Years	Female	Prophylaxis	GARDASIL	23/09/2011 -	.5 ml	Rash	24/09/2011		Not recovered at time of reporting		
2011-007207	04/10/2011	12 Years	Female	Prophylaxis	GARDASIL	29/09/2011 -	.5 ml	Vomiting Dizziness	29/09/2011 29/09/2011		Recovered/resolved		Syncope
2011-007210	04/10/2011	12 Years	Female	Prophylaxis	GARDASIL	29/09/2011 -	.5 ml	Vomiting Nausea	29/09/2011 29/09/2011		Recovered/resolved		
2011-007211	04/10/2011	12 Years	Female	Prophylaxis	GARDASIL	29/09/2011 -		Headache	29/09/2011		Recovered/resolved		
2011-007212	04/10/2011	13 Years	Female	Prophylaxis	GARDASIL	20/09/2011 -	.5 ml	Rash macular Pyrexia	21/09/2011 21/09/2011	24/09/2011 24/09/2011	Recovered/resolved	PINAMOX	
2011-007239	04/10/2011	17 Years	Female	Prophylaxis	GARDASIL	29/09/2011 -	.5 ml	Bronchospasm Swollen tongue Erythema Pruritus Cough Chest discomfort Wheezing	30/09/2011 30/09/2011 30/09/2011		Recovered/resolved		
2011-007242	05/10/2011	14 Years	Female	Prophylaxis	GARDASIL	27/09/2011 -	.5 ml	Medication error			Recovered/resolved		Comment-Patient received 4th dose in error
2011-007243	05/10/2011	18 Years	Female	Prophylaxis	GARDASIL	22/09/2011 -	.5 ml	Convulsion	22/09/2011		Unknown		
2011-007274	06/10/2011	12 Years	Female	Prophylaxis	GARDASIL	23/11/2010 - 23/11/2010	.5 ml	Hypoaesthesia Paraesthesia Sensory loss Headache	23/11/2010 23/11/2010 23/11/2010		Recovered/resolved		
2011-007294	07/10/2011	12 Years	Female	Prophylaxis	GARDASIL	05/10/2011 -		Syncope	05/10/2011		Recovered/resolved		

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2011-007323	10/10/2011	12 Years	Female	Prophylaxis	GARDASIL	20/09/2011 -	.5 ml	Vomiting	20/09/2011		Recovered/resolved		
2011-007384	12/10/2011	18 Years	Female	Prophylaxis	GARDASIL	20/09/2011 -	.5 ml	Maternal exposure during pregnancy No adverse event			Recovered/resolved		
2011-007389	12/10/2011	16 Years	Female	Prophylaxis	GARDASIL	03/10/2011 -	.5 ml	Syncope	03/10/2011		Recovered/resolved		Syncope
2011-007413	12/10/2011	13 Years	Female	Prophylaxis	GARDASIL	26/09/2011 -	.5 ml	Urticaria	03/10/2011	05/10/2011	Unknown		
2011-007432	13/10/2011	17 Years	Female	Prophylaxis	GARDASIL	06/10/2011 -	.5 ml	Urticaria	06/10/2011		Not recovered at		
2011-007474	13/10/2011	13 Years	Female	Prophylaxis	GARDASIL	03/10/2011 -	.5 ml	Hypoaesthesia Muscular weakness	07/10/2011 07/10/2011		Not recovered at time of		
2011-007551	18/10/2011	18 Years	Female	Prophylaxis	GARDASIL	26/09/2011 -		Pyrexia Chills Fatigue Sinusitis			Recovered/resolved		
2011-007676	24/10/2011	13 Years	Female	Prophylaxis	GARDASIL	13/09/2011 - 13/09/2011	.5 ml	Pain in extremity Joint swelling	20/09/2011 20/09/2011		Not recovered at time of reporting		
2011-008001	09/11/2011	17 Years	Female	Prophylaxis	GARDASIL	19/09/2011 -		Headache Rash	21/09/2011 21/09/2011		Recovered/resolved		
2011-008002	09/11/2011	17 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -	.5 ml	Guttate psoriasis	24/09/2011		Recovered/resolved		
2011-008006	09/11/2011	17 Years	Female	Prophylaxis	GARDASIL	15/09/2011 -		Headache	18/09/2011	24/10/2011	Recovered/resolved		
2011-008131	15/11/2011	18 Years	Female	Prophylaxis	GARDASIL	13/09/2011 -	.5 ml	Fatigue Asthenia	13/09/2011 13/09/2011		Recovered/resolved		
2011-008133	15/11/2011	12 Years	Female	Prophylaxis	GARDASIL	15/09/2011 -	.5 ml	Asthenia Vision blurred Headache Cough Cold sweat Flushing Wheezing	15/09/2011 15/09/2011 15/09/2011 15/09/2011 15/09/2011 15/09/2011 15/09/2011		Recovered/resolved		Asthma
2011-008301	23/11/2011	17 Years	Female	Prophylaxis	GARDASIL	14/11/2011 -		Urticaria	14/11/2011		Not recovered at time of reporting		Asthma Hypersensitivity Atopy
2011-008390	25/11/2011	18 Years	Female	Prophylaxis	GARDASIL	29/09/2011 -	.5 ml	Pain in extremity Paraesthesia	01/10/2011		Recovered/resolved		

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2011-008394	25/11/2011	11 Years	Female	Prophylaxis	GARDASIL	21/11/2011 -	.5 ml	Syncope	21/11/2011		Recovered/resolved		Syncope
2011-008409	28/11/2011	16 Years	Female	Prophylaxis	GARDASIL	21/11/2011 -	.5 ml	Panic attack	21/11/2011		Recovered/resolved		
2011-008410	28/11/2011	13 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -		Rash			Recovered/resolved		
2011-008412	28/11/2011	13 Years	Female	Prophylaxis	GARDASIL	20/12/2010 -		Rash			Recovered/resolved		
2011-008414	28/11/2011	13 Years	Female	Prophylaxis	GARDASIL	18/04/2011 -		Erythema nodosum			Recovered/resolved		
2011-008416	28/11/2011	12 Years	Female	Prophylaxis	GARDASIL	21/11/2011 -	.5 ml	Headache	21/11/2011		Recovered/resolved		
2011-008453	29/11/2011		Female	Prophylaxis	GARDASIL	12/09/2011 -	.5 ml	Rash Headache Migraine	22/09/2011		Not recovered at time of reporting		
2011-008455	29/11/2011		Female	Prophylaxis	GARDASIL	25/11/2011 -	.5 ml	Syncope	25/11/2011		Recovered/resolved		Syncope
2011-008457	29/11/2011	12 Years	Female	Prophylaxis	GARDASIL	21/11/2011 -	.5 ml	Pruritus Vomiting Rash	21/11/2011 22/11/2011 21/11/2011		Recovered/resolved		
2011-008466	29/11/2011	16 Years	Female	Prophylaxis	GARDASIL	29/09/2011 -	.5 ml	Maternal exposure during pregnancy No adverse event			Recovered/resolved		
2011-008491	30/11/2011	18 Years	Female	Prophylaxis	GARDASIL	15/09/2011 -	.5 ml	Malaise Pain in extremity	15/09/2011 15/09/2011		Recovered/resolved		
2011-008520	01/12/2011	12 Years	Female	Prophylaxis	GARDASIL	11/10/2011 -	.5 ml	Malaise Headache	11/10/2011		Not recovered at time of reporting		
2011-008527	01/12/2011	13 Years	Female	Prophylaxis	GARDASIL	22/09/2011 -	.5 ml	Asthenia Headache	22/09/2011 22/09/2011		Recovered/resolved		
2011-008582	05/12/2011	17 Years	Female	Prophylaxis	GARDASIL	16/11/2011 -	.5 ml	Urticaria	19/11/2011		Recovered/resolved		Asthma Decreased appetite
2011-008583	05/12/2011	13 Years	Female	Prophylaxis	GARDASIL	18/11/2011 -	.5 ml	Headache Pyrexia Dizziness Vomiting	18/11/2011 18/11/2011 18/11/2011		Recovered/resolved		

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2011-008597	06/12/2011	17 Years	Female	Prophylaxis	GARDASIL	01/12/2011 -	.5 ml	Syncope Tremor Vision blurred Hypopnoea Chest discomfort Muscular weakness	01/12/2011 01/12/2011 01/12/2011 01/12/2011		Recovered/resolved		
2011-008601	06/12/2011	16 Years	Female	Prophylaxis	GARDASIL	10/10/2011 -	.5 ml	Urticaria Chest discomfort	10/10/2011 10/10/2011		Recovered/resolved		Asthma
2011-008614	07/12/2011	13 Years	Female	Prophylaxis	GARDASIL	26/09/2011 -	.5 ml	Injection site pain Injection site erythema Injection site oedema	26/09/2011 26/09/2011 26/09/2011		Recovered/resolved		
2011-008616	07/12/2011	13 Years	Female	Prophylaxis	GARDASIL	05/12/2011 -	.5 ml	Rash maculo-papular Pruritus	05/12/2011 05/12/2011		Recovered/resolved		
2011-008617	07/12/2011	12 Years	Female	Prophylaxis	GARDASIL	20/09/2011 -	.5 ml	Headache	20/09/2011		Recovered/resolved		
2011-008690	09/12/2011	12 Years	Female	Prophylaxis	GARDASIL	23/09/2011 -		Urticaria	24/09/2011		Recovered/resolved		
2011-008692	09/12/2011	13 Years	Female	Prophylaxis	GARDASIL	29/09/2011 -	.5 ml	Urticaria	30/09/2011		Recovered/resolved		
2011-008702	12/12/2011	13 Years	Female	Prophylaxis	GARDASIL	16/09/2011 -	.5 ml	Urticaria	16/09/2011		Recovered/resolved		
2011-008704	12/12/2011	16 Years	Female	Prophylaxis	GARDASIL	17/10/2011 -	.5 ml	Abortion spontaneous	18/10/2011		Recovered/resolved		
2011-008725	13/12/2011	13 Years	Female	Prophylaxis	GARDASIL	24/11/2011 -	.5 ml	Fatigue Cough	24/11/2011		Recovered/resolved		
2011-008812	16/12/2011	17 Years	Female	Prophylaxis	GARDASIL	06/10/2011 -	.5 ml	Headache	06/10/2011		Recovered/resolved		
2011-008833	19/12/2011	17 Years	Female	Prophylaxis	GARDASIL	30/09/2011 -	.5 ml	maternal exposure during pregnancy No adverse event			Recovered/resolved		
2011-008836	19/12/2011	18 Years	Female	Prophylaxis	GARDASIL	10/10/2011 -		maternal exposure during pregnancy No adverse event			Recovered/resolved		
2011-008837	19/12/2011	12 Years	Female	Prophylaxis	GARDASIL	03/10/2011 -	.5 ml	Pain in extremity	03/10/2011		Recovered/resolved		
2011-008841	19/12/2011	12 Years	Female	Prophylaxis	GARDASIL	03/10/2011 -	.5 ml	Vomiting	03/10/2011		Recovered/resolved		
2011-008845	19/12/2011	12 Years	Female	Prophylaxis	GARDASIL	29/09/2011 -	.5 ml	Panic attack Stress Dyspnoea	29/09/2011 29/09/2011 29/09/2011		Recovered/resolved		Panic attack

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2011-008848	19/12/2011	16 Years	Female	Prophylaxis	GARDASIL	25/11/2011 -	.5 ml	Pruritus	25/11/2011		Recovered/resolved		
2011-008895	21/12/2011	17 Years	Female	Prophylaxis	GARDASIL	30/09/2011 -	.5 ml	Urticaria			Recovered/resolved		
2011-008899	21/12/2011	16 Years	Female	Prophylaxis	GARDASIL	30/09/2011 -	.5 ml	Urticaria	30/09/2011		Recovered/resolved		
2011-008929	22/12/2011		Female	Prophylaxis	GARDASIL			Abdominal pain lower			Not recovered at		
2011-008957	23/12/2011	17 Years	Female	Prophylaxis	GARDASIL	14/09/2011 -	.5 ml	Urticaria	14/09/2011		Recovered/resolved		
2012-009098	05/01/2012		Female	Prophylaxis	GARDASIL		.5 ml	Nausea Abdominal pain Headache			Recovered/resolved		
2012-009278	17/01/2012	17 Years	Female	Prophylaxis	GARDASIL			Abdominal pain Nausea Vomiting			Not recovered at time of reporting	DIANETTE TRAMADOL HYDROCHLORIDE STEMETIL	
2012-009481	26/01/2012	13 Years	Female	Prophylaxis	GARDASIL	13/12/2011 -	.5 ml	Rash macular Pruritus Rash erythematous	14/12/2011 14/12/2011 05/01/2012		Not recovered at time of reporting		
2012-009697	25/01/2012		Female	Prophylaxis	GARDASIL			Migraine			Not recovered at		
2012-009945	17/02/2012	12 Years	Female	Prophylaxis	GARDASIL	09/2011 - 09/2011		Listless Syncope Restlessness	09/2011 09/2011 09/2011		Not recovered at time of reporting		Parvovirus B19 test positive
2012-010136	28/02/2012	17 Years	Female	Prophylaxis	GARDASIL	21/02/2012 - 20/12/2011 -		Rash erythematous Pruritus Paraesthesia oral Angioedema Throat tightness Anaphylactic reaction	21/02/2012 21/02/2012 21/02/2012 21/02/2012 21/02/2012 21/02/2012		Recovered/resolved		Anaphylactic reaction Urticaria chronic
2012-010296	08/03/2012	13 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	07/03/2012 - 07/03/2012 -	.5 ml .5 ml	Urticaria Malaise Pyrexia Dizziness Abdominal pain	07/03/2012		Recovered/resolved		Urticaria
2012-010407	13/03/2012	18 Years	Female	Prophylaxis	GARDASIL	22/11/2011 -	.5 ml	Fatigue Lip blister Headache	22/11/2011		Recovered/resolved	VENTOLIN	
2012-010427	13/03/2012	18 Years	Female	Prophylaxis	GARDASIL	15/11/2011 -		Fatigue Lymphadenopathy Malaise	15/11/2011 15/11/2011 15/11/2011		Not recovered at time of reporting		

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2012-010428	14/03/2012	18 Years	Female	Prophylaxis	GARDASIL	20/09/2011 - 23/11/2011 -	.5 ml .5 ml	Maternal exposure during pregnancy No adverse event			Recovered/resolved		
2012-010434	14/03/2012	17 Years	Female	Prophylaxis	GARDASIL	25/11/2011 -	.5 ml	Rash macular Fatigue Local swelling Dermatitis allergic	25/11/2011		Not recovered at time of reporting		
2012-010461	15/03/2012	24 Years	Female	Prophylaxis	GARDASIL	30/01/2012 -	.5 ml	Arthralgia	04/02/2012		Not recovered at time of reporting		
2012-010467	15/03/2012	16 Years	Female	Prophylaxis	GARDASIL	14/09/2011 - 16/11/2011 -		Maternal exposure during pregnancy No adverse event			Recovered/resolved	CONTRACEPTIVE PILL	
2012-010527	20/03/2012	12 Years	Female	Prophylaxis	GARDASIL	13/03/2012 -	.5 ml	Headache Vomiting	13/03/2012 13/03/2012		Recovered/resolved		
2012-010617	23/03/2012	17 Years	Female	Prophylaxis	GARDASIL	14/11/2011 -	.5 ml	Nausea Lethargy Weight decreased Amnesia Chest pain Headache Syncope	14/11/2011 14/11/2011 14/11/2011 14/11/2011 14/11/2011 14/11/2011		Not recovered at time of reporting		
2012-010694	28/03/2012	12 Years	Female	Prophylaxis	GARDASIL	24/11/2011 -	.5 ml	Vomiting Rash	24/11/2011 24/11/2011		Recovered/resolved		
2012-010695	28/03/2012	12 Years	Female	Prophylaxis	GARDASIL	23/09/2011 - 28/11/2011 -	.5 ml .5 ml	Pyrexia Nausea Injection site pain Pallor	28/11/2011 23/09/2011 23/09/2011 23/09/2011		Recovered/resolved		
2012-010735	29/03/2012	13 Years	Female	Prophylaxis	GARDASIL	20/03/2012 - 26/09/2011 - 02/12/2011 -	.5 ml .5 ml .5 ml	Asthenia Pallor Pyrexia Nausea Decreased appetite	20/03/2012 20/03/2012 20/03/2012 20/03/2012 20/03/2012		Not recovered at time of reporting		Urinary tract infection
2012-010745	30/03/2012	17 Years	Female	Prophylaxis	GARDASIL	28/11/2011 -	.5 ml	maternal exposure during pregnancy No adverse event			Recovered/resolved		

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2012-010746	30/03/2012	18 Years	Female	Prophylaxis	GARDASIL	22/03/2012 -	.5 ml	Nausea Headache Malaise Cough Wheezing Lower respiratory tract infection	23/03/2012 23/03/2012 23/03/2012 23/03/2012 23/03/2012		Unknown		
2012-010747	30/03/2012	13 Years	Female	Prophylaxis	GARDASIL	23/03/2012 - 23/11/2011 -	.5 ml .5 ml	Erythema Pruritus	23/03/2012 23/03/2012		Recovered/ resolved		Pruritus Erythema
2012-010748	02/04/2012	18 Years	Female	Prophylaxis	GARDASIL	21/11/2011 - 22/03/2012 - 20/09/2011 -		Migraine Epilepsy			Unknown	OVRANETTE FOLIC ACID	Epilepsy
2012-010749	30/03/2012	13 Years	Female	Prophylaxis	GARDASIL	22/03/2012 -	.5 ml	Malaise Headache Vomiting Pyrexia	22/03/2012 22/03/2012 22/03/2012 22/03/2012		Recovered/ resolved		
2012-010792	02/04/2012	12 Years	Female	Prophylaxis	GARDASIL	24/11/2011 -	.5 ml	Pain in extremity	25/11/2011		Recovered/ resolved		
2012-010793	30/03/2012	13 Years	Female	Prophylaxis	GARDASIL	23/11/2011 -	.5 ml	Pruritus Erythema	23/11/2011 23/11/2011		Recovered/ resolved		
2012-010796	02/04/2012	12 Years	Female	Prophylaxis	GARDASIL	20/03/2012 -	.5 ml	Rash pruritic Injection site rash Rash erythematous	22/03/2012 22/03/2012 22/03/2012		Recovered/ resolved		Asthma Drug hypersensitivity
2012-010798	02/04/2012	12 Years	Female	Prophylaxis	GARDASIL	28/03/2012 -	.5 ml	Hypoaesthesia Injection site pain	28/03/2012		Recovered/ resolved		
2012-010835	04/04/2012	17 Years	Female	Prophylaxis	GARDASIL	30/03/2012 - 15/09/2011 - 17/11/2011 -	.5 ml .5 ml .5 ml	Paraesthesia Muscular weakness	01/04/2012 01/04/2012		Recovered/ resolved		
2012-010840	04/04/2012	17 Years	Female	Prophylaxis	GARDASIL	15/09/2011 - 17/11/2011 -	.5 ml .5 ml	Paraesthesia			Recovered/ resolved		
2012-010878	04/04/2012	13 Years	Female	Prophylaxis	GARDASIL	29/11/2011 - 27/09/2011 -		Vllth nerve paralysis	03/2012		Recovered/ resolved		

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2012-011007	12/04/2012	13 Years	Female	Prophylaxis	GARDASIL	15/03/2012 - 15/03/2012	.5 Milligram	Malaise Nausea Dizziness Feeling of body temperature change Headache Oropharyngeal pain Neck pain Pyrexia Lymphadenopathy Lethargy Tonsillitis bacterial Abdominal pain	15/03/2012 15/03/2012 15/03/2012 27/03/2012 28/03/2012 30/03/2012 30/03/2012 28/03/2012 23/04/2012		Not recovered at time of reporting		
2012-011130	19/04/2012	16 Years	Female	Prophylaxis	GARDASIL	01/12/2011 - 17/04/2012 -	.5 ml .5 ml	Ovarian abscess	01/2012		Recovered/resolved		Drug hypersensitivity
2012-011131	19/04/2012	17 Years	Female	Prophylaxis	GARDASIL	03/10/2011 - 03/10/2011	.5 ml	Injection site rash	04/10/2011		Recovered/resolved		
2012-011170	20/04/2012	17 Years	Female	Prophylaxis	GARDASIL	16/11/2011 -	.5 ml	Hyperthyroidism	03/2012		Not recovered at		
2012-011233	25/04/2012	18 Years	Female	Prophylaxis	GARDASIL	30/11/2011 -	.5 ml	Abortion spontaneous			Recovered/resolved		
2012-011329	01/05/2012	17 Years	Female	Prophylaxis	GARDASIL	17/04/2012 -		Syncope	18/04/2012		Recovered/resolved		
2012-011335	01/05/2012	13 Years	Female	Prophylaxis	GARDASIL	15/11/2011 - 15/11/2011 13/09/2011 - 13/03/2012 -	.5 ml	Post viral fatigue syndrome Lymphadenopathy Dizziness Muscular weakness			Not recovered at time of reporting		
2012-011346	01/05/2012	18 Years	Female	Prophylaxis	GARDASIL	04/01/2012 -	.5 ml	Convulsion Fatigue Dyspnoea	14/02/2012 14/02/2012 14/02/2012		Not recovered at time of reporting	SIMPONI ARCOXIA	Psoriatic arthropathy Tonsillitis Arthritis Herpes zoster
2012-011353	02/05/2012	12 Years	Female	Prophylaxis	GARDASIL	02/12/2011 - 02/12/2011	.5 ml	Diplopia Dizziness	03/12/2011 03/12/2011		Recovered/resolved		
2012-011383	03/05/2012	18 Years	Female	Prophylaxis	GARDASIL	05/10/2011 - 05/10/2011	.5 ml	Maternal exposure during pregnancy No adverse event			Recovered/resolved		

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2012-011384	03/05/2012	13 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	26/03/2012 - 26/03/2012 26/03/2012 - 26/03/2012	.5 ml .5 ml	Psychogenic seizure Epilepsy Loss of consciousness Syncope Drop attacks Head injury Fall Eye movement disorder Headache Dizziness Nausea Malaise Body temperature Chills Pallor Fatigue Somnolence Fatigue Headache Injection site reaction	27/03/2012 27/03/2012 27/03/2012 27/03/2012 26/03/2012 26/03/2012 27/03/2012 27/03/2012 27/03/2012 27/03/2012 27/03/2012		Unknown		
2012-011458	08/05/2012	17 Years	Female	Prophylaxis	GARDASIL	20/09/2011 -	.5 ml	Pityriasis rosea Oropharyngeal pain	20/09/2011		Recovered/resolved		
2012-011459	08/05/2012	17 Years	Female	Prophylaxis	GARDASIL	22/09/2011 - 17/11/2011 -	.5 ml .5 ml	Eyelid oedema	29/09/2011		Recovered/resolved		
2012-011468	09/05/2012	17 Years	Female	Prophylaxis	GARDASIL	25/11/2011 - 25/11/2011	.5 ml	Maternal exposure during pregnancy No adverse event			Recovered/resolved		
2012-011474	09/05/2012	13 Years	Female	Prophylaxis	GARDASIL	30/09/2011 - 01/12/2011 -	.5 ml .5 ml	Urticaria Rash pruritic Injection site rash	04/12/2011 04/12/2011		Recovered/resolved		
2012-011475	09/05/2012	18 Years	Female	Prophylaxis	GARDASIL	04/05/2012 - 27/09/2011 -	.5 ml	Dizziness Fatigue Chest discomfort Bronchospasm	04/05/2012 04/05/2012 04/05/2012 04/05/2012		Not recovered at time of reporting	SALAMOL	Asthma Lower respiratory tract infection
2012-011737	28/05/2012	13 Years	Female	Prophylaxis	GARDASIL	13/07/2011 -		Pyrexia Chest pain Vomiting Abdominal pain Lethargy	13/07/2011 13/07/2011 13/07/2011 13/07/2011 13/07/2011		Not recovered at time of reporting		Vaccination complication
2012-011815	30/05/2012	17 Years	Female	Prophylaxis	GARDASIL	17/11/2011 - 27/08/2012 -		Face oedema Acne Eyelid oedema	24/11/2011 24/11/2011 24/11/2011		Not recovered at time of reporting		

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2012-012043	12/06/2012	13 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	16/04/2012 - 16/04/2012 -	.5 ml .5 ml	Dizziness Pallor	16/04/2012 16/04/2012		Recovered/r esolved		
2012-012050	12/06/2012	17 Years	Female	Prophylaxis	GARDASIL	07/12/2011 -	.5 ml	Nausea Decreased appetite	08/12/2011 08/12/2011		Recovered/r esolved		
2012-012128	15/06/2012	18 Years	Female	Acne Prophylaxis Prophylaxis	GARDASIL YASMIN	2011 - 2011		Pulmonary embolism Upper respiratory tract infection Cough Chest discomfort	30/01/2012 13/01/2012 30/01/2012 30/01/2012		Recovered/r esolved		Acne Prophylaxis
2012-012353	29/06/2012	18 Years	Female	Prophylaxis	GARDASIL	21/06/2012 -	.5 ml	Hypersensitivity Rash pruritic Erythema Swollen tongue Swelling face	21/06/2012 21/06/2012 21/06/2012 21/06/2012 21/06/2012		Recovered/r esolved		
2012-012879	24/07/2012	13 Years	Female	Prophylaxis	GARDASIL	21/09/2011 - 23/11/2011 -	.5 ml .5 ml	Fatigue Lethargy Somnolence			Not recovered at time of reporting		
2012-012935	25/07/2012	18 Years	Female	Prophylaxis	GARDASIL	21/09/2011 - 23/11/2011 -	.5 ml	Fatigue Pain Epistaxis Headache	12/2011 12/2011 12/2011 12/2011		Not recovered at time of reporting		
2012-013357	08/08/2012	17 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -	.5 ml	Maternal exposure prior to pregnancy No adverse event			Recovered/r esolved		
2012-013360	08/08/2012	16 Years	Female	Prophylaxis	GARDASIL	21/09/2011 - 23/11/2011 -	.5 ml	Maternal exposure during pregnancy No adverse event			Recovered/r esolved		
2012-013815	27/08/2012	18 Years	Female	Prophylaxis	GARDASIL	06/12/2011 -		Henoch-Schonlein purpura	16/12/2011		Recovered/r esolved		
2012-013841	29/08/2012	13 Years	Female	Prophylaxis	GARDASIL	21/08/2012 -	.5 ml	Rash macular Rash papular	23/08/2012 23/08/2012		Recovered/r esolved		Pityriasis rosea
2012-013856	30/08/2012	16 Years	Female	Prophylaxis	GARDASIL	18/04/2012 - 08/12/2011 -		Maternal exposure during pregnancy No adverse event			Recovered/r esolved		
2012-014348	12/09/2012	12 Years	Female	Prophylaxis	GARDASIL	11/09/2012 -	.5 ml	Vomiting	11/09/2012		Recovered/r esolved		

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2012-014351	12/09/2012	12 Years	Female	Prophylaxis	GARDASIL	11/09/2012 -		Pain in extremity Dizziness Abdominal discomfort Anxiety	11/09/2012 11/09/2012 11/09/2012 11/09/2012		Recovered/resolved		
2012-014396	13/09/2012	16 Years	Female	Prophylaxis	GARDASIL	13/09/2012 -	.5 ml	Anaphylactic reaction Syncope Rash Pulse abnormal Hypopnoea	13/09/2012 13/09/2012 13/09/2012 13/09/2012 13/09/2012		Recovered/resolved		
2012-014409	14/09/2012	12 Years	Female	Prophylaxis	GARDASIL	13/09/2012 -	.5 ml	Dizziness Nausea	13/09/2012 13/09/2012		Not recovered at time of reporting		
2012-014418	14/09/2012	12 Years	Female	Prophylaxis	GARDASIL	13/09/2012 -	.5 ml	Presyncope	13/09/2012		Recovered/resolved		
2012-014420	14/09/2012	17 Years	Female	Prophylaxis	GARDASIL	13/09/2012 -	.5 ml	Presyncope Nausea Abdominal pain upper Musculoskeletal pain	13/09/2012 13/09/2012 13/09/2012 13/09/2012		Recovered/resolved		Presyncope
2012-014481	12/09/2012	14 Years	Female	Prophylaxis	GARDASIL	15/04/2011 - 14/12/2010 -		Alopecia	08/2011		Not recovered at		
2012-014493	18/09/2012	17 Years	Female	Prophylaxis	GARDASIL	17/09/2012 -	.5 ml	Anaphylactic reaction Circulatory collapse Chest discomfort Dyspnoea Rash Syncope Fatigue Somnolence Hypoaesthesia oral Myalgia Influenza like illness Cough Tracheitis Dizziness Vertigo	17/09/2012 17/09/2012 17/09/2012 17/09/2012 17/09/2012 17/09/2012 17/09/2012 17/09/2012 17/09/2012 17/09/2012 06/10/2012 06/10/2012 06/10/2012 06/10/2012 06/10/2012		Recovered/resolved		Premature baby Urinary tract infection Syncope Blood pressure Neurological symptom Social problem Pigmentation disorder
2012-014508	18/09/2012	13 Years	Female	Prophylaxis	GARDASIL	13/09/2012 -	.5 ml	Dizziness Asthenia Nausea	13/09/2012 13/09/2012 13/09/2012		Recovered/resolved		Syncope
2012-014519	19/09/2012	17 Years	Female	Prophylaxis	GARDASIL	18/09/2012 -	.5 ml	Dizziness Asthenia	18/09/2012 18/09/2012		Recovered/resolved		
2012-014520	19/09/2012	17 Years	Female	Prophylaxis	GARDASIL	18/09/2012 -	.5 ml	Syncope	18/09/2012		Recovered/resolved		

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2012-014545	19/09/2012	13 Years		Prophylaxis	GARDASIL	19/09/2012 -	.5 ml	Throat tightness Dysphagia Dyspnoea	19/09/2012 19/09/2012 19/09/2012		Recovered/resolved	YASMIN	Dysmenorrhoea
2012-014546	19/09/2012	17 Years	Female	Prophylaxis	GARDASIL	19/09/2012 -	.5 ml	Rash erythematous Feeling hot Rash pruritic Dizziness	19/09/2012 19/09/2012 19/09/2012 19/09/2012		Recovered/resolved		
2012-014587	20/09/2012	18 Years	Female	Prophylaxis	GARDASIL	06/12/2011 -	.5 ml	Epilepsy	03/2012		Not recovered at		Hypersensitivity
2012-014588	20/09/2012	14 Years	Female	Prophylaxis	GARDASIL	12/09/2011 -	.5 ml	Abdominal pain Thyroid function test abnormal	09/2011 09/2011		Unknown		Familial risk factor
2012-014589	20/09/2012	15 Years	Female	Prophylaxis	GARDASIL	09/05/2011 - 01/10/2010 -	.5 ml .5 ml	Vestibulitis	09/10/2011		Not recovered at		
2012-014591	20/09/2012	13 Years	Female	Prophylaxis	GARDASIL	12/09/2011 - 09/12/2011 -	.5 ml .5 ml	Convulsion	11/2011		Unknown		
2012-014594	20/09/2012	15 Years		Prophylaxis	GARDASIL	18/01/2011 - 07/12/2011 -	.5 ml .5 ml	Malaise Oropharyngeal pain Rash Abdominal pain Flushing	10/2011 10/2011 10/2011 10/2011 10/2011		Not recovered at time of reporting		Gluten free diet Food intolerance
2012-014719	25/09/2012	17 Years	Female	Prophylaxis	GARDASIL	12/09/2012 -		Lower respiratory tract infection	13/09/2012		Recovered/resolved		
2012-014752	25/09/2012	13 Years	Female	Prophylaxis	GARDASIL	14/09/2012 -	.5 ml	Asthenia Vomiting Headache Rash	14/09/2012 14/09/2012 14/09/2012 14/09/2012		Recovered/resolved		
2012-014766	26/09/2012	17 Years	Female	Prophylaxis	GARDASIL	12/09/2012 -		Headache	12/09/2012		Not recovered at time of reporting		
2012-014809	27/09/2012	12 Years	Female	Prophylaxis	GARDASIL	17/09/2012 -	.5 ml	Syncope	17/09/2012		Recovered/resolved		
2012-014824	27/09/2012	12 Years	Female	Prophylaxis	GARDASIL	18/09/2012 -	.5 ml	Syncope	18/09/2012		Recovered/resolved		
2012-014825	27/09/2012	17 Years	Female	Prophylaxis	GARDASIL	19/09/2012 -	.5 ml	Syncope Myoclonus	19/09/2012 19/09/2012		Recovered/resolved		
2012-014832	27/09/2012	17 Years	Female	Prophylaxis	GARDASIL	20/09/2012 -	.5 ml	Syncope	20/09/2012		Recovered/resolved		
2012-014840	28/09/2012	17 Years	Female	Prophylaxis	GARDASIL	21/09/2012 -	.5 ml	Dizziness Syncope	21/09/2012 21/09/2012		Recovered/resolved		

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2012-014842	28/09/2012	12 Years	Female	Prophylaxis	GARDASIL	24/09/2012 -		Lymphadenopathy Face oedema Local reaction	26/09/2012 26/09/2012 26/09/2012		Recovered/resolved		
2012-014874	01/10/2012	16 Years	Female	Prophylaxis	GARDASIL	19/09/2012 -	.5 ml	Syncope	19/09/2012		Recovered/resolved		Syncope
2012-014907	02/10/2012	12 Years	Female	Prophylaxis	GARDASIL	24/09/2012 -	.5 ml	Panic attack	24/09/2012		Recovered/resolved		Anxiety disorder
2012-014915	02/10/2012	12 Years	Female	Prophylaxis	GARDASIL	11/09/2012 -	.5 ml	Pain in extremity Injection site pain	11/09/2012 11/09/2012		Recovered/resolved		
2012-014992	03/10/2012	17 Years	Female	Prophylaxis	GARDASIL	28/09/2012 -	.5 ml	Purpura Chest discomfort	28/09/2012 28/09/2012		Recovered/resolved		
2012-015012	04/10/2012	13 Years	Female	Prophylaxis	GARDASIL	28/09/2012 - 23/03/2012 - 21/11/2011 -		Erythema nodosum	30/09/2012		Not recovered at time of reporting		
2012-015026	05/10/2012	12 Years	Female	Prophylaxis	GARDASIL	24/09/2012 -	.5 ml	Syncope	24/09/2012		Recovered/resolved		
2012-015027	05/10/2012	12 Years	Female	Prophylaxis	GARDASIL	01/10/2012 -	.5 ml	Dizziness Hyperventilation	01/10/2012 01/10/2012		Recovered/resolved		Panic attack
2012-015031	05/10/2012	13 Years	Female	Prophylaxis	GARDASIL	04/10/2012 -	.5 ml	Syncope Tonic clonic movements	04/10/2012 04/10/2012		Recovered/resolved		
2012-015041	08/10/2012	12 Years	Female	Prophylaxis	GARDASIL	28/09/2012 -	.5 ml	Pallor Asthenia Headache Vomiting	28/09/2012 28/09/2012 28/09/2012 28/09/2012		Recovered/resolved		
2012-015042	08/10/2012	13 Years	Female	Prophylaxis	GARDASIL	25/09/2012 -	.5 ml	Pallor Asthenia Disorientation Dyskinesia Fatigue Muscle twitching	25/09/2012 25/09/2012 25/09/2012 25/09/2012		Not recovered at time of reporting		Coeliac disease Asthma Cardiac murmur
2012-015051	10/10/2012	16 Years	Female	Prophylaxis	GARDASIL	13/09/2012 -	.5 ml	Abdominal pain Diarrhoea Pyrexia	14/09/2012 14/09/2012 14/09/2012		Recovered/resolved		
2012-015057	10/10/2012	17 Years	Female	Prophylaxis	GARDASIL	10/10/2012 -	.5 ml	Hypersensitivity Pain in extremity Agitation Flushing	10/10/2012 10/10/2012 10/10/2012 10/10/2012		Recovered/resolved		Food allergy

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**Summary details of suspected adverse reactions/events
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HPRA ID	Date of first notification to HPRA	Patient Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Reaction Cessation Date	Outcome	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
2012-015132	17/10/2012	18 Years	Female	Prophylaxis	GARDASIL	08/10/2012 -		Maternal exposure during pregnancy			Unknown		Comment-No further information provided regarding impact of exposure to vaccine in pregnancy.
2012-015150	18/10/2012	12 Years	Female	Prophylaxis	GARDASIL	20/09/2012 -		Rash pruritic	20/09/2012		Recovered/resolved		
2012-015245	25/10/2012	17 Years	Female	Prophylaxis	GARDASIL	10/10/2012 -	.5 ml	Vllth nerve paralysis	16/10/2012		Recovered/resolved		
2012-015357	24/10/2012	13 Years	Female	Prophylaxis	GARDASIL	05/12/2011 -	.5 ml	Pityriasis rosea	20/03/2012		Unknown		
2012-015359	05/11/2012	18 Years	Female	Prophylaxis	GARDASIL	26/09/2012 -	.5 ml	Urticaria Pruritus			Not recovered at time of reporting		
2012-015453	10/11/2012	16 Years	Female	Prophylaxis	GARDASIL	11/09/2012 -	.5 ml	Headache	11/09/2012		Recovered/resolved		
2012-015454	10/11/2012	12 Years	Female	Prophylaxis	GARDASIL	11/09/2012 -	.5 ml	Headache	11/09/2012		Recovered/resolved		
2012-015455	10/11/2012	12 Years	Female	Prophylaxis	GARDASIL	11/09/2012 -	.5 ml	Influenza like illness Arthralgia	12/09/2012 12/09/2012		Recovered/resolved		Influenza like illness
2012-015458	11/11/2012	17 Years	Female	Prophylaxis	GARDASIL	13/09/2012 -	.5 ml	Pain in extremity Injection site joint pain Injection site joint swelling	13/09/2012 13/09/2012 13/09/2012		Recovered/resolved		Overweight
2012-015459	11/11/2012	16 Years	Female	Prophylaxis	GARDASIL	13/09/2012 -	.5 ml	Headache	13/09/2012		Recovered/resolved		
2012-015460	11/11/2012	12 Years	Female	Prophylaxis	GARDASIL	14/09/2012 -	.5 ml	Vomiting	14/09/2012		Recovered/resolved		
2012-015461	12/11/2012	19 Years	Female	Prophylaxis	GARDASIL	07/11/2012 -	.5 ml	Anaphylactic reaction	07/11/2012		Recovered/resolved		
2012-015476	13/11/2012	17 Years	Female	Prophylaxis	GARDASIL	05/09/2012 -		Vision blurred Headache Paraesthesia	07/09/2012 07/09/2012 07/09/2012		Recovered/resolved		
2012-015481	13/11/2012	17 Years	Female	Prophylaxis	GARDASIL	10/09/2012 -		Headache Dizziness Back pain	17/09/2012 17/09/2012 17/09/2012		Not recovered at time of reporting		Asthma
2012-015483	13/11/2012	12 Years	Female	Prophylaxis	GARDASIL	18/09/2012 -		Pyrexia	18/09/2012		Recovered/resolved		
2012-015486	13/11/2012	16 Years	Female	Prophylaxis	GARDASIL	18/09/2012 -	.5 ml	Urticaria	18/09/2012		Recovered/resolved		Food allergy
2012-015487	13/11/2012	17 Years	Female	Prophylaxis	GARDASIL	18/09/2012 -	.5 ml	Injection site pain	13/11/2012		Recovering/resolving		
2012-015488	13/11/2012	17 Years	Female	Prophylaxis	GARDASIL	13/11/2012 -	.5 ml	Syncope	13/11/2012		Recovered/resolved		

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2012-015526	15/11/2012	17 Years	Female	Prophylaxis	GARDASIL	03/10/2011 - 16/04/2012 -	1 Dosage forms	Alopecia	02/2012		Recovering/resolving		Familial risk factor
2012-015527	15/11/2012	18 Years	Female	Prophylaxis	GARDASIL	07/11/2012 -	.5 ml	Urticaria Dizziness Syncope Somnolence Decreased appetite	07/11/2012		Unknown		
2012-015528	15/11/2012	13 Years	Female	Prophylaxis	GARDASIL	19/07/2010 - 18/05/2010 - 18/11/2010 -		Visual impairment Eye pain	10/08/2010 10/08/2010		Not recovered at time of reporting		
2012-015529	15/11/2012	17 Years	Female	Prophylaxis	GARDASIL	13/11/2012 - 11/09/2012 -	1 Dosage forms	Rash pruritic Asthenia Nausea Decreased appetite Fatigue Liver function test abnormal	13/11/2012		Unknown	MINOCYCLINE	
2012-015530	15/11/2012	12 Years	Female	Prophylaxis	GARDASIL	21/09/2012 -	.5 ml	Headache			Recovered/resolved		
2012-015531	15/11/2012	17 Years	Female	Prophylaxis	GARDASIL	21/09/2012 -	.5 ml	Oral mucosal blistering	21/09/2012		Recovered/resolved		
2012-015532	15/11/2012	16 Years	Female	Prophylaxis	GARDASIL	21/09/2012 -	.5 ml	Injection site pain	21/09/2012		Recovered/resolved		
2012-015536	15/11/2012	12 Years	Female	Prophylaxis	GARDASIL	15/11/2012 - 15/11/2012	.5 ml	Asthma	15/11/2012		Recovered/resolved		Asthma
2012-015553	18/11/2012	12 Years	Female	Prophylaxis	GARDASIL	12/11/2012 - 18/09/2012 -	.5 ml	Extrasystoles Palpitations	14/11/2012	18/11/2012	Recovered/resolved		
2012-015603	23/11/2012	16 Years	Female	Prophylaxis	GARDASIL	25/09/2012 -	.5 ml	Headache	25/09/2012		Recovered/resolved		
2012-015604	23/11/2012	12 Years	Female	Prophylaxis	GARDASIL	09/11/2012 - 14/09/2012 -	.5 ml	Hot flush Insomnia Urticaria Lymphadenopathy	09/11/2012 09/11/2012		Recovered/resolved		Lymphadenopathy
2012-015609	23/11/2012	16 Years	Female	Prophylaxis	GARDASIL	05/09/2012 -		maternal exposure during pregnancy No adverse event			Recovered/resolved		
2012-015610	23/11/2012	12 Years	Female	Prophylaxis	GARDASIL	19/09/2012 -	.5 ml	Headache	19/09/2012		Recovered/resolved		

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2012-015649	28/11/2012	17 Years	Female	Prophylaxis	GARDASIL	14/11/2012 - 09/09/2012 -	.5 ml	Pain in extremity Injection site erythema Injection site warmth Injection site pain Insomnia Monoplegia	14/11/2012 14/11/2012 14/11/2012 14/11/2012		Recovering/resolving		
2012-015659	29/11/2012	17 Years	Female	Prophylaxis	GARDASIL	19/09/2012 -	.5 ml	Maternal exposure during pregnancy No adverse event			Recovered/resolved		
2012-015662	28/11/2012		Female	Prophylaxis	GARDASIL			Extensive swelling of vaccinated limb			Unknown		
2012-015694	03/12/2012	12 Years	Female	Prophylaxis	GARDASIL	30/11/2012 -		Presyncope Loss of consciousness	30/11/2012 30/11/2012		Recovered/resolved		
2012-015695	03/12/2012	13 Years	Female	Prophylaxis	GARDASIL	15/11/2012 -		Pain in extremity Muscular weakness Sensory disturbance Neuralgia	15/11/2012 15/11/2012 15/11/2012		Not recovered at time of reporting		
2012-015700	03/12/2012	17 Years	Female	Prophylaxis	GARDASIL	22/11/2012 -	.5 ml	Eye irritation Hallucination Eye swelling Chest discomfort	23/11/2012 23/11/2012 23/11/2012 23/11/2012		Not recovered at time of reporting		
2012-015718	05/12/2012	12 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	29/11/2012 - 27/09/2012 - 29/11/2012 -		Anaphylactic reaction Dyspnoea Pallor Cough Tachycardia	29/11/2012 29/11/2012 29/11/2012 29/11/2012 29/11/2012		Recovered/resolved		
2012-015720	05/12/2012	18 Years	Female	Prophylaxis	GARDASIL	10/10/2012 -	.5 ml	Urticaria Eyelid oedema	11/10/2012 11/10/2012		Recovered/resolved		
2012-015799	13/12/2012	17 Years	Female	Prophylaxis	GARDASIL	26/11/2012 -		Urticaria			Not recovered at time of reporting		
2012-015805	13/12/2012	13 Years	Female	Prophylaxis	GARDASIL	03/12/2012 -		Feeling hot Hypoaesthesia Dizziness Disorientation Decreased appetite Pallor Hyperhidrosis Somnolence	03/12/2012 03/12/2012 03/12/2012 03/12/2012		Recovered/resolved		

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2012-015824	14/12/2012	13 Years	Female	Prophylaxis	GARDASIL	26/11/2012 -	.5 ml	Rash erythematous Swelling face	27/11/2012 27/11/2012		Recovered/r esolved	BOOSTRIX	
2012-015851	19/12/2012	13 Years	Female	Prophylaxis	GARDASIL	13/09/2012 -	.5 ml	Urticaria	13/12/2012		Recovered/r esolved		
2012-015852	19/12/2012	12 Years	Female	Prophylaxis	GARDASIL PRIORIX.	05/12/2012 - 01/10/2012 - 05/12/2012 -		Pyrexia Oropharyngeal pain Malaise Asthenia Pain	07/12/2012 07/12/2012 07/12/2012 07/12/2012 07/12/2012		Recovered/r esolved		
2013-015918	02/01/2013	13 Years	Female	Prophylaxis	BOOSTRIX GARDASIL	05/12/2012 - 05/12/2012 -	.5 ml .5 ml	Personality change Inappropriate affect Somnolence Dysarthria	05/12/2012 05/12/2012 05/12/2012		Recovered/r esolved		
2013-015940	02/01/2013	17 Years	Female	Prophylaxis	GARDASIL	05/11/2012 -	1 Dosage forms	Pyrexia Vomiting Headache Abdominal pain Muscle spasms	05/11/2012 05/11/2012 05/11/2012 05/11/2012 05/11/2012		Recovered/r esolved	YASMINELLE	
2013-015946	02/01/2013		Female	Prophylaxis	GARDASIL	10/12/2012 -	.5 ml	Oedema peripheral	10/12/2012				
2013-015947	02/01/2013	18 Years	Female	Prophylaxis	GARDASIL	10/10/2012 -	.5 ml	Headache	11/10/2012		Not recovered at time of reporting		
2013-015959	02/01/2013	13 Years	Female	Prophylaxis	GARDASIL	04/12/2012 - 04/12/2012	.5 ml	Eye pain Chills Arthralgia Pyrexia Headache Pain in extremity Photophobia	04/12/2012 04/12/2012 04/12/2012 04/12/2012 04/12/2012 04/12/2012	05/12/2012 01/01/2013 06/12/2012 01/01/2013 05/12/2012	Recovered/r esolved		
2013-015968	03/01/2013	13 Years	Female	Prophylaxis	GARDASIL	11/09/2012 -		Rash pruritic	11/09/2012		Recovered/r esolved		
2013-015987	07/01/2013	13 Years	Female	Prophylaxis	GARDASIL	06/11/2012 -	.5 ml	Malaise Headache Pain Pain in extremity	06/11/2012 06/11/2012 06/11/2012 06/11/2012	21/11/2012	Recovered/r esolved		
2013-016024	11/01/2013	12 Years	Female	Prophylaxis	GARDASIL	05/12/2012 -	.5 ml	Medication error			Recovered/r esolved		Comment-Patient received 3rd dose early.
2013-016065	16/01/2013	12 Years	Female	Prophylaxis	GARDASIL	02/10/2012 -	.5 ml	Sneezing Eye pruritus Influenza like illness	02/10/2012 02/10/2012 02/10/2012		Recovered/r esolved		

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2013-016066	16/01/2013	12 Years	Female	Prophylaxis	GARDASIL	12/12/2012 -	.5 ml	Sneezing Eye pruritus Influenza like illness	12/12/2012 12/12/2012 12/12/2012		Recovered/resolved		
2013-016207	31/01/2013	12 Years	Female	Prophylaxis	GARDASIL	15/10/2012 -		Respiratory distress Pyrexia Blister Oropharyngeal pain Cough	15/10/2012 15/10/2012 15/10/2012 15/10/2012		Recovered/resolved	BECLAZONE VENTOLIN SINGULAIR	Asthma Hyperventilation
2013-016280	07/02/2013	12 Years	Female	Prophylaxis	GARDASIL	13/09/2012 - 14/11/2012 -	.5 ml .5 ml	Dizziness Influenza like illness Nausea Somnolence Fatigue Headache Narcolepsy Hypersomnia	14/09/2012 14/09/2012 14/09/2012 14/09/2012		Not recovered at time of reporting		Comment-Investigations are ongoing.
2013-016360	15/02/2013	14 Years	Female	Prophylaxis	GARDASIL	04/2012 -	.5 ml	Headache Dizziness	04/2012 04/2012		Not recovered at time of reporting		
2013-016556	06/03/2013	17 Years	Female	Prophylaxis	GARDASIL	25/09/2012 -		Pain Decreased appetite Erythema Headache	26/09/2012 26/09/2012 26/09/2012 26/09/2012		Recovered/resolved		
2013-016588	11/03/2013	18 Years	Female	Prophylaxis	GARDASIL	24/09/2012 -	.5 ml	Lethargy Pain in extremity Headache	24/09/2012 24/09/2012 24/09/2012		Recovered/resolved		
2013-016589	11/03/2013	18 Years	Female	Prophylaxis	GARDASIL	19/11/2012 -	.5 ml	Lethargy Pain in extremity Headache Pyrexia	19/11/2012 19/11/2012 19/11/2012 19/11/2012		Recovered/resolved		
2013-016600	12/03/2013	14 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	12/03/2013 - 12/11/2012 - 10/09/2012 - 12/03/2013 -	.5 ml .5 ml .5 ml .5 ml	Anaphylactic reaction Dizziness Pallor Chest discomfort Wheezing Tongue oedema Hypotension	12/03/2013 12/03/2013 12/03/2013 12/03/2013 12/03/2013 12/03/2013		Unknown	MEFAC	

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2013-016625	14/03/2013	17 Years	Female	Prophylaxis	GARDASIL	03/12/2012 - 03/12/2012 24/09/2012 -	.5 ml	Malaise Body temperature increased Arthralgia Vllth nerve paralysis	07/12/2012 07/12/2012 07/12/2012		Recovered/resolved	GABAPENTIN PARACETAMOL/CODEINE	Rheumatoid arthritis Fibromyalgia
2013-016643	15/03/2013	13 Years	Female	Prophylaxis	GARDASIL	13/03/2013 -	.5 ml	Erythema Flushing	13/03/2013 13/03/2013		Unknown	BOOSTRIX	Asthma Seasonal allergy
2013-016695	22/03/2013	13 Years	Female	Prophylaxis	GARDASIL	11/03/2013 -	.5 ml	Pyrexia Musculoskeletal stiffness Lethargy Fatigue Nausea Feeling of body temperature change Malaise Flushing	11/03/2013 11/03/2013 11/03/2013 11/03/2013 11/03/2013		Recovered/resolved		Cardiac disorder
2013-016711	25/03/2013	13 Years	Female	Prophylaxis	GARDASIL	17/09/2012 -	1 Dosage forms	Erythema Pain in extremity	17/09/2012 17/09/2012		Recovered/resolved		
2013-016713	25/03/2013	13 Years	Female	Prophylaxis	GARDASIL	21/03/2013 -	1 Dosage forms	Syncope Fall	21/03/2013 21/03/2013		Recovered/resolved		Syncope
2013-016717	25/03/2013	12 Years	Female	Prophylaxis	GARDASIL	10/09/2012 - 06/11/2012 - 14/04/2013 -		Tenderness	10/09/2012		Not recovered at time of reporting		
2013-016719	25/03/2013	17 Years	Female	Prophylaxis	GARDASIL	14/03/2013 -	.5 ml	Pain in extremity Erythema	14/03/2013 14/03/2013		Recovered/resolved		
2013-016723	25/03/2013	17 Years	Female	Prophylaxis	GARDASIL	08/11/2012 - 08/11/2012		Pain in extremity			Recovered/resolved		
2013-016758	27/03/2013	17 Years	Female	Prophylaxis	GARDASIL	19/03/2013 -	.5 ml	Rash pruritic Feeling hot Rash macular Rash erythematous	19/03/2013 19/03/2013 19/03/2013		Recovered/resolved		
2013-016803	25/03/2013	17 Years	Female	Prophylaxis	GARDASIL	08/11/2012 -		Pain in extremity	08/11/2012		Recovered/resolved		
2013-016853	08/04/2013	17 Years	Female	Prophylaxis	GARDASIL	22/11/2012 -		Pain in extremity Tenderness	22/11/2012 22/11/2012		Recovered/resolved		
2013-016863	10/04/2013	18 Years	Female	Prophylaxis	GARDASIL	12/11/2012 -	.5 ml	Rash pruritic Urticaria	13/11/2012 13/11/2012		Recovered/resolved		

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2013-016869	10/04/2013	18 Years	Female	Prophylaxis	GARDASIL	01/10/2012 - 01/10/2012		Postural orthostatic tachycardia syndrome Palpitations	08/11/2012 08/11/2012		Not recovered at time of reporting		
2013-016871	10/04/2013	12 Years	Female	Prophylaxis	BOOSTRIX GARDASIL	09/04/2013 - 09/04/2013 - 20/11/2012 - 18/09/2012 -	1 Dosage forms 1 Dosage forms 1 Dosage forms	Feeling hot Dizziness Malaise Dysphagia Flushing Urticaria Throat tightness Hypersensitivity	09/04/2013 09/04/2013 09/04/2013 09/04/2013 09/04/2013 09/04/2013		Recovered/resolved	ELTROXIN	Hypothyroidism
2013-016877	11/04/2013	13 Years	Female	Prophylaxis	BOOSTRIX GARDASIL	09/04/2013 - 09/04/2013 -	1 Dosage forms 1 Dosage forms	Headache Feeling hot Flushing Urticaria Dysphagia Hypersensitivity	09/04/2013 09/04/2013 09/04/2013 09/04/2013 09/04/2013		Recovered/resolved		
2013-016890	12/04/2013		Female	Prophylaxis	GARDASIL	08/11/2012 -	1 Dosage forms	Oedema peripheral			Unknown		
2013-016896	12/04/2013	13 Years	Female	Prophylaxis	GARDASIL	05/12/2012 - 01/10/2012 -		Nausea	05/12/2012		Recovered/resolved		Epistaxis
2013-016907	15/04/2013	13 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	11/04/2013 - 11/04/2013 -	.5 ml .5 ml	Urticaria Pruritus	11/04/2013 11/04/2013		Recovered/resolved		
2013-016909	15/04/2013	19 Years	Female	Prophylaxis	GARDASIL	10/04/2013 - 03/12/2012 - 03/10/2012 -		Rash erythematous Urticaria	10/04/2013 10/04/2013		Recovered/resolved		
2013-016932	16/04/2013	18 Years	Female	Prophylaxis	GARDASIL	11/03/2013 -		Injection site pain Musculoskeletal stiffness	11/03/2013 11/03/2013		Not recovered at time of reporting		
2013-016974	19/04/2013	19 Years	Female	Prophylaxis	GARDASIL PRIORIX.	14/11/2012 - 19/09/2012 - 14/11/2012 -	.5 ml	Maternal exposure during pregnancy			Unknown		Comment-No further information provided regarding impact of exposure to vaccine in pregnancy. Patient reported to have also had a previous pregnancy.
2013-016975	19/04/2013	17 Years	Female	Prophylaxis	GARDASIL	20/11/2012 - 25/09/2012 -	.5 ml	Headache	20/11/2012		Recovered/resolved		
2013-016993	22/04/2013	16 Years	Female	Prophylaxis	GARDASIL	17/12/2012 -		Maternal exposure during pregnancy			Unknown		Comment-No further information provided regarding impact of exposure to vaccine in pregnancy.

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**Summary details of suspected adverse reactions/events
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HPRA ID	Date of first notification to HPRA	Patient Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Reaction Cessation Date	Outcome	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
2013-017000	22/04/2013	16 Years	Female	Prophylaxis	GARDASIL	28/09/2012 - 19/11/2012 -	.5 ml .5 ml	Maternal exposure during pregnancy No adverse event			Recovered/resolved		
2013-017091	01/05/2013	13 Years	Female	Prophylaxis	GARDASIL	08/04/2013 -	.5 ml	Abdominal pain Back pain Decreased appetite Pyrexia	08/04/2013 08/04/2013 08/04/2013		Recovered/resolved		
2013-017100	01/05/2013	13 Years	Female	Prophylaxis	GARDASIL	19/04/2013 -		Rash	26/04/2013		Recovered/resolved		
2013-017119	03/05/2013	17 Years	Female	Prophylaxis	GARDASIL	08/10/2012 - 26/11/2012 - 23/04/2013 -		Psoriasis	10/2012		Not recovered at time of reporting	DOVOBET	Psoriasis Tonsillectomy
2013-017126	07/05/2013	17 Years	Female	Prophylaxis	GARDASIL	12/04/2013 -	1 Dosage forms	Influenza like illness Headache Myalgia Arthralgia Lethargy Sinusitis	14/04/2013 14/04/2013 14/04/2013 14/04/2013 14/04/2013		Recovered/resolved		
2013-017185	13/05/2013	13 Years	Female	Prophylaxis	BOOSTRIX GARDASIL	08/05/2013 - 08/05/2013 08/05/2013 - 08/05/2013	.5 ml .5 ml	Headache Fatigue Dizziness	08/05/2013 08/05/2013 08/05/2013		Recovered/resolved		
2013-017198	14/05/2013	17 Years	Female	Prophylaxis	GARDASIL	11/09/2011 - 14/11/2011 -		Maternal exposure during pregnancy No adverse event			Recovered/resolved		
2013-017202	14/05/2013	17 Years	Female	Prophylaxis	GARDASIL	26/09/2011 - 16/11/2011 -		Maternal exposure during pregnancy No adverse event			Recovered/resolved		
2013-017285	23/05/2013	13 Years	Female	Prophylaxis	GARDASIL	17/05/2013 -	.5 ml	Epilepsy Asthenia Syncope Tonic clonic movements Fatigue Headache	17/05/2013 17/05/2013 17/05/2013 17/05/2013 17/05/2013		Recovered/resolved		Syncope
2013-017346	31/05/2013	14 Years	Female	Prophylaxis	GARDASIL	13/03/2013 -		Convulsion	14/03/2013		Not recovered at time of reporting		

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HPRA ID	Date of first notification to HPRA	Patient Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Reaction Cessation Date	Outcome	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
2013-017358	04/06/2013	18 Years	Female	Prophylaxis	GARDASIL	14/05/2013 -		Influenza like illness Pain Body temperature Headache Oropharyngeal pain Musculoskeletal stiffness	27/05/2013 27/05/2013 27/05/2013 27/05/2013 27/05/2013		Recovered/resolved	DIANETTE	
2013-017433	12/06/2013	17 Years	Female	Prophylaxis	GARDASIL	11/04/2013 - 03/12/2012 - 04/10/2012 -		Nausea Headache Body temperature Face oedema Dysphagia	11/04/2013 11/04/2013 11/04/2013 11/04/2013		Recovered/resolved	TRIMETHOPRIM DIFFERIN MICROLITE	
2013-017446	13/06/2013	18 Years	Female	Prophylaxis	GARDASIL	29/04/2013 -	.5 ml	Fatigue Lymphadenopathy Pyrexia	29/04/2013 29/04/2013 29/04/2013		Recovered/resolved	YASMIN	
2013-017672	08/07/2013	17 Years	Female	Prophylaxis	GARDASIL	12/03/2013 -	.5 ml	Injection site pain	12/03/2013		Not recovered at time of reporting		
2013-017770	17/07/2013	13 Years	Female	Prophylaxis	GARDASIL	19/04/2013 - 15/03/2013 - 20/09/2012 -	1 Dosage forms 1 Dosage	No adverse event Inappropriate schedule of drug administration			Recovered/resolved	BOOSTRIX	Asthma
2013-017835	24/07/2013	14 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	14/03/2013 - 14/03/2013 -		Pallor Cold sweat Hypotension	14/03/2013 14/03/2013 14/03/2013		Recovered/resolved		
2013-017837	24/07/2013	17 Years	Female	Prophylaxis	GARDASIL	06/11/2012 -		Syncope	06/11/2012		Recovered/resolved		
2013-017839	24/07/2013	17 Years	Female	Prophylaxis	GARDASIL	11/09/2012 -		Presyncope Syncope	11/09/2012 11/09/2012		Recovered/resolved		Syncope
2013-017840	24/07/2013	12 Years	Female	Prophylaxis	GARDASIL	13/09/2012 -		Syncope Hypotension	13/09/2012 13/09/2012		Recovered/resolved		
2013-018105	26/08/2013	17 Years	Female	Prophylaxis	PANDEMRIX GARDASIL	25/02/2010 - 06/10/2010 - 02/12/2010 - 15/03/2011 -		Fatigue Somnolence Headache Dizziness Chronic fatigue syndrome	01/2011		Recovering/resolving	FYBOGEL SANOMIGRAN TERBINAFINE TETRALYSAL	Dermatillomania Impetigo
2013-018229	09/09/2013	18 Years	Female	Prophylaxis	GARDASIL	09/09/2013 -		Dizziness Nausea	09/09/2013 09/09/2013		Recovered/resolved		
2013-018254	11/09/2013	12 Years	Female	Prophylaxis	GARDASIL	10/09/2013 -		Nausea	10/09/2013		Recovered/resolved		

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**Summary details of suspected adverse reactions/events
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2013-018275	13/09/2013	13 Years	Female	Prophylaxis	GARDASIL	13/09/2013 -		Sensation of foreign body Rash erythematous Tachycardia Headache	13/09/2013 13/09/2013 13/09/2013		Unknown		
2013-018284	13/09/2013	12 Years	Female	Prophylaxis	GARDASIL	09/09/2013 -		Malaise Pyrexia Oropharyngeal pain Oedema peripheral	10/09/2013 09/09/2013 11/09/2013 11/09/2013		Recovering/resolving		
2013-018290	16/09/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Syncope	12/09/2013	12/09/2013	Recovered/resolved		
2013-018292	16/09/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Syncope	12/09/2013		Recovered/resolved		
2013-018296	16/09/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Syncope	12/09/2013		Recovered/resolved		
2013-018297	16/09/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Panic attack	12/09/2013		Recovered/resolved		
2013-018299	16/09/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Syncope	12/09/2013		Recovered/resolved		
2013-018309	17/09/2013	12 Years	Female	Prophylaxis	GARDASIL	16/09/2013 -		Body temperature increased	16/09/2013		Not recovered at time of reporting		
2013-018316	18/09/2013	18 Years	Female	Prophylaxis	GARDASIL	17/09/2013 -		Headache Stress Dizziness Panic attack	17/09/2013 17/09/2013 17/09/2013 17/09/2013		Recovered/resolved	GALFER	Anaemia
2013-018317	18/09/2013	16 Years	Female	Prophylaxis	GARDASIL	17/09/2013 -		Headache Amnesia Syncope Fall	17/09/2013 17/09/2013 17/09/2013 17/09/2013		Recovered/resolved		
2013-018318	18/09/2013	12 Years	Female	Prophylaxis	GARDASIL	18/09/2013 -	.5 ml	Rash Hypersensitivity	18/09/2013 18/09/2013		Recovered/resolved		Asthma
2013-018319	18/09/2013	12 Years	Female	Prophylaxis	GARDASIL	18/09/2013 -	.5 ml	Hypersensitivity Rash pruritic	18/09/2013 18/09/2013		Recovered/resolved		
2013-018320	18/09/2013	12 Years	Female	Prophylaxis	GARDASIL	18/09/2013 -	.5 ml	Hypersensitivity Rash pruritic	18/09/2013 18/09/2013		Not recovered at time of reporting		Eczema Psoriasis
2013-018321	18/09/2013	12 Years	Female	Prophylaxis	GARDASIL	18/09/2013 -	.5 ml	Hypersensitivity Rash Nausea	18/09/2013 18/09/2013 18/09/2013		Recovered/resolved		

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HPRA ID	Date of first notification to HPRA	Patient Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Reaction Cessation Date	Outcome	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
2013-018323	18/09/2013	12 Years	Female	Prophylaxis	GARDASIL	18/09/2013 -	.5 ml	Hypersensitivity Rash pruritic Nausea	18/09/2013 18/09/2013 18/09/2013		Recovered/resolved		
2013-018339	20/09/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Pain in extremity Headache Pyrexia Asthenia Fatigue Injection site warmth	16/09/2013 16/09/2013 16/09/2013 16/09/2013 16/09/2013		Unknown		
2013-018349	23/09/2013	16 Years	Female	Prophylaxis	GARDASIL	18/09/2013 - 05/10/2010 - 09/12/2010 - 06/04/2011 -	.5 ml .5 ml .5 ml .5 ml	Incorrect dose administered No adverse event	18/09/2013		Recovered/resolved		
2013-018354	23/09/2013	12 Years	Female	Prophylaxis	GARDASIL	23/09/2013 -		Syncope Dizziness	23/09/2013 23/09/2013		Recovered/resolved		Asthma
2013-018355	23/09/2013	12 Years	Female	Prophylaxis	GARDASIL	23/09/2013 -		Nausea	23/09/2013		Recovered/resolved		
2013-018357	23/09/2013	18 Years	Female	Prophylaxis	GARDASIL	16/09/2013 -	.5 ml	Asthenia Pain in extremity Asthma Body temperature increased	16/09/2013 16/09/2013 09/2013 16/09/2013		Not recovered at time of reporting		Asthma
2013-018363	23/09/2013	14 Years	Female	Prophylaxis	GARDASIL	18/01/2011 - 18/02/2011 - 20/05/2011 -		Fatigue	02/2011		Not recovered at time of reporting		
2013-018377	25/09/2013	12 Years	Female	Prophylaxis	GARDASIL	24/09/2013 -		Vomiting	24/09/2013		Recovered/resolved		
2013-018378	25/09/2013	12 Years	Female	Prophylaxis	GARDASIL	24/09/2013 -		Syncope	24/09/2013		Recovered/resolved		Syncope
2013-018379	25/09/2013		Female	Prophylaxis	GARDASIL	24/09/2013 -		Headache	24/09/2013	24/09/2013	Recovered/resolved		Upper respiratory tract infection
2013-018386	25/09/2013	12 Years	Female	Prophylaxis	GARDASIL	17/09/2013 -	.5 ml	Vomiting Retching Syncope Headache	17/09/2013 18/09/2013 17/09/2013 18/09/2013		Not recovered at time of reporting		
2013-018389	25/09/2013	17 Years	Female	Prophylaxis	GARDASIL	10/09/2013 -	.5 ml	Erythema nodosum Oropharyngeal pain Fatigue	11/09/2013 11/09/2013 11/09/2013	09/2013	Unknown		Hiatus hernia Lymphadenopathy
2013-018391	26/09/2013	12 Years	Female	Prophylaxis	GARDASIL	24/09/2013 -	.5 ml	Nasal congestion Eye swelling	24/09/2013 24/09/2013		Not recovered at time of reporting		

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**Summary details of suspected adverse reactions/events
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2013-018415	30/09/2013	18 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -	.5 ml	Rash erythematous	12/09/2013		Recovered/resolved		
2013-018416	30/09/2013	13 Years	Female	Prophylaxis	GARDASIL	27/09/2013 -	.5 ml	Rash macular Dizziness Butterfly rash Pallor			Recovered/resolved		
2013-018448	02/10/2013	12 Years	Female	Prophylaxis	GARDASIL	01/10/2013 -		Syncope	01/10/2013		Recovered/resolved		
2013-018450	02/10/2013	13 Years	Female	Prophylaxis	GARDASIL	25/09/2013 -		Urticaria	25/09/2013		Recovered/resolved		
2013-018453	02/10/2013	13 Years	Female	Prophylaxis	GARDASIL	25/09/2013 -		Rash pruritic	26/09/2013		Not recovered at time of reporting		
2013-018462	03/10/2013	18 Years	Female	Prophylaxis	GARDASIL	01/10/2013 -	.5 ml	Incorrect dose administered Malaise	01/10/2013 01/10/2013		Recovered/resolved	IMPLANON YASMIN	
2013-018464	03/10/2013	17 Years	Female	Prophylaxis	GARDASIL	03/10/2013 -		Syncope	03/10/2013		Recovered/resolved		
2013-018465	03/10/2013	13 Years	Female	Prophylaxis	GARDASIL	03/10/2013 -		Dizziness	03/10/2013		Recovered/resolved		
2013-018467	03/10/2013	17 Years	Female	Prophylaxis	GARDASIL	27/09/2013 -	.5 ml	Incorrect dose administered No adverse event	27/09/2013		Recovered/resolved		
2013-018468	03/10/2013	17 Years	Female	Prophylaxis	GARDASIL	26/09/2013 -		Asthenia Nausea Lethargy	26/09/2013 26/09/2013 26/09/2013		Not recovered at time of reporting	CLONAMOX	Influenza Oropharyngeal pain
2013-018480	04/10/2013	12 Years	Female	Prophylaxis	GARDASIL	03/10/2013 -		Syncope	03/10/2013		Recovered/resolved		
2013-018481	04/10/2013	17 Years	Female	Prophylaxis	GARDASIL	03/10/2013 -		Syncope	03/10/2013		Recovered/resolved		
2013-018490	07/10/2013	13 Years	Female	Prophylaxis	GARDASIL	02/10/2013 -	.5 ml	Nausea Asthenia Presyncope Syncope	02/10/2013 02/10/2013		Unknown		
2013-018505	03/10/2013	18 Years	Female	Prophylaxis	GARDASIL	02/10/2013 -	1 Dosage forms	Limb discomfort Pain in extremity Pyrexia Syncope Vision blurred Hyperhidrosis Vomiting	02/10/2013 02/10/2013 02/10/2013 03/10/2013 03/10/2013 03/10/2013 02/10/2013		Not recovered at time of reporting	MICROLITE	

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2013-018525	09/10/2013	12 Years	Female	Prophylaxis	GARDASIL	26/09/2013 -		Dizziness Pallor Asthenia Cold sweat	26/09/2013 26/09/2013 26/09/2013 26/09/2013		Recovered/resolved		
2013-018536	10/10/2013	18 Years	Female	Prophylaxis	GARDASIL	27/09/2013 - 27/09/2013	.5 ml	Rash pustular			Not recovered at time of reporting		
2013-018541	10/10/2013		Female	Prophylaxis	GARDASIL	23/09/2013 -	.5 ml	Oedema peripheral	23/09/2013		Recovered/resolved		
2013-018584	16/10/2013	13 Years	Female	Prophylaxis	GARDASIL	09/09/2013 -	.5 ml	Tachycardia Headache Flushing Heart rate irregular Dizziness	09/09/2013 09/09/2013 09/09/2013 09/09/2013 09/09/2013		Recovered/resolved		
2013-018751	04/11/2013	12 Years	Female	Prophylaxis	GARDASIL	03/10/2013 -		Herpes zoster	23/10/2013		Recovered/resolved		
2013-018774	07/11/2013	13 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	19/09/2011 - 21/03/2012 - 21/03/2012 -		Syncope Post viral fatigue syndrome Pain	28/03/2012 28/03/2012		Unknown		
2013-018788	08/11/2013	16 Years	Female	Prophylaxis	GARDASIL	24/09/2013 -	.5 ml	Incorrect dose administered No adverse event	24/09/2013		Recovered/resolved		
2013-018789	08/11/2013	16 Years	Female	Prophylaxis	GARDASIL	24/09/2013 -	.5 ml	Incorrect dose administered No adverse event	24/09/2013		Recovered/resolved		
2013-018829	13/11/2013	13 Years	Female	Prophylaxis	GARDASIL	13/11/2013 -		Pallor Cold sweat Tremor Syncope	13/11/2013 13/11/2013 13/11/2013 13/11/2013		Recovered/resolved		
2013-018856	17/11/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Headache Dizziness Muscular weakness Myalgia	14/09/2013 14/09/2013 14/09/2013 14/09/2013		Recovered/resolved		
2013-018857	17/11/2013	17 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Headache	12/09/2013		Recovered/resolved		
2013-018889	19/11/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Headache	12/09/2013		Recovered/resolved		

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2013-018890	19/11/2013	17 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Nausea Dizziness	12/09/2013 12/09/2013		Recovered/resolved		
2013-018897	20/11/2013	12 Years	Female	Prophylaxis	GARDASIL	19/09/2013 -		Headache Dizziness	19/09/2013 19/09/2013		Recovered/resolved		
2013-018899	20/11/2013	17 Years	Female	Prophylaxis	GARDASIL	19/09/2013 -		Vomiting	19/09/2013		Recovered/resolved		
2013-018929	22/11/2013	12 Years	Female	Prophylaxis	GARDASIL	19/09/2013 -		Local swelling	20/09/2013		Recovered/resolved		
2013-018950	25/11/2013	13 Years	Female	Prophylaxis	GARDASIL	12/11/2013 - 10/09/2013 -	.5 ml	Urticaria	12/11/2013		Recovered/resolved		Eczema Food allergy
2013-018966	25/11/2013	13 Years	Female	Prophylaxis	GARDASIL	12/2010 - 03/2011 -		Headache Dizziness Anxiety Depression Mood swings Quality of life decreased Vomiting Abnormal behaviour Memory impairment Confusional state Tremor	12/2010 2011 2011 2011 2011 2011 2011 2011 2011 2011		Not recovered at time of reporting	Learning disability Previous speech disorder Enuresis	
2013-018980	27/11/2013	17 Years	Female	Prophylaxis	GARDASIL	24/09/2013 -	.5 ml	Lip swelling Joint swelling Rash Throat tightness	24/09/2013 24/09/2013 24/09/2013 24/09/2013		Recovered/resolved		
2013-019017	29/11/2013	13 Years	Female	Prophylaxis	GARDASIL	26/09/2013 -	.5 ml	Injection site paraesthesia Muscle spasms Dyspnoea	13/10/2013 13/10/2013 13/10/2013		Recovered/resolved		
2013-019028	02/12/2013	13 Years	Female	Prophylaxis	GARDASIL	27/11/2013 -		Headache Dyspepsia	27/11/2013 27/11/2013		Recovered/resolved	NASOFAN	Appendicectomy Constipation
2013-019033	02/12/2013	17 Years	Female	Prophylaxis	GARDASIL	23/09/2013 -	.5 ml	Syncope Headache Urticaria	23/09/2013 23/09/2013 23/09/2013		Recovered/resolved		
2013-019103	10/12/2013	13 Years	Female	Prophylaxis	GARDASIL	02/10/2013 -		Headache Dizziness Nausea	02/10/2013 02/10/2013 02/10/2013		Recovered/resolved		
2013-019150	16/12/2013		Female	Prophylaxis	GARDASIL	20/10/2010 - 02/10/2013 - 04/12/2013 -		Drug prescribing error No adverse event			Recovered/resolved		Syncope

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2013-019180	13/12/2013	12 Years	Female	Prophylaxis	GARDASIL	25/11/2013 -	.5 ml	Cough Throat tightness Wheezing	25/11/2013 25/11/2013 25/11/2013		Recovered/resolved	SALBUTAMOL VENTOLIN	Asthma
2013-019223	23/12/2013	13 Years	Female	Prophylaxis	GARDASIL	30/09/2013 -	.5 ml	Idiopathic thrombocytopenic purpura Haemorrhage	07/11/2013 07/11/2013		Not recovered at time of reporting		
2014-019231	30/12/2013	12 Years	Female	Prophylaxis	GARDASIL	09/09/2013 - 04/11/2013 -	.5 ml .5 ml	Platelet count decreased Mucosal haemorrhage Idiopathic thrombocytopenic purpura	28/12/2013 28/12/2013 28/12/2013		Unknown		
2014-019235	30/12/2013	12 Years	Female	Prophylaxis	GARDASIL	26/09/2013 -		Haemorrhage Contusion Thrombocytopenia Idiopathic thrombocytopenic purpura	30/12/2013 30/12/2013 30/12/2013 30/12/2013		Not recovered at time of reporting	BOOSTRIX	
2014-019311	08/01/2014	13 Years	Female	Prophylaxis	GARDASIL	23/09/2013 -		Diarrhoea Colitis			Unknown		Asthma
2014-019334	10/01/2014	18 Years	Female	Prophylaxis	GARDASIL	09/01/2014 -		Headache	09/01/2014		Recovered/resolved		Headache
2014-019336	10/01/2014	18 Years	Female	Prophylaxis	GARDASIL	09/01/2014 -		Headache Malaise	09/01/2014 09/01/2014		Recovered/resolved		Systemic lupus erythematosus
2014-019345	13/01/2014	18 Years	Female	Prophylaxis	GARDASIL	09/01/2014 -		Nausea Dizziness	09/01/2014 09/01/2014	10/01/2014 10/01/2014	Recovered/resolved		
2014-019368	10/01/2014	18 Years	Female	Prophylaxis	GARDASIL			Headache			Recovered/resolved		Headache
2014-019429	23/01/2014	18 Years	Female	Prophylaxis	GARDASIL	16/09/2013 -	.5 ml	Periorbital oedema Swelling face Vision blurred Local swelling	17/09/2013 17/09/2013 17/09/2013 17/09/2013		Recovered/resolved		Coeliac disease
2014-019430	23/01/2014	17 Years	Female	Prophylaxis	GARDASIL	10/09/2013 -	.5 ml	Local swelling Erythema Pruritus	12/09/2013 12/09/2013 12/09/2013		Recovered/resolved		
2014-019580	06/02/2014	12 Years	Female	Prophylaxis	GARDASIL	12/11/2013 -	.5 ml	Headache Pyrexia Rash papular	15/11/2013 15/11/2013 15/11/2013		Recovered/resolved		
2014-019586	06/02/2014	12 Years	Female	Prophylaxis	GARDASIL	11/2013 -		Migraine with aura Asthenia Amnesia Aphasia Headache			Not recovered at time of reporting		Familial risk factor

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**Summary details of suspected adverse reactions/events
associated with the use of Gardasil
to 31/05/2015**

HPRA ID	Date of first notification to HPRA	Patient Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Reaction Cessation Date	Outcome	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
2014-019844	04/03/2014	13 Years	Female	Prophylaxis	GARDASIL	04/12/2013 -		Nausea Headache Vomiting Asthenia Fatigue Decreased appetite	04/12/2013 04/12/2013 04/12/2013 04/12/2013 04/12/2013	06/12/2013 06/12/2013 06/12/2013 06/12/2013 06/12/2013	Recovered/resolved	ONDANSETRON KWELLS	Cerebral haemorrhage
2014-019893	07/03/2014	18 Years	Female	Prophylaxis	GARDASIL	26/09/2012 -		Incorrect dose administered No adverse event	26/09/2012		Recovered/resolved		Asthma
2014-020050	24/03/2014	13 Years	Female	Prophylaxis	GARDASIL	20/03/2014 -		Disorientation Abnormal behaviour Memory impairment Fatigue Malaise Syncope	20/03/2014 20/03/2014 21/03/2014 21/03/2014 21/03/2014		Recovered/resolved	IPV-BOOSTRIX	
2014-020057	24/03/2014	13 Years	Female	Prophylaxis	GARDASIL	20/03/2014 -		Nausea	20/03/2014		Recovered/resolved		
2014-020058	24/03/2014		Female	Prophylaxis	GARDASIL BOOSTRIX	20/03/2014 - 20/03/2014 -		Headache	20/03/2014		Recovered/resolved		Headache
2014-020073	26/03/2014	13 Years	Female	Prophylaxis	GARDASIL	13/09/2013 - 18/11/2013 -		Headache Dizziness Feeling cold Muscular weakness Lethargy Fatigue Pharyngitis	18/11/2013 18/11/2013 18/11/2013 18/11/2013 18/11/2013		Not recovered at time of reporting		
2014-020190	07/04/2014		Female	Prophylaxis	GARDASIL	27/01/2013 -	.5 ml	Trance transient Muscle twitching Headache			Recovered/resolved		
2014-020199	07/04/2014	13 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	31/03/2014 - 31/03/2014 -		Vomiting	31/03/2014		Recovered/resolved		
2014-020200	07/04/2014		Female	Prophylaxis	GARDASIL PRIORIX.	31/03/2014 - 31/03/2014 -		Vomiting Dizziness	31/03/2014 31/03/2014		Recovered/resolved		
2014-020210	07/04/2014	13 Years	Female	Prophylaxis	GARDASIL	04/04/2014 -		Sensation of heaviness Injection site streaking Skin hypopigmentation Acne	04/04/2014		Not recovered at time of reporting		
2014-020212	08/04/2014	12 Years	Female	Prophylaxis	GARDASIL	02/04/2014 -	.5 ml	Psychomotor hyperactivity	02/04/2014		Recovered/resolved		
2014-020218	08/04/2014	18 Years	Female	Prophylaxis	GARDASIL	20/03/2014 -	.5 ml	Syncope	20/03/2014		Recovered/resolved		

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**Summary details of suspected adverse reactions/events
associated with the use of Gardasil
to 31/05/2015**

HPRA ID	Date of first notification to HPRA	Patient Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Reaction Cessation Date	Outcome	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
2014-020224	08/04/2014	13 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	27/03/2014 - 27/03/2014 -		Asthenia Vomiting Pain in extremity Pyrexia Malaise	27/03/2014 27/03/2014 27/03/2014 27/03/2014		Recovered/r esolved	MOVICOL	Constipation
2014-020231	09/04/2014	12 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	24/03/2014 - 24/03/2014 -		Headache	24/03/2014		Recovered/r esolved		
2014-020232	09/04/2014	13 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	08/04/2014 - 08/04/2014 -		Syncope Asthenia	08/04/2014 08/04/2014		Recovered/r esolved		
2014-020233	09/04/2014	12 Years	Female	Prophylaxis	GARDASIL	27/09/2013 - 29/11/2013 -		Local swelling Tenderness Erythema			Recovered/r esolved		
2014-020234	09/04/2014	13 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	08/04/2014 - 08/04/2014 -		Syncope	08/04/2014		Recovered/r esolved		
2014-020235	09/04/2014	13 Years	Female	Prophylaxis	GARDASIL	24/03/2014 -		Nausea	24/03/2014		Recovered/r esolved		
2014-020263	11/04/2014	13 Years	Female	Prophylaxis	GARDASIL	03/04/2014 -		Pyrexia Vomiting Nausea Erythema Arthralgia	03/04/2014 03/04/2014 03/04/2014 03/04/2014		Recovered/r esolved		
2014-020267	11/04/2014	13 Years	Female	Prophylaxis	GARDASIL	16/09/2013 -		Syncope Headache Convulsion Hyperventilation Vision blurred Nausea Muscular weakness	11/2013 11/2013 11/2013 11/2013 11/2013 11/2013		Not recovered at time of reporting		Abdominal migraine
2014-020397	28/04/2014	12 Years	Female	Prophylaxis	GARDASIL	03/04/2014 -	.5 ml	Fatigue Dizziness Headache Abdominal pain Nausea Influenza like illness Feeling hot	03/04/2014 03/04/2014 03/04/2014 03/04/2014 03/04/2014		Recovered/r esolved		
2014-020434	01/05/2014		Female	Acne Prophylaxis	GARDASIL DIANETTE	20/09/2013 - 19/11/2013 -		Thrombosis	03/2014		Recovered/r esolved		Acne
2014-020488	07/05/2014	32 Years	Female		GARDASIL	19/12/2013 -		Blister Rash	19/12/2013	21/12/2013	Recovered/r esolved		

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**Summary details of suspected adverse reactions/events
associated with the use of Gardasil
to 31/05/2015**

HPRA ID	Date of first notification to HPRA	Patient Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Reaction Cessation Date	Outcome	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
2014-020513	09/05/2014	17 Years	Female	Prophylaxis	GARDASIL	24/04/2014 -		Sensation of foreign body Dysphagia Cough Dry mouth	24/04/2014 24/04/2014 24/04/2014		Recovered/resolved		
2014-020540	13/05/2014	13 Years	Female	Prophylaxis	GARDASIL PRIORIX.	12/05/2014 - 12/05/2014 -		Pyrexia Lethargy	12/05/2014 12/05/2014		Recovered/resolved		
2014-020602	18/05/2014	18 Years	Female	Prophylaxis	GARDASIL	02/05/2014 -		Hypoaesthesia Panic attack Hyperventilation	02/05/2014 02/05/2014 02/05/2014		Recovered/resolved	OXYTETRACYCLINE	Panic attack
2014-020603	18/05/2014	17 Years	Female	Prophylaxis	GARDASIL	06/12/2013 -		Injection site erythema Injection site pain	06/12/2013 06/12/2013		Recovered/resolved		
2014-020606	18/05/2014	18 Years	Female	Prophylaxis	GARDASIL	12/09/2013 - 14/11/2013 -		Nausea			Recovered/resolved		
2014-020607	18/05/2014	18 Years	Female	Prophylaxis	GARDASIL	14/11/2013 -		Urticaria	14/11/2013		Recovered/resolved		
2014-020821	10/06/2014	13 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	13/05/2014 - 13/05/2014 -		Dizziness Flushing Decreased appetite Fatigue	14/05/2014 14/05/2014 14/05/2014 14/05/2014		Recovered/resolved		
2014-021036	25/06/2014	19 Years	Female	Prophylaxis	GARDASIL			Papilloma viral infection			Not recovered at time of reporting		Comment-The patients screen was negative for HPV genotypes 16 & 18.
2014-021042	02/07/2014	14 Years	Female	Prophylaxis	GARDASIL	01/07/2014 -		Syncope	01/07/2014		Recovered/resolved		
2014-021212	25/07/2014	13 Years	Female	Prophylaxis	GARDASIL	12/05/2014 -	.5 ml	Headache Asthenia Confusional state Otitis media Body temperature increased	12/05/2014 12/05/2014 12/05/2014 12/05/2014	17/05/2014 17/05/2014 17/05/2014 17/05/2014	Recovered/resolved		

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2014-021605	12/09/2014	14 Years	Female	Prophylaxis	GARDASIL	28/09/2010 - 02/2011 - 10/05/2011 -	.5 ml .5 ml .5 ml	Headache Pain in extremity Fatigue Convulsion Sleep disorder Disturbance in attention Personality change Mouth ulceration Hyperacusis Visual acuity reduced Asthenia Muscular weakness Chills Hyperhidrosis Paraesthesia Alopecia Clumsiness Memory impairment Urticaria Dizziness Syncope Pruritus Menstrual disorder Dyspnoea Malaise Loss of consciousness Dry skin Pain	10/05/2011 05/2011		Not recovered at time of reporting	AMITRIPTYLINE MICROLITE	
2014-021628	17/09/2014	13 Years	Female	Prophylaxis	GARDASIL	-		Pruritus Transient Insomnia Rash generalised Contusion Blister Hypersensitivity	15/09/2014 15/09/2014 16/09/2014 16/09/2014 16/09/2014 15/09/2014		Recovering/resolving		
2014-021639	18/09/2014	12 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	15/09/2014 - 15/09/2014 -	.5 ml .5 ml	Syncope	15/09/2014		Recovered/resolved		
2014-021640	18/09/2014	12 Years	Female	Prophylaxis	GARDASIL BOOSTRIX		.5 ml .5 ml	Syncope	15/09/2014		Recovered/resolved		Syncope
2014-021641	18/09/2014	12 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	05/09/2014 - 05/09/2014 -	.5 ml .5 ml	Syncope	05/09/2014		Recovered/resolved		Asthma
2014-021665	22/09/2014	12 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	18/09/2014 - 18/09/2014 -	.5 ml .5 ml	Syncope Haematoma	18/09/2014 18/09/2014		Not recovered at time of		Syncope
2014-021666	22/09/2014	12 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	18/09/2014 - 18/09/2014 -	.5 ml .5 ml	Syncope	18/09/2014		Recovered/resolved		

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2014-021779	01/10/2014	14 Years	Female	Prophylaxis	GARDASIL	25/03/2011 - 26/11/2010 - 24/09/2010 -		Local swelling Pain in extremity Hodgkin's disease	06/2011		Recovered/resolved		Familial risk factor
2014-021799	02/10/2014	12 Years	Female	Prophylaxis	GARDASIL	09/2011 - 11/2011 - 04/2012 -		Tonsillitis Hyperaesthesia Skin discolouration Fatigue Headache			Not recovered at time of reporting		Autism Body dysmorphic disorder Hyperaesthesia Familial risk factor
2014-022114	06/11/2014	13 Years	Female	Prophylaxis	GARDASIL TETRAVAC DIPHTHERIA, TETANUS, ACELLULAR PERTUSSIS	22/09/2014 - 22/09/2014 22/09/2014 - 22/09/2014		Convulsion Malaise			Not recovered at time of reporting		
2014-022215	19/11/2014	12 Years	Female	Prophylaxis	GARDASIL	21/09/2012 - 27/11/2012 - 22/03/2013 -		Headache Chest pain Fatigue Dizziness Malaise Insomnia	21/09/2014 21/09/2012 21/09/2012 21/09/2012		Not recovered at time of reporting	BOOSTRIX	Asthma
2014-022243	20/11/2014	12 Years	Female	Prophylaxis	GARDASIL	10/09/2014 -	.5 ml	Medication error Emotional distress Fatigue	10/09/2014		Recovered/resolved		Comment-Patient received two Gardasil injections on the same day in error.

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2014-022438	16/12/2014	12 Years	Female	Prophylaxis	GARDASIL	19/09/2011 - 09/12/2011 - 22/03/2012 -	.5 ml .5 ml .5 ml	Fatigue Pain Headache Somnolence Pyrexia			Not recovered at time of reporting	OVRANETTE	Ehlers-Danlos syndrome Postural orthostatic tachycardia syndrome Hypermobility syndrome Meier-Gorlin syndrome High arched palate Mechanical urticaria Syncope Facial bones fracture Tremor Dizziness Palpitations Loss of consciousness Multiple allergies Abdominal distension Menstruation irregular Disturbance in attention Memory impairment Syncope Vomiting Nausea Stress urinary incontinence Comment-Investigations are on-going
2014-022442	17/12/2014	12 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	22/09/2014 - 22/09/2014 -	.5 ml .5 ml	Asthenia Dysstasia Poverty of speech Asthenia	22/09/2014 22/09/2014 22/09/2014 22/09/2014		Recovered/resolved		
2015-022601	13/01/2015	13 Years	Female	Prophylaxis	BOOSTRIX GARDASIL	28/04/2014 - 28/04/2014 -		Pyrexia Chills Hallucination	29/04/2014 29/04/2014 29/04/2014		Recovered/resolved		

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2015-022720	28/01/2015		Female	Prophylaxis	GARDASIL	27/09/2010 - 17/10/2010 - 14/03/2011 -	1 Dosage forms 1 Dosage forms 1 Dosage forms	Injection site haemorrhage Injection site pain Oropharyngeal pain Headache Lymphadenopathy Weight increased Somnolence Pain Vomiting Diarrhoea Dizziness Fatigue Vision blurred Nausea Disturbance in attention Muscular weakness Chest discomfort Skin discomfort Arthralgia Blindness transient Eye pain Amenorrhoea Abdominal pain lower Injection site mass Visual field defect Chronic fatigue syndrome	14/03/2011 14/03/2011 2011 2011 2011 10/2011 10/2011 01/2012 01/2012 2012 2012 2012 2012 2012 2012 2012 2012 06/2014 01/2015 14/03/2011 09/2014 03/2013		Not recovered at time of reporting		
2015-023381	20/04/2015	13 Years	Female	Prophylaxis	GARDASIL	22/09/2014 -	.5 ml	Type III immune complex Injection site induration Injection site erythema Injection site pruritus Purpura			Recovered/resolved	BOOSTRIX	
2015-023382	20/04/2015	13 Years	Female	Prophylaxis	GARDASIL MENJUGATE KIT	23/03/2015 - 23/03/2015 -	.5 ml .5 ml	Injection site reaction Oedema peripheral Rash Erythema Pruritus Skin warm Contusion	03/2015 31/03/2015 05/04/2015 31/03/2015 31/03/2015 31/03/2015		Recovering/resolving		
2015-023418	22/04/2015	12 Years	Female	Prophylaxis	GARDASIL BOOSTRIX	10/09/2014 - 10/09/2014 -	.5 ml .5 ml	Headache Fatigue	10/09/2014 10/09/2014	2014 2014	Recovered/resolved		
2015-023478	30/04/2015	13 Years	Female	Prophylaxis	GARDASIL MENJUGATE KIT	16/04/2015 - 16/04/2015 -		Pyrexia			Recovered/resolved		Influenza
2015-023576	11/05/2015	12 Years	Female	Prophylaxis	GARDASIL	29/09/2014 -	.5 ml	Alopecia	01/10/2014	10/2014	Recovered/resolved	BOOSTRIX	

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2015-023577	11/05/2015	12 Years	Female	Prophylaxis	GARDASIL	27/04/2015 - 29/09/2014 -	.5 ml .5 ml	Alopecia	29/04/2015		Not recovered at time of reporting	MENJUGATE KIT	
2015-023609	14/05/2015	13 Years	Female	Prophylaxis	GARDASIL	27/04/2015 -		Urticaria	27/04/2015		Not recovered at time of reporting	MENJUGATE KIT	
2015-023619	15/05/2015	13 Years	Female	Prophylaxis	GARDASIL	30/04/2015 -	.5 ml	Injection site pain	30/04/2015		Not recovered at time of reporting	MENJUGATE KIT	
2015-023703	26/05/2015	13 Years	Female	Prophylaxis	GARDASIL	10/09/2014 -	.5 ml	Graves disease	09/2014		Recovering/resolving	MENJUGATE KIT BOOSTRIX	
2015-023715	27/05/2015	14 Years	Female		GARDASIL BOOSTRIX	19/09/2014 - 19/09/2014 -		Urticaria Eye swelling Lip swelling	10/2014 10/2014 10/2014		Recovered/resolved		
2015-023733	22/05/2015	17 Years	Female		GARDASIL			Headache Fatigue Cognitive disorder Abdominal discomfort Neuralgia Sleep disorder Photophobia Post viral fatigue syndrome Chronic fatigue syndrome			Not recovered at time of reporting		
2015-023734	22/05/2015	17 Years	Female		GARDASIL			Headache Fatigue Cognitive disorder Abdominal discomfort Neuralgia Sleep disorder Photophobia Depression Fibromyalgia Pain			Not recovered at time of reporting		

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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.
- 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.

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- 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 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.

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- 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 Medicines, 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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