

	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
046961	14/09/2010	12 Years	Female	Prophylaxis	GARDASIL	13/09/2010 -		Injection site erythema	13/09/2010		Unknown		Erythema
								Pruritus	13/09/2010				
								Hypersensitivity	13/09/2010				
								Erythema	13/09/2010				
046962	14/09/2010	13 Years	Female	Prophylaxis	GARDASIL	13/09/2010 -	.5 ml	Ocular hyperaemia	13/09/2010		Recovered/r		
								Pallor	13/09/2010		esolved		
								Dizziness	13/09/2010				
								Flushing	13/09/2010				
								Erythema	13/09/2010				
								Feeling hot	13/09/2010				
								Hypersensitivity	13/09/2010				
046982	17/09/2010	13 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -	.5 ml	Syncope	15/09/2010	15/09/2010	Recovered/r esolved		Syncope
046983	17/09/2010	13 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -	.5 ml	Dizziness	15/09/2010		Recovered/r		
								Headache	15/09/2010		esolved		
047014	20/09/2010	14 Years	Female	Prophylaxis	GARDASIL	17/09/2010 -	.5 ml	Peripheral coldness	17/09/2010		Recovered/r		
								Cyanosis	18/09/2010		esolved		
047022	22/09/2010	13 Years	Female	Prophylaxis	GARDASIL	17/09/2010 -	.5 ml	Rash	17/09/2010		Not		
								Vomiting	17/09/2010		recovered at		
								Periorbital oedema	17/09/2010		time of		
								Dizziness	17/09/2010		reporting		
047024	22/09/2010	13 Years	Female	Prophylaxis	GARDASIL	13/09/2010 -	.5 ml	Syncope	13/09/2010		Recovered/r		
											esolved		
047025	22/09/2010	13 Years	Female	Prophylaxis	GARDASIL	22/09/2010 -	.5 ml	Syncope	22/09/2010		Recovered/r esolved		
047030	22/09/2010	13 Years	Female	Prophylaxis	GARDASIL	20/09/2010 - 20/09/2010	.5 ml	Tremor	20/09/2010	26/09/2010	Recovered/r		
								Dizziness	20/09/2010	26/09/2010	esolved		
								Nausea	20/09/2010	26/09/2010			
047031	22/09/2010	13 Years	Female	Prophylaxis	GARDASIL	13/09/2010 -	.5 ml	Panic attack	13/09/2010		Recovered/r		Abdominal pain
								Hyperventilation	13/09/2010		esolved		Vertigo
047039	23/09/2010	12 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -	1	Pain in extremity	15/09/2010		Unknown		
								Abdominal discomfort	15/09/2010		1		
								Oropharyngeal pain	15/09/2010				
047052	24/09/2010	13 Years	Female	Prophylaxis	GARDASIL	21/09/2010 -	.5 ml	Urticaria	21/09/2010		Recovered/r		
047067	28/09/2010	13 Years	Female	Prophylaxis	GARDASIL	23/09/2010 -	.5 ml	Syncope	23/09/2010	1	esolved Recovered/r		
0+1001	20/03/2010	10 18418	i ciliale	Τοριιγιαλίδ	GANDAGIL	20/03/2010 -	.5 1111	Эупсоре	23/03/2010		esolved		
047068	28/09/2010	13 Years	Female	Prophylaxis	GARDASIL	24/09/2010 -	.5 ml	Syncope	24/09/2010		Recovered/r		
									1		esolved		



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HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
047073	28/09/2010	12 Years	Female	Prophylaxis	GARDASIL	21/09/2010 -	.5 ml	Abdominal discomfort	21/09/2010		Recovered/r		
								Chest discomfort	21/09/2010		esolved		
								Throat tightness	21/09/2010				
047074	28/09/2010	12 Years	Female	Prophylaxis	GARDASIL	24/09/2010 -	.5 ml	Syncope	24/09/2010		Recovered/r		Syncope
				., ,				Bradycardia	24/09/2010		esolved		3, 11,1
								Hypotension	24/09/2010				
047075	28/09/2010		Female	Prophylaxis	GARDASIL	23/09/2010 -		Cyanosis	23/09/2010		Recovered/r		
								Peripheral coldness	23/09/2010		esolved		
								Cold sweat	23/09/2010				
047077	28/09/2010	12 Years	Female	Prophylaxis	GARDASIL	21/09/2010 -	.5 ml	Hypoaesthesia	21/09/2010		Recovered/r		
				- 1-1-7-1-11-1	· · · · ·		1	Pain in extremity	21/09/2010		esolved		
1								Gait disturbance	21/09/2010				
								Chest discomfort	21/09/2010				
								Dizziness	21/09/2010				
								Myalgia					
								Groin pain					
0.47000	00/00/0040		Famala	Danahadaada	GARDASIL	00/00/0040		Danasathasia	00/00/0040		D		
047082	29/09/2010		Female	Prophylaxis	GARDASIL	23/09/2010 -		Paraesthesia Paresis	23/09/2010 23/09/2010		Recovered/r esolved		
								Palesis	23/09/2010		estived		
047096	29/09/2010		Female	Prophylaxis	GARDASIL	22/09/2010 - 22/09/2010		Chronic fatigue syndrome			Not		
								Viral infection	22/09/2010		recovered at		
								Lethargy	22/09/2010		time of		
								Somnolence	22/09/2010		reporting		
								Dysstasia	22/09/2010				
								Blood alkaline	09/2010				
								phosphatase increased					
								Fatigue	22/09/2010				
								Dizziness					
								Pallor					
								Headache					
								Joint swelling	06/2011				
								Rash	06/2011				
								Arthralgia	06/2011				
047097	30/09/2010	12 Years	Female	Prophylaxis	GARDASIL	23/09/2010 - 23/09/2010	.5 ml	Myalgia	23/09/2010		Recovered/r		
								Lethargy	23/09/2010		esolved		
								Headache	23/09/2010				
247424	00/00/00 5	40.14			0.455.4011	00/00/00/00 00/00/	ļ <u>.</u> .		00/00/00/				
047101	30/09/2010	12 Years	remale	Prophylaxis	GARDASIL	30/09/2010 - 30/09/2010	.5 ml	Presyncope	30/09/2010		Recovered/r		
1								Mydriasis	30/09/2010		esolved		
1								Dizziness	30/09/2010				
1								Fatigue Visual impairment	30/09/2010 30/09/2010		1		
1								Photopsia	30/09/2010		1		
1								Ποιορεία	30/03/2010		1		
		l	L				1		1	l	1	1	l .



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
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/r esolved		
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/r esolved		
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/r esolved		
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/r esolved		
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/r esolved		
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/r esolving		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
047133	06/10/2010		Female		GARDASIL			Fatigue			Unknown		
								Lethargy Somnolence					
								Sommolence					
047134	06/10/2010	12 Years	Female	Prophylaxis	GARDASIL	06/10/2010 -		Syncope	06/10/2010		Recovered/r		
											esolved		
047146	08/10/2010	13 Years	Female	Prophylaxis	GARDASIL	05/10/2010 -		Blood glucose increased	05/10/2010		Recovered/r	LANTUS	
								Ketonuria	05/10/2010		esolved	APIDRA	
								Asthenia	05/10/2010			ELTROXIN	
047156	11/10/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Vomiting	04/10/2010		Recovered/r		
				., ,							esolved		
047157	11/10/2010	13 Years	Female	Prophylaxis	GARDASIL		.5 ml	Rash	30/09/2010		Recovered/r		
								Headache	30/09/2010		esolved		
								Asthenia	30/09/2010				
								Nausea	30/09/2010				
								Syncope	30/09/2010 30/09/2010				
								Anxiety	30/09/2010				
047159	07/10/2010	13 Years	Female	Prophylaxis	GARDASIL	01/10/2010 -	.5 ml	Polydipsia	02/10/2010		Not		
								Thirst	02/10/2010		recovered at		
											time of		
											reporting		
047160	11/10/2010	13 Years	Female	Prophylaxis	GARDASIL		.5 ml	Asthenia	16/09/2010		Recovered/r		
											esolved		
047161	11/10/2010	13 Years	Female	Prophylaxis	GARDASIL		.5 ml	Clonus			Recovered/r		
								Syncope			esolved		
047162	11/10/2010	12 Years	Female	Prophylaxis	GARDASIL	17/09/2010 - 17/09/2010	.5 ml	Dizziness	17/09/2010		Recovered/r		
											esolved		
047190	14/10/2010	14 Years	Female	Prophylaxis	GARDASIL	06/10/2010 - 06/10/2010		Livedo reticularis	06/10/2010		Recovered/r		Asthma
								Throat irritation	06/10/2010		esolved		
								Asthenia	06/10/2010				
								Dizziness Hypersensitivity	06/10/2010 06/10/2010				
								riypersensitivity	00/10/2010				
047192	14/10/2010	13 Years	Female	Prophylaxis	GARDASIL	12/10/2010 -	.5 ml	Dizziness	12/10/2010		Not		
								Nausea	12/10/2010	1	recovered at		
								Gait disturbance	12/10/2010		time of		
2.17121	4.4/4.0/004.5	40.14	ļ		CARRAGE	00/00/00/0	1	10	00/00/00:5		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	06/10/2010		Not		Atrial septal defect
		,		- 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1				Headache	06/10/2010		recovered at		Petit mal epilepsy
								Dizziness	06/10/2010		time of		Asthma
								Pallor	06/10/2010		reporting		Constipation
								Somnolence	06/10/2010	1			



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HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2010-000020	19/10/2010	13 Years	Female	Prophylaxis	GARDASIL	08/10/2010 - 08/10/2010	.5 ml	Injection site reaction	08/10/2010		Not		
								Contusion	08/10/2010		recovered at		
								Oedema peripheral	08/10/2010		time of		
								Nausea	08/10/2010		reporting		
								Fatigue	08/10/2010				
2010-000034	20/10/2010	14 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -		Urticaria	07/10/2010		Recovered/r		
				, , , ,							esolved		
2010-000035	20/10/2010	13 Years	Female	Prophylaxis	GARDASIL	21/09/2010 - 21/09/2010	.5 ml	Headache	23/09/2010		Recovered/r		
								Fatigue	23/09/2010		esolved		
								Malaise	23/09/2010				
2010-000052	21/10/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 - 27/09/2010	1	Pruritus	02/10/2010	+	Recovered/r		
2010 000002	21/10/2010	10 Touro	Tomalo	Tophylaxio	O, III D, IOIE	2770072010 2770072010		Rash erythematous	02/10/2010		esolved		
								Nausea	06/10/2010				
2010-000053	21/10/2010	12 Years	Female	Prophylaxis	GARDASIL	05/10/2010 -	.5 ml	Dizziness	05/10/2010		Recovered/r		
								Decreased appetite	05/10/2010		esolved		
								Feeling cold	05/10/2010				
								Chills	05/10/2010				
2010-000055	21/10/2010	13 Years	Female	Prophylaxis	GARDASIL PER CENT	21/09/2010 -		Syncope	21/09/2010		Not		
				' '				Nausea			recovered at		
								Asthenia			time of		
								Fatigue			reporting		
								Malaise					
2010-000070	22/10/2010	14 Years	Female	Prophylaxis	GARDASIL	06/10/2010 - 06/10/2010		Dizziness	06/10/2010		Recovered/r	AMOXIL	Asthma
				., ,				Crying	06/10/2010		esolved		Lower respiratory tract
								Emotional distress	06/10/2010				infection
								Cough	06/10/2010				
								Flushing	06/10/2010				
								Stridor	06/10/2010				
								Hyperventilation	06/10/2010				
								Tetany	06/10/2010				
								Malaise	06/10/2010				
2010-000071	22/10/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 - 04/10/2010	1	Headache	04/10/2010	+	Unknown		
		. 5 . 5 . 10]		<i>5.</i>	3,2010 01,10,2010		Pain in extremity	04/10/2010				
	ĺ							Rash	1				
	1							Photophobia			1		
	1							Fatigue			1		
	1							Feeling hot			1		
								Pallor					
2010-000073	22/10/2010	13 Years	Female	Prophylaxis	GARDASIL	22/09/2010 -		Oedema peripheral	22/09/2010	1	Recovered/r		
2010-000073	22/10/2010	13 Teals	emale	ι τυριτιγιαλίο	GANDASIL	19/05/2010 -		Gederiia periprierai	22/03/2010		esolved		
	ļ	<u> </u>		ļ		15/55/2010				1	COOIVCG		<u> </u>



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
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 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/r esolved		
2010-000578	04/11/2010	13 Years	Female		GARDASIL	04/10/2010 - 04/10/2010		Hypersensitivity Urticaria Pruritus		12/10/2010 07/10/2010 12/10/2010	Recovered/r esolved		
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 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/r esolved		Headache



	Date of first									Reaction			
HDD A ID			Patient	Indications	Sucpost Drug(s)	Thorany Dates	Doco	Adverse Reaction(s)	Reaction	Cessation	Outcome	Concomitant Modication(s)	Medical History
HPRA ID 2010-000793	to HPRA	Age 12 Years	Sex	Indications Prophylaxis	Suspect Drug(s) GARDASIL	Therapy Dates 13/09/2010 - 13/09/2010	Dose	(MedDRA PT) Syncope Loss of consciousness Asthenia Disorientation Urinary incontinence Abdominal pain upper Nausea Pyrexia Headache Influenza like illness Dizziness Muscular weakness Cyanosis Dyspnoea	Onset Date	Date	Outcome Not recovered at time of reporting	Medication(s)	(MedDRA PT)/Comment
								Back pain Pain in extremity Myalgia					
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/r esolved		
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/r esolved		
2010-000884	17/11/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Syncope Headache	04/10/2010 04/10/2010		Recovered/r esolved		
2010-000927	18/11/2010		Female	Prophylaxis	GARDASIL	17/11/2010 -	.5 ml	Dizziness	17/11/2010	17/11/2010	Recovered/r esolved		
2010-000929	18/11/2010	12 Years		Prophylaxis	GARDASIL	17/11/2010 - 17/11/2010	.5 ml	Dizziness	17/11/2010	17/11/2010	Recovered/r esolved		
2010-000931	18/11/2010	12 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -		Paraesthesia Pyrexia	28/09/2010 28/09/2010		Recovered/r esolved		
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/r esolved		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/r esolved		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/r esolved		



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HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
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/r esolved		
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/r esolved		
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/r esolved		
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/r esolved		
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	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/r esolved		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/r esolved		
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/r esolved		
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 28/09/2010		Recovered/r esolved		
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/r esolved		
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/r esolved		
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/r esolved		



	Date of first									Reaction			
HPRA ID	notification to HPRA	Patient Age	Patient Sex	Indications	Suggest Davids	Therese Dates	Donne	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Cessation Date	0	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
2010-001090	24/11/2010	14 Years		Prophylaxis	Suspect Drug(s) GARDASIL	Therapy Dates 22/11/2010 - 22/11/2010	Dose	Headache	22/11/2010	22/11/2010	Not recovered at time of reporting	EPILIM	(MedDRA F1 //Comment
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/r esolved		
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/r esolved		
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/r esolved		
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/r esolved	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/r esolved		
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/r esolved		
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/r esolved		
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/r esolved		
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/r esolved		
2010-001195	29/11/2010	13 Years	Female	Prophylaxis	GARDASIL	21/09/2010 -	.5 ml	Urticaria Pruritus	22/09/2010 22/09/2010		Recovered/r esolved		
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/r esolved		
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/r esolved		
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/r esolved		
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/r esolved		
2010-001217	01/12/2010	12 Years	Female	Prophylaxis	GARDASIL	26/11/2010 - 26/11/2010	.5 ml	Asthenia	26/11/2010		Recovered/r esolved		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2010-001219	01/12/2010	13 Years	Female	Prophylaxis	GARDASIL	22/09/2010 - 22/09/2010		Lethargy	22/09/2010	23/09/2010	Recovered/r		
								Headache	22/09/2010	07/00/00/0	esolved		
								Local reaction	22/09/2010	27/09/2010			
2010-001220	01/12/2010	13 Years	Female	Prophylaxis	GARDASIL	26/11/2010 - 26/11/2010	.5 ml	Limb discomfort	26/11/2010		Recovered/r		
2040 004204	00/44/0040	40 Vaana	Famala	Decelo de vie	GARDASIL	04/44/0040 04/44/0040		Durania	24/11/2010		esolved		A diverse a constitution
2010-001304	26/11/2010	13 Years	Female	Prophylaxis	GARDASIL	24/11/2010 - 24/11/2010		Pyrexia Oropharyngeal pain	24/11/2010		Unknown		Adverse event following Prophylaxis
								Lymphadenopathy	24/11/2010				Tophylaxio
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/r esolved		
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/r esolved		
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		
2010 001011	00/12/2010		· omaio	. roprijiazao	07.11.127.10.12	2 1/ 1 1/2010 2 1/ 1 1/2010		injustion one entering	2171172010	00,11,2010	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/r		
					2.22.20						esolved		
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/r esolved		
2010-001362	07/12/2010	13 Years	Female	Prophylaxis	GARDASIL	06/12/2010 -	.5 ml	Oropharyngeal pain	06/12/2010	06/12/2010	Recovered/r		
								Swollen tongue	06/12/2010	06/12/2010	esolved		
2010-001387	07/12/2010	13 Years	Female	Prophylaxis	GARDASIL	05/10/2010 - 05/10/2010	.5 ml	Deep vein thrombosis	18/10/2010		-	WARFARIN	
								Pulmonary embolism	18/10/2010		esolving		
2010-001389	08/12/2010	14 Years	Female	Prophylaxis	GARDASIL	05/10/2010 - 05/10/2010	.5 ml	Cellulitis	19/10/2010		Recovered/r		
								Injection site mass	19/10/2010		esolved		
								Pyrexia	19/10/2010				
2010-001390	09/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 - 29/09/2010		Skin reaction	30/09/2010	02/10/2010	Recovered/r		
								Urticaria	30/09/2010	02/10/2010	esolved		
2010-001391	09/12/2010	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Local reaction	16/11/2010		Unknown		
								Injection site induration	16/11/2010				
								Pain in extremity	16/11/2010				
								Rash macular Urticaria	16/11/2010 16/11/2010				
			<u> </u>						13/11/2010	<u> </u>			
2010-001402	10/12/2010	13 Years	Female	Prophylaxis	GARDASIL	23/09/2010 - 23/09/2010	.5 ml	Pallor	23/09/2010	23/09/2010	Recovered/r		
								Dizziness Limb discomfort	23/09/2010 23/09/2010	23/09/2010 23/09/2010	esolved		
								Eye pruritus	23/09/2010	23/09/2010			
2010-001420	13/12/2010	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Urticaria	22/11/2010		Recovered/r		
2010-001420	13/12/2010	1+ 1 tals	emale	Τοριιγιαλίδ	GANDAGIL	22/11/2010 -	.5 1111	Unicalia	22/11/2010		esolved		
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	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
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	12/10/2010		Recovered/r		
								Vomiting	12/10/2010		esolved		
								Lethargy	12/10/2010				
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/r		Vaccination complication
											esolved		
2010-001435	14/12/2010		Female	Prophylaxis	GARDASIL	17/11/2010 -		Chest pain	17/11/2010		Recovered/r esolved		
2010-001436	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Dizziness			Recovered/r		
								Vision blurred			esolved		
								Pallor					
2010-001437	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL			Headache			Not		
								Hyperhidrosis			recovered at time of		
2010-001439	14/12/2010		Female		GARDASIL	15/09/2010 -		Syncope	15/09/2010		Recovered/r		
											esolved		
2010-001440	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	05/10/2010 -		Dizziness	05/10/2010		Recovered/r		
								Flushing	05/10/2010		esolved		
2010-001441	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	19/05/2010 -		Syncope	19/05/2010		Recovered/r		
											esolved		
2010-001442	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Feeling hot	05/10/2010		Recovered/r		
								Dizziness Asthenia	05/10/2010 05/10/2010		esolved		
								Astrierila	03/10/2010				
2010-001443	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL			Pain in extremity	05/10/2010		Recovered/r		
											esolved		
								Headache	05/10/2010				
2010-001444	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	05/10/2010 -		Nausea	05/10/2010		Recovered/r		
								Malaise			esolved		
2010-001445	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Presyncope			Recovered/r		
											esolved		
2010-001446	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Nausea	05/10/2010		Recovered/r esolved		
2010-001447	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL		1	Dizziness	05/10/2010		Recovered/r		
								Pallor	05/10/2010		esolved		
2010-001448	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	05/10/2010 -		Dizziness	05/10/2010		Recovered/r		
			2111013		0, 11, 15, 10, 12	15, 15,25 15			30, 10,2010		esolved		
2010-001449	14/12/2010	12 Years	Female		GARDASIL	04/10/2010 -		Headache	04/10/2010		Recovered/r		
											esolved		



	Date of first									Reaction			
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HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2010-001450	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL			Headache	15/09/2010		Recovered/r esolved		
								Pallor	15/09/2010				
2010-001451	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -		Abdominal pain upper	15/09/2010		Recovered/r esolved		
								Dizziness	15/09/2010				
2010-001452	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -		Dizziness	15/09/2010		Recovered/r esolved		
2010-001453	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -		Pain in extremity	15/09/2010		Recovered/r		
								Back pain	15/09/2010		esolved		
2010-001454	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	24/11/2010 -		Chills			Not recovered at	ACICLOVIR MONTELUKAST	Food allergy Eczema
											time of	SERETIDE	Asthma
											reporting	GRAZAX	Herpes simplex
												SALAMOL	, ,
2010-001456	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Dizziness	15/09/2010		Recovered/r esolved		
2010-001457	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -		Abdominal pain upper	15/09/2010		Recovered/r esolved		
2010-001458	14/12/2010		Female	Prophylaxis	GARDASIL	05/10/2010 -		Nausea	05/10/2010		Recovered/r esolved		
2010-001459	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Abdominal pain	15/09/2010		Recovered/r esolved		
2010-001460	14/12/2010	12 Years	Male	Prophylaxis	GARDASIL	21/09/2010 -		Dizziness	21/09/2010		Recovered/r esolved		
2010-001461	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL			Nausea			Recovered/r		
2010 001101	1,12,2010	12 10010	· omaio	i ropriyidado	0,110,10,12			Headache			esolved		
2010-001464	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	06/10/2010 -		Dizziness	06/10/2010		Recovered/r esolved		
2010-001465	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL			Dizziness	07/10/2010		Recovered/r		
								Asthenia	07/10/2010		esolved		
2010-001470	13/12/2010	19 Years	Female	Prophylaxis	GARDASIL	06/2010 -		Panic attack Anxiety	07/2010 07/2010		Not recovered at		
								Chest pain	07/2010		time of		
								Dizziness	07/2010		reporting		
								Limb discomfort	07/2010				
2010-001475	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL			Nausea			Recovered/r		
								Vomiting			esolved		
2010-001476	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Dizziness Headache			Recovered/r esolved		
								Tiodddollo			COOIVCG		
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	Date of first		_							Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2010-001477	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	21/09/2010 -		Headache	21/09/2010		Recovered/r		
								Dizziness	21/09/2010		esolved		
								Asthenia	21/09/2010				
2010-001478	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	17/11/2010 -		Feeling hot	17/11/2010		Recovered/r		
				. ,				Hyperhidrosis	17/11/2010		esolved		
0040 004470	4.4/4.0/004.0	44.7/	F	Daniel India	O A DD A OU	00/44/0040		D::	00/44/0040		D		
2010-001479	14/12/2010	14 Years	remaie	Prophylaxis	GARDASIL	03/11/2010 -		Dizziness	03/11/2010		Recovered/r esolved		
2010-001480	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	03/11/2010 -	.5 ml	Malaise	03/11/2010		Recovered/r		
				. ,				Headache	03/11/2010		esolved		
2010-001483	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Anxiety	30/09/2010	30/09/2010	Recovered/r		
								Feeling of body temperature change	30/09/2010	30/09/2010	esolved		
2010-001484	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Dizziness	30/09/2010		Recovered/r		
2010 001101	, .2,20.0	10 100.0	· omaio	1 Topinyianio	07.11.127.10.12	00,00,2010		Abdominal discomfort	30/09/2010		esolved		
2010-001486	15/12/2010	12 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Urticaria	27/09/2010		Not		
								Lethargy	27/09/2010		recovered at		
								Fatigue	27/09/2010		time of		
								Rash vesicular	27/09/2010		reporting		
								Pruritus	27/09/2010				
								Hypersensitivity	27/09/2010				
2010-001487	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Abdominal discomfort	30/09/2010	30/09/2010	Recovered/r		
2010-001467	14/12/2010	13 Teals	remale	Fiopilylaxis	GARDASIL			Dizziness	30/09/2010	30/09/2010	esolved		
								DIZZINOOO	00/00/2010	00/00/2010	Coolvod		
2010-001488	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Pain in extremity	30/09/2010		Recovered/r		
								Headache	30/09/2010		esolved		
								Nausea	30/09/2010				
2010-001490	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Headache	30/09/2010		Recovered/r		
20.0000.00	, .2,20.0	10 100.0	· omaio	. roprijianio	07.11.127.10.12	00,00,2010		Nausea	30/09/2010		esolved		
2010-001492	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Nausea	30/09/2010		Recovered/r		
								Dizziness	30/09/2010		esolved		
2010-001493	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Dizziness	30/09/2010		Recovered/r		
				','"				Asthenia	30/09/2010		esolved		
2010-001494	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -		Nausea	29/09/2010	29/09/2010	Recovered/r		
								Dizziness	29/09/2010	29/09/2010	esolved		
2010-001495	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -		Dizziness	29/09/2010	29/09/2010	Recovered/r		
								Pallor	29/09/2010	29/09/2010	esolved		
2010 001406	14/12/2010	13 Years	Eomolo	Prophylovic	GARDASIL	30/09/2010 -		Hoodoobo	30/09/2010	30/09/2010	Pagayarad/r		
2010-001496	14/12/2010	13 rears	Female	Prophylaxis	GAKDASIL	30/09/2010 -		Headache			Recovered/r		
								Abdominal discomfort	30/09/2010	30/09/2010	esolved		
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	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2010-001497	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Headache	30/09/2010		Recovered/r		
								Dizziness	30/09/2010		esolved		
2010-001498	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Dizziness	30/09/2010	30/09/2010	Recovered/r		
								Abdominal discomfort	30/09/2010	30/09/2010	esolved		
0010 001100	4.4/4.0/004.0	40			0.455.400	44/40/0040		D: :	11/10/0010		5 "		
2010-001499	14/12/2010	13	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness	11/10/2010		Recovered/r		
		Weeks									esolved		
2010-001500	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Dizziness	30/09/2010	30/09/2010	Recovered/r		
								Nausea	30/09/2010	30/09/2010	esolved		
2040 004504	4.4/4.0/004.0	42 Vaara	Famala	Deschidents	CARRACII	44/40/0040		Diminana	44/40/0040	1	D /-		
2010-001501	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness Pallor	11/10/2010 11/10/2010		Recovered/r esolved		
								Fallul	11/10/2010		esoived		
2010-001502	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Asthenia	30/09/2010	30/09/2010	Recovered/r		
2010 001002	1-1/12/2010	10 10010	Tomaio	Торпушло	O, II (B) (O)E	00/00/2010		Dizziness	30/09/2010	30/09/2010	esolved		
2010-001503	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness	11/10/2010		Recovered/r		
				. ,				Pallor	11/10/2010		esolved		
2010-001504	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Syncope	30/09/2010	30/09/2010	Recovered/r		
								Dizziness	30/09/2010	30/09/2010	esolved		
2010-001505	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness	11/10/2010		Recovered/r		
								Asthenia	11/10/2010		esolved		
2010-001506	14/12/2010	13 Years	Female	Drophylovia	GARDASIL			Dizziness	_	-	Recovered/r		
2010-001506	14/12/2010	13 Teals	remale	Prophylaxis	GARDASIL			Dizziness			esolved		
2010-001507	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -	.5 ml	Dizziness	29/09/2010				
2010-001507	14/12/2010	12 rears	remale	Propriyiaxis	GARDASIL	29/09/2010 -	.5 1111	DIZZITIESS	29/09/2010		Recovered/r esolved		
2010-001508	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Asthenia	11/10/2010	-	Recovered/r		
2010-001506	14/12/2010	13 rears	remale	Propriyiaxis	GARDASIL			Dizziness	11/10/2010		esolved		
								Pain in extremity	11/10/2010		0001100		
2010-001509	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL			Oropharyngeal pain			Recovered/r		
				, ,				, , , , ,			esolved		
2010-001510	14/12/2010	15 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -	.5 ml	Dizziness	29/09/2010		Recovered/r		
				, ,				Emotional distress	29/09/2010		esolved		
								Headache	29/09/2010				
								Nausea	29/09/2010				
										1			
2010-001511	14/12/2010	12 Years	Female		GARDASIL	29/09/2010 -	.5 ml	Pallor	29/09/2010	1	Recovered/r		
		ļ								1	esolved		
2010-001512	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -	.5 ml	Dizziness	29/09/2010		Recovered/r		
1								Headache	29/09/2010	1	esolved		
2010 001510	14/12/2010	12 V	Fom -!-	Drophylovia	GARDASIL	20/00/2010	F!	Novece	20/00/2012		Doggrand 4	METHOTBEVATE	Dhoumate intended
2010-001513	14/12/2010	13 Years	remale	Prophylaxis	GAKDASIL	29/09/2010 -	.5 ml	Nausea	29/09/2010	1	Recovered/r esolved	METHOTREXATE LOSAMEL	Rheumatoid arthritis
								Headache Malaise	29/09/2010 29/09/2010		CSUIVEU	NAPROSYN	
1								Maiaise	23/03/2010	1		TOO IN	



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2010-001514	14/12/2010		Female	Prophylaxis	GARDASIL	29/09/2010 - 29/09/2010	.5 ml	Syncope	29/09/2010		Recovered/r	(5)	
				. ,							esolved		
2010-001515	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	29/09/2010 - 29/09/2010	.5 ml	Feeling hot	29/09/2010		Recovered/r		
				. ,				Cold sweat	29/09/2010		esolved		
2010-001516	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -	.5 ml	Dizziness	29/09/2010		Recovered/r		
								Nausea	29/09/2010		esolved		
											ļ		
2010-001517	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Dizziness	04/10/2010		Recovered/r		
											esolved		
2010-001518	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	04/04/2010 -	.5 ml	Dizziness	04/04/2010		Recovered/r		
											esolved		
2010-001519	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Dizziness	04/10/2010		Recovered/r esolved		
2012 201522	1.1/10/0010	10.11		5	0.4.00.4.00	0.4/4.0/00.4.0		D: :	0.4/4.0/0.04.0	0.4/4.0/004.0			
2010-001520	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Dizziness	04/10/2010	04/10/2010	Recovered/r esolved		
								Nausea	04/10/2010	04/10/2010	esoived		
2010-001521	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Dizziness	04/10/2010	04/10/2010	Recovered/r		
2010-001321	14/12/2010	15 Tears	Telliale	Τοριιγιαλίδ	GANDAGIL	04/10/2010 -	.5 1111	DIZZIIIESS	04/10/2010	04/10/2010	esolved		
2010-001522	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness	28/09/2010		Recovered/r		
2010-001322	14/12/2010	13 Teals	remale	Fiophylaxis	GANDASIL	28/09/2010 -	.5 1111	Somnolence	28/09/2010		esolved		
								Sommorence	20/03/2010		CSOIVCG		
2010-001523	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Dizziness	04/10/2010	04/10/2010	Recovered/r		
				., ,				Headache	04/10/2010	04/10/2010	esolved		
								Emotional distress	04/10/2010	04/10/2010			
2010-001524	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness	28/09/2010		Recovered/r		
											esolved		
2010-001525	16/12/2010	13 Years	Female	Prophylaxis	GARDASIL	29/11/2010 -	.5 ml	Grand mal convulsion	03/12/2010		Recovered/r		
											esolved		
2010-001526	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness	28/09/2010	28/09/2010	Recovered/r		
								Pallor	28/09/2010	28/09/2010	esolved		
2212 221525	1.1/10/0010	10.11		D	0.4.00.4.00	00/00/00/0			00/00/0040		5 "		
2010-001527	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Malaise	28/09/2010		Recovered/r esolved		
0040 004500	4.4/4.0/004.0	44.1/	E I .	Daniel de de	O A DD A OII	10/10/0010 10/10/0010	E1	D''	40/40/0040	40/40/0040			
2010-001528	14/12/2010	14 Years	remaie	Prophylaxis	GARDASIL	13/10/2010 - 13/10/2010	.5 ml	Dizziness	13/10/2010	13/10/2010	Recovered/r esolved		
2040 004500	4.4/4.0/004.0	44 //	Famala	Deservation	CADDACII	20/00/2010	F	Diminos	00/00/0040				
2010-001529	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness Pallor	28/09/2010 28/09/2010		Recovered/r esolved		
								Palloi	26/09/2010		esoived		
2010-001531	16/12/2010	13 Years	Female	Prophylaxis	GARDASIL	14/12/2010 -	.5 ml	Headache	14/12/2010	14/12/2010	Recovered/r		
2010 001001	. 5/ 12/2010	.5 10013	. omaio		3,1110,1012	, 12,2010	.5	Nausea	14/12/2010	14/12/2010	esolved		
2010-001532	16/12/2010	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -		Malaise	16/11/2010		Unknown		
				' '				Hypoaesthesia	16/11/2010				
								Pyrexia	16/11/2010			1	
								Vomiting	16/11/2010				
								Lethargy	16/11/2010				
					·			·					



	Date of first									Reaction			
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HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2010-001533	16/12/2010	14 Years	Female	Prophylaxis	GARDASIL	14/12/2010 -	.5 ml	Malaise	14/12/2010	14/12/2010	Recovered/r esolved		
2010-001534	16/12/2010	14 Years	Female	Prophylaxis	GARDASIL	14/12/2010 -	.5 ml	Headache	14/12/2010		Recovered/r		
								Dizziness	14/12/2010		esolved		
2010-001535	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	13/10/2010 -	.5 ml	Dizziness	13/10/2010	13/10/2010	Recovered/r		
											esolved		
2010-001536	16/12/2010	14 Years	Female	Prophylaxis	GARDASIL	24/09/2010 -	.5 ml	Nausea	24/09/2010		Recovered/r		
											esolved		
2010-001537	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Abdominal discomfort	28/09/2010	28/09/2010	Recovered/r		
								Headache	28/09/2010	28/09/2010	esolved		
								Nausea	28/09/2010	28/09/2010			
2010-001538	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 - 28/09/2010	.5 ml	Dizziness	28/09/2010		Recovered/r		
				. ,							esolved		
2010-001539	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Abdominal discomfort	28/09/2010		Recovered/r		
											esolved		
2010-001540	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Abdominal discomfort	28/09/2010		Recovered/r esolved		
2010-001541	14/12/2010	13 Years	Female	Prophylovic	GARDASIL	28/09/2010 -	.5 ml	Dizziness	28/09/2010		1		
2010-001541	14/12/2010	13 Years	remaie	Prophylaxis		28/09/2010 -	.s mi	Dizziness			Recovered/r esolved		
2010-001542	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 - 28/09/2010	.5 ml	Dizziness	28/09/2010	28/09/2010	Recovered/r		
								Abdominal discomfort	28/09/2010	28/09/2010	esolved		
								Headache	28/09/2010	28/09/2010			
2010-001543	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness	28/09/2010		Recovered/r		
											esolved		
2010-001544	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Presyncope	28/09/2010	28/09/2010	Recovered/r		
								Pallor	28/09/2010	28/09/2010	esolved		
								Hyperhidrosis	28/09/2010	28/09/2010			
2010-001545	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL		.5 ml	Nausea	11/10/2010		Unknown		
								Dizziness	11/10/2010				
2010-001547	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness	11/10/2010		Recovered/r		
2010 001011	, .2,20.0	10 10010	· omaio	. ropinylazao	0,11,0,10,12	1.17.1072010		5.22000	11,10,2010		esolved		
2010-001548	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness	01/10/2010		Recovered/r		
								Chills	11/10/2010		esolved		
2010-001549	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Presyncope	27/09/2010	27/09/2010	Recovered/r		
								Headache	27/09/2010	27/09/2010	esolved		
2010-001550	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Headache	28/09/2010	28/09/2010	Recovered/r esolved		
2010-001551	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -	<u> </u>	Dizziness	29/09/2010		Recovered/r		
								Nausea	29/09/2010		esolved		
2010-001552	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Dizziness			Recovered/r esolved		
											esoiveu		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2010-001556	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -		Dizziness	29/09/2010		Recovered/r		
								Pallor	29/09/2010		esolved		
2010-001557	14/12/2010	13 Years	Fomalo	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness	28/09/2010		Recovered/r		
2010 001007	1-1/12/2010	10 Tours	Tomalo	Торпушлю	O/ II (D/ (O)E	20/00/2010		DIZZINOOS	20/00/2010		esolved		
2010-001558	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Headache	28/09/2010		Recovered/r		
				' '				Nausea	28/09/2010		esolved		
2010-001559	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -		Dizziness	29/09/2010		Recovered/r		
				' '				Headache	29/09/2010		esolved		
2010-001560	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Dizziness	04/10/2010		Recovered/r		
				, ,							esolved		
2010-001561	14/12/2010	14 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Nausea	28/09/2010		Recovered/r		
							10				esolved		
2010-001562	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Abdominal pain	28/09/2010		Recovered/r		+
2010 001002	1-1/12/2010	10 10010	Tomalo	Tophylaxio	G, II E, IOIE	20/00/2010	.0 1111	Dizziness	28/09/2010		esolved		
								Feeling of body	28/09/2010		COOIVCG		
								temperature change	20/00/2010				
2010-001563	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL			Dizziness			Unknown		
2010 001303	14/12/2010	12 Tours	Tomaic	Tophylaxis	GARBAGIE			Panic attack			Officiowit		
								I allic attack					
2010-001564	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -	.5 ml	Dizziness	28/09/2010		Recovered/r		
2010 001304	14/12/2010	10 TCars	Tomaic	Tophylaxis	GARBAGIE	20/03/2010	.5 1111	Feeling of body	28/09/2010		esolved		
								temperature change	20/00/2010		COOIVCG		
2010-001565	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Dizziness			Unknown		+
2010 001000	1-1/12/2010	10 10010	Tomalo	Гторпушлю	O, III D, IOIE			Pallor			Onthown		
								1					
2010-001566	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Dizziness	27/09/2010	27/09/2010	Recovered/r		
								Asthenia	27/09/2010	27/09/2010	esolved		
2010-001567	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL			Headache			Unknown		
				,,,,,				Pain in extremity					
2010-001568	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Dizziness	27/09/2010		Recovered/r		
				, ,							esolved		
2010-001569	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	11/10/2010 -		Dizziness	11/10/2010		Recovered/r		
								Hypoaesthesia	11/10/2010		esolved		
								,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					
2010-001570	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Presyncope	27/09/2010	27/09/2010	Recovered/r	1	
				-1			1	7			esolved		
2010-001571	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Dizziness	27/09/2010	1	Recovered/r		1
					S	2.755,2516	1.5		2.,55,2510		esolved		
2010-001572	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Abdominal pain	27/09/2010	27/09/2010	Recovered/r		1
2010 001012	, 12,2010	.2 10013	. omaio		3,110,1012	2770072010		Headache	27/09/2010	27/09/2010	esolved		
	ĺ								2770072010	2.700/2010			
2010-001573	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Presyncope	27/09/2010		Recovered/r		
				-1	[.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	1	1 - 3,			esolved		
L	i	L	1	1						1		i	



	Date of first									Reaction			
HPRA ID	notification to HPRA	Patient Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Cessation Date	Outcome	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
2010-001574	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Dizziness	27/09/2010	Date	Recovered/r	wedication(s)	(MedDRA PT)/Comment
2010-001374	14/12/2010	15 Tears	i emale	Торпуналіз	GANDAGIL	21/03/2010 -	.5 1111	Headache	27/09/2010		esolved		
2010-001575	15/12/2010	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Malaise	22/11/2010	22/11/2010	Recovered/r		
											esolved		
2010-001576	15/12/2010	13 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Malaise	22/11/2010	22/11/2010	Recovered/r		
								Fatigue	22/11/2010	22/11/2010	esolved		
2010-001577	15/12/2010	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Fatigue	22/11/2010	22/11/2010	Recovered/r		Asthenia
								l angus			esolved		
2010-001578	15/12/2010	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Malaise	22/11/2010	22/11/2010	Recovered/r		
								Dizziness	22/11/2010	22/11/2010	esolved		
2010 201572	45/40/0040	40.14			0.4.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0	20/11/2012			00/11/0010	00/44/0040			
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/r esolved		
								riedudorie	22/11/2010	22/11/2010	esoived		
2010-001580	14/12/2010	13 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Headache	27/09/2010		Recovered/r		
				, ,							esolved		
2010-001581	14/12/2010	12 Years	Female	Prophylaxis	GARDASIL	27/09/2010 -	.5 ml	Abdominal pain	27/09/2010		Recovered/r		
											esolved		
2010-001584	14/12/2010	12 Years	Female		GARDASIL	27/09/2010 -	.5 ml	Presyncope	27/09/2010		Recovered/r		
								Nausea	27/09/2010		esolved		
2010-001590	17/12/2010		Female		GARDASIL			Cyanosis			Unknown		
								,					
2010-001591	17/12/2010		Female		GARDASIL			Cyanosis			Recovered/r		
											esolved		
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/r esolved	LAMICTAL	Epilepsy
2010-001608	20/12/2010	13 Years	Female	Prophylaxis	GARDASIL	15/12/2010 - 15/12/2010	.5 ml	Abdominal discomfort	15/12/2010		Recovered/r		
2010-001000	20/12/2010	15 Teals	i emale	Торпуналіз	GANDAGIL	13/12/2010 - 13/12/2010	.5 1111	Headache	15/12/2010		esolved		
2010-001610	20/12/2010	13 Years	Female	Prophylaxis	GARDASIL	15/12/2010 - 15/12/2010	.5 ml	Dermatitis allergic	15/12/2010		Recovered/r		
								Pruritus	15/12/2010		esolved		
								Rash erythematous	15/12/2010				
2010-001616	20/12/2010	12 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	1	Nausea	04/10/2010		Recovered/r		
20.0001010	23/12/2010	10013	. Jiliaio		0,110,1012	3.710/2010		Vomiting	04/10/2010		esolved		
							<u> </u>	· ·					
2010-001617	20/12/2010	13 Years	Female	Prophylaxis	GARDASIL	10/2010 -	.5 ml	Rash	22/11/2010		Recovered/r		
								Headache			esolved		
								Urticaria					
2010-001671	23/12/2010	13 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -	.5 ml	Headache	04/10/2010		Recovered/r		
										1	esolved		



	Date of first	Bartani.	Barriago I					A book Brooks (a)	Barrellan	Reaction		0	Ma Paul I Paterna
HPRA ID	notification to HPRA	Patient Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Cessation Date	Outcome	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
2010-001675	23/12/2010	14 Years		Prophylaxis	GARDASIL	20/10/2010 - 20/10/2010	Dose	Rash pruritic	Offset Date	Date	Recovered/r	PREDNISOLONE	Myasthenia gravis
2010-001073	23/12/2010	14 Teals	Temale	Τοριιγιαλίο	GANDAGIE	20/10/2010 - 20/10/2010		Sleep disorder			esolved	AZATHIOPRINE	wyasulelia gravis
2011-001706	04/01/2011	12 Years	Female	Prophylaxis	GARDASIL	19/09/2010 -	.5 ml	Headache Dizziness	19/09/2010		Unknown		
								Presyncope Tonsillitis	10/2010				
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/r esolved		
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/r esolved		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/r esolved		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/r esolved		
2011-001800	13/01/2011	14 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Dizziness	22/11/2010	22/11/2010	Recovered/r esolved		
2011-001801	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	22/11/2010 -	.5 ml	Nausea Dizziness	22/11/2010 22/11/2010		Recovered/r esolved		
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/r esolved		
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/r esolved		



	Date of first									Reaction			
	notification	Patient	Patient		200	_, _,		Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA 13/01/2011	Age	Sex	Indications	Suspect Drug(s) GARDASIL	Therapy Dates	.5 ml	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2011-001804	13/01/2011	14 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 MI	Malaise Headache	16/11/2010 16/11/2010		Recovered/r esolved		
								neadache	16/11/2010		esoiveu		
2011-001805	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	28/09/2010 -		Headache	28/09/2010		Recovered/r		
2011 001003	13/01/2011	10 TCars	Terriale	Τοριιγιαλίο	GARDAGIE	20/03/2010		Dizziness	28/09/2010		esolved		
								Nausea	28/09/2010		000.104		
2011-001806	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -		Abdominal pain upper	16/11/2010		Recovered/r		
								Feeling hot	16/11/2010		esolved		
								Dysgeusia	16/11/2010				
								Headache	16/11/2010				
								Cold sweat	16/11/2010				
2011-001807	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Chills	16/11/2010		Recovered/r		
								Fatigue	16/11/2010		esolved		
								Dizziness	16/11/2010				
2011-001809	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Malaise	16/11/2010		Recovered/r		
2011 001003	13/01/2011	10 TCars	Terriale	Τοριιγιαλίο	GARDAGIE	10/11/2010	.5 1111	Walaise	10/11/2010		esolved		
2011-001818	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -		Dizziness	16/11/2010		Recovered/r		
2011-001010	13/01/2011	15 Teals	lemale	Τοριιγιαλίο	GANDASIE	10/11/2010 -		Headache	16/11/2010		esolved		
								1 loadaone	10/11/2010		COOIVCG		
2011-001819	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Headache	16/11/2010		Recovered/r		
											esolved		
2011-001824	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Headache	16/11/2010		Recovered/r		
								Nausea	16/11/2010		esolved		
2011-001826	13/01/2011	14 Years	Female	Prophylaxis	GARDASIL	16/11/2010 - 16/11/2010	.5 ml	Headache	16/11/2010		Recovered/r		
											esolved		
2011-001827	13/01/2011	12 Years	Female		GARDASIL	16/11/2010 - 16/11/2010	.5 ml	Dizziness	16/11/2010		Recovered/r		
											esolved		
2011-001828	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	09/12/2010 -	.5 ml	Dizziness	09/12/2010		Recovered/r		
								Nausea	09/12/2010		esolved		
2011-001829	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	09/12/2010 - 19/12/2010	.5 ml	Dizziness	09/12/2010		Recovered/r		
								Nausea	09/12/2010		esolved		
2011-001830	12/01/2011	12 Vaa	Famala	Drophylovia	GARDASIL	16/11/2010 -		Dizzinoso	16/11/2010		December 1/2		
2011-001830	13/01/2011	12 Years	Female	Prophylaxis	GAKDASIL	16/11/2010 -		Dizziness Visual impairment	16/11/2010 16/11/2010		Recovered/r esolved		
								Headache	16/11/2010		esoiveu		
								Ticauacric	10/11/2010				
2011-001831	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Chills	16/11/2010		Recovered/r		
		. 5 . 5 . 10	. 5		0202			Feeling cold	16/11/2010		esolved		
								Abdominal discomfort	16/11/2010				
2011-001832	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Headache	16/11/2010		Recovered/r		
								Dizziness	16/11/2010		esolved		
		<u> </u>											
												-	



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2011-001849	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	15/11/2010 -	.5 ml	Feeling hot	15/11/2010		Recovered/r		
								Dizziness	15/11/2010		esolved		
2011-001854	13/01/2011	12 Years	Fomale	Prophylaxis	GARDASIL			Dizziness			Not		
2011-001034	13/01/2011	12 16013	lemale	Τοριιγιαλίδ	GANDAGIE			Nausea			recovered at		
								Nausca			time of		
											reporting		
2011-001856	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	15/11/2010 -		Nausea	15/11/2010		Not		
2011-001030	13/01/2011	12 16013	lemale	Τοριιγιαλίδ	GANDAGIE	13/11/2010 -		Headache	15/11/2010		recovered at		
								Dizziness	15/11/2010		time of		
								Abdominal pain	15/11/2010		reporting		
								7 Ibaariinai pairi	10/11/2010				
2011-001857	13/01/2011	14 Years	Female	Prophylaxis	GARDASIL	15/11/2010 -		Dizziness	15/11/2010		Recovering/r		
											esolving		
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/r		
2011 001000	10,01,2011	10 100.0	· omaio	. ropinyianao	0,, 0, 1			3.22000			esolved		
2011-001864	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	15/11/2010 -		Nausea	15/11/2010		Recovered/r		
								Dizziness	15/11/2010		esolved		
2011-001866	13/01/2011	14 Years	Female	Prophylaxis	GARDASIL	15/11/2010 -		Dizziness	15/11/2010		Recovered/r		
											esolved		
2011-001869	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL			Asthenia			Recovered/r		
								Dizziness			esolved		
								Pallor					
2011 2012	10/01/0011	40.14			0.455.4011			B					
2011-001870	13/01/2011	13 Years	remale	Prophylaxis	GARDASIL			Dizziness			Recovered/r		
								Headache			esolved		
2011-001872	13/01/2011	14 Years	Female	Prophylaxis	GARDASIL			Headache			Recovered/r		
2011 001072	13/01/2011	14 Todis	Ciliaic	Τορπγιαλίο	GARBAGIE			ricadacric			esolved		
2011-001873	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL			Syncope	10/12/2010		Recovered/r		
2011 001070	10/01/2011	12 10010	Tomalo	Γιορπγιαλίο	G/ II G/ IOIE			Dizziness	10/12/2010		esolved		
									15, 12, 25 10		12000		
2011-001874	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL	13/10/2010 -	.5 ml	Dizziness	13/10/2010		Recovered/r		
				-							esolved		
2011-001875	13/01/2011	13 Years	Female	Prophylaxis	GARDASIL		.5 ml	Dizziness			Recovered/r		
								Headache			esolved		
								Nausea					



	Date of first notification	Patient	Patient					Adverse Reaction(s)	Reaction	Reaction Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
	20/01/2011	14 Years		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 01/12/2010	22/12/2010 22/12/2010 22/12/2010 22/12/2010 22/12/2010	Recovered/r esolved		
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/r esolved		
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/r esolved		
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 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/r esolved		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/r esolved		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/r esolved		Phobia
2011-002037	28/01/2011	14 Years	Female	Prophylaxis	GARDASIL	25/01/2011 -		Arthralgia	25/01/2011		Recovered/r esolved		
2011-002222	13/01/2011	12 Years	Female	Prophylaxis	GARDASIL	21/09/2010 - 21/09/2010		Dizziness	21/09/2010		Recovered/r esolved		



	Date of first notification	Patient	Patient					Adverse Reaction(s)	Reaction	Reaction Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(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			Not recovered at time of reporting		
								Headache					
2011-002757	14/03/2011	13 Years	Female	Prophylaxis	GARDASIL	10/03/2011 -	.5 ml	Dizziness	10/03/2011		Recovered/r esolved		
2011-002758	14/03/2011	14 Years	Female	Prophylaxis	GARDASIL	09/03/2011 -	.5 ml	Pallor	09/03/2011	09/03/2011	Recovered/r esolved		
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/r esolved		
2011-002763	14/03/2011	13 Years	Female	Prophylaxis	GARDASIL	10/03/2011 -	.5 ml	Malaise	10/03/2011		Recovered/r esolved		Coeliac disease
2011-002765	14/03/2011	13 Years	Female	Prophylaxis	GARDASIL	10/03/2011 -	.5 ml	Dizziness Malaise			Recovered/r esolved		
2011-002766	14/03/2011	14 Years	Female	Prophylaxis	GARDASIL	09/03/2011 - 09/03/2011	.5 ml	Headache	09/03/2011		Recovered/r esolved		
2011-002767	14/03/2011	13 Years	Female	Prophylaxis	GARDASIL	09/03/2011 -	.5 ml	Asthenia	09/03/2011		Recovered/r esolved		
2011-002768	14/03/2011	14 Years	Female	Prophylaxis	GARDASIL	09/03/2011 - 09/03/2011	.5 ml	Headache	09/03/2011		Recovered/r esolved		
2011-002769	14/03/2011		Female	Prophylaxis	GARDASIL DITEBOOSTER	09/03/2011 - 09/03/2011 09/03/2011 - 09/03/2011	.5 ml	Dizziness	09/03/2011		Recovered/r esolved		
2011-002883	21/03/2011	14 Years	Female	Prophylaxis	GARDASIL	09/2010 -	.0 1111	Vision blurred			Not	PHARMATON	
						11/2010 -		Syncope Dermal cyst Fatigue Tremor			recovered at time of reporting		
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		



	Date of first notification	Patient	Patient					Adverse Reaction(s)	Reaction	Reaction Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2011-002930	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	29/11/2010 -	.5 ml	Dizziness	29/11/2010		Unknown	(-)	
								Tremor	29/11/2010				
2011-002934	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	29/11/2010 -	.5 ml	Dizziness	29/11/2010		Recovered/r		
				. ,							esolved		
2011-002935	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	24/11/2010 -	.5 ml	Dizziness	24/11/2010		Unknown		
								Feeling hot	24/11/2010				
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		
								rieadacrie	13/10/2010				
2011-002941	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL		.5 ml	Headache			Unknown		
								Dizziness					
								Abdominal discomfort					
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	23/11/2010		Unknown		
								Pallor	23/11/2010				
2011-002946	24/03/2011	14 Years	Not	Prophylaxis	GARDASIL	24/11/2010 -	.5 ml	Feeling of body	24/11/2010		Unknown		
			specified	, ,				temperature change					
								Tachycardia	24/11/2010				
2011-002947	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL	23/11/2010 -	.5 ml	Dizziness	23/11/2010		Unknown		
				, ,				Headache	23/11/2010				
								Tremor	23/11/2010				
								Feeling hot	23/11/2010				
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	23/11/2010		Unknown		
								Abdominal discomfort	23/11/2010				
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	23/11/2010		Unknown		
								Cold sweat	23/11/2010				
L	1	1	<u> </u>	ļ			<u></u>			<u> </u>	Į	ļ	



	Unknown Unknown Unknown Unknown Unknown Unknown Unknown	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
HPRA ID to HPRA Age Sex Indications Suspect Drug(s) Therapy Dates Dose (MedDRA PT) Onset Date Date 2011-002955 24/03/2011 13 Years Female Prophylaxis GARDASIL 23/11/2010 - .5 ml Oropharyngeal pain pain pain nextremity 23/11/2010 cough 23/11/2010 cough 23/11/2010 cough 23/11/2010 cough 23/11/2010 cough 23/11/2010 cough .5 ml Abdominal pain Muscle spasms Muscle spasms Discount of the pain cough pain pain masses 23/11/2010 cough pain pain pain masses 23/11/2010 cough pain pain pain masses 23/11/2010 cough pain pain pain pain pain pain pain pain	Unknown Unknown Unknown Unknown Unknown		
Pain in extremity 23/11/2010 Headache 23/11/2010 Cough 23/11/2010 Cough 23/11/2010	Unknown Unknown Unknown		
Headache Cough C	Unknown		
Cough 23/11/2010	Unknown		
2011-002956 24/03/2011 12 Years Female Prophylaxis GARDASIL .5 ml Abdominal pain Muscle spasms 2011-002957 24/03/2011 12 Years Female Prophylaxis GARDASIL 23/11/20105 ml Headache 23/11/2010 2011-002958 24/03/2011 12 Years Female Prophylaxis GARDASIL .5 ml Dizziness Headache 2011-002959 24/03/2011 12 Years Female Prophylaxis GARDASIL .5 ml Dizziness D	Unknown		
Muscle spasms Muscle spasms 2011-002957 24/03/2011 12 Years Female Prophylaxis GARDASIL 23/11/20105 ml Headache 23/11/2010 2011-002958 24/03/2011 12 Years Female Prophylaxis GARDASIL .5 ml Dizziness Headache 2011-002959 24/03/2011 12 Years Female Prophylaxis GARDASIL .5 ml Dizziness Dizziness Dizziness Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis CARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis CARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years 2011-002959 24/03/2011 2 Years Prophylaxis 2011-002959 24/03/2011 2 Years 2011-002959 2	Unknown		
Muscle spasms Muscle spasms 2011-002957 24/03/2011 12 Years Female Prophylaxis GARDASIL 23/11/20105 ml Headache 23/11/2010 2011-002958 24/03/2011 12 Years Female Prophylaxis GARDASIL .5 ml Dizziness Headache 2011-002959 24/03/2011 12 Years Female Prophylaxis GARDASIL .5 ml Dizziness Dizziness Dizziness Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis GARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis CARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years Female Prophylaxis CARDASIL .5 ml Dizziness 2011-002959 24/03/2011 2 Years 2011-002959 24/03/2011 2 Years Prophylaxis 2011-002959 24/03/2011 2 Years 2011-002959 2	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 2011-002959 24/03/2011 12 Years Female Prophylaxis GARDASIL .5 ml Dizziness	Unknown		
2011-002958 24/03/2011 12 Years Female Prophylaxis GARDASIL .5 ml Dizziness Headache 2011-002959 24/03/2011 12 Years Female Prophylaxis GARDASIL .5 ml Dizziness	Unknown		_
Headache			
2011-002959 24/03/2011 12 Years Female Prophylaxis GARDASIL .5 ml Dizziness	Unknown		
	Unknown	1	
	Unknown		
2011-002960 24/03/2011 12 Years Female Prophylaxis GARDASIL 29/11/20105 ml Dizziness 29/11/2010	1		
12011-002300 24/03/2011 12 Teals Felliale Flophylaxis GANDASIL 23/11/2010 - .5 IIII DIZZIIIESS 123/11/2010	Unknown		
Chest discomfort 29/11/2010	Ulkilowii		
2011-002961 24/03/2011 14 Years Female Prophylaxis GARDASIL 25/11/20105 ml Dizziness 25/11/2010	Unknown		
Abdominal pain lower 25/11/2010			
Headache 25/11/2010			
2011-002962 24/03/2011 13 Years Female Prophylaxis GARDASIL 13/12/20105 ml Dizziness 13/12/2010	Not		
247 002502 247002501 15 Teals 1 Children 107122515	recovered at	1	
	time of		
	reporting		
2011-002963 24/03/2011 13 Years Female Prophylaxis GARDASIL 24/11/20105 ml Dizziness 24/11/2010	Unknown		
2011-002964 24/03/2011 13 Years Female Prophylaxis GARDASIL 13/12/20105 ml Nausea 13/12/2010	Unknown		
2011-002965 24/03/2011 12 Years Female Prophylaxis GARDASIL 29/11/2010 - .5 ml Dizziness 29/11/2010	Not		Asthma
Headache 29/11/2010	recovered at time of		
	reporting		
	, ,		
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 29/11/20105 ml Dizziness 29/11/2010	Unknown		
20/11-002967 24/05/2011 14 feals Female Propriyaxis GARDASIL 29/11/2010 - .5 mil Dizzmess 29/11/2010 Ear discomfort 29/11/2010	Unknown		
2011-002968	Unknown		
Headache 13/12/2010			
Feeling cold 13/12/2010			
2011-002970	Recovered/r		
22/03/2011 13 Years Female Propriyraxis GARDASIL 22/03/2011 13 Years Female Propriyraxis GARDASIL 22/03/2011 Pain in extremity 22/03/2011	esolved		
Rash macular 22/03/2011			



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2011-002971	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	22/03/2011 -	.5 ml	Dizziness	22/03/2011		Recovered/r esolved		
2011-002972	24/03/2011	13 Years	Female	Prophylaxis	GARDASIL	22/03/2011 -	.5 ml	Nausea	22/03/2011		Recovered/r		
								Headache	22/03/2011		esolved		
2011-002973	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	22/03/2011 -	.5 ml	Dizziness	22/03/2011		Recovered/r esolved		Anaemia
2011-002983	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	22/03/2010 -	.5 ml	Dizziness	22/03/2011		Recovered/r esolved		
2011-002985	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	22/03/2011 -	.5 ml	Dizziness	22/03/2011		Recovered/r		
				. ,				Headache	22/03/2011		esolved		
								Nausea	22/03/2011				
2011-002991	24/03/2011	14 Years	Female	Prophylaxis	GARDASIL	24/11/2010 -	.5 ml	Pain in extremity	24/11/2010		Not		
								Injection site pain	24/11/2010		recovered at time of		
2011-002992	24/03/2011	12 Years	Female	Prophylaxis	GARDASIL	23/11/2010 -	.5 ml	Nausea	23/11/2010		Not		
								Paraesthesia	23/11/2010		recovered at		
											time of reporting		
2011-003081	29/03/2011	13 Years	Female	Prophylaxis	GARDASIL			Lymphadenopathy			Not		
								Oropharyngeal pain			recovered at		
								Chills			time of reporting		
2011-003104	31/03/2011		Female	Prophylaxis	GARDASIL	28/03/2011 -	.5 ml	Anaphylactoid reaction	28/03/2011		Recovered/r		Asthma
								Hypotension	28/03/2011		esolved		Anaphylactic reaction
								Tachycardia	28/03/2011				, ,
								Nausea	28/03/2011				
								Asthenia	28/03/2011				
								Dyspnoea	28/03/2011				
								Throat tightness	28/03/2011				
2011-003108	31/03/2011	13 Years	Female	Prophylaxis	GARDASIL	30/03/2011 - 30/03/2011	.5 ml	Dizziness	30/03/2011		Not		
								Asthenia	30/03/2011		recovered at		
								Syncope	30/03/2011		time of reporting		
2011-003122	01/04/2011	13 Years	Female	Prophylaxis	GARDASIL	29/09/2010 -	.5 ml	Chest pain			Recovered/r		
								Dyspnoea			esolved		
2011-003148	04/04/2011	13 Years	Female	Prophylaxis	GARDASIL	22/03/2011 -	.5 ml	Erythema	22/03/2011		Recovered/r		
								Pain in extremity	22/03/2011		esolved		
2011-003154	04/04/2011	12 Years	Female	Prophylaxis	GARDASIL	28/03/2011 -	.5 ml	Headache	28/03/2011	29/03/2011	Recovered/r		
						18/11/2010 -		Dizziness	28/03/2011	29/03/2011	esolved		
						20/09/2010 -		Vomiting	28/03/2011	29/03/2011			



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2011-003160	04/04/2011	14 Years	Female	Prophylaxis	GARDASIL	10/10/2010 - 14/12/2010	.5 ml	Headache	10/10/2010		Not		
						14/12/2010 -	.5 ml	Abdominal discomfort	10/10/2010		recovered at		
								Asthenia	10/10/2010		time of		
								Decreased appetite	10/10/2010		reporting		
								Weight decreased	10/10/2010				
2011-003161	04/04/2011	12 Years	Female	Prophylaxis	GARDASIL	18/11/2010 -		Malaise			Recovered/r		
								Headache	28/03/2011		esolved		
								Dizziness					
2011-003167	05/04/2011	13 Years	Female	Prophylaxis	GARDASIL	30/11/2010 -		Fatigue	12/2010		Not		Abdominal pain upper
								Nausea	12/2010		recovered at		
								Headache	12/2010		time of		
								Vomiting	12/2010		reporting		
								Sleep disorder					
								Fatigue					
2011-003255	08/04/2011	13 Years	Female	Prophylaxis	GARDASIL	04/04/2011 -		Urticaria	05/04/2011		Not		
								Pruritus	05/04/2011		recovered at		
											time of		
											reporting		
2011-003276	08/04/2011	13 Years	Female	Prophylaxis	GARDASIL	31/03/2011 -	.5 ml	Dizziness	31/03/2011		Recovered/r		
								Pyrexia	01/04/2011		esolved		
								Chills	01/04/2011				
								Nausea	01/04/2011				
								Headache	01/04/2011				
								Rash generalised	03/04/2011				
2011-003281	11/04/2011	13 Years	Female	Prophylaxis	GARDASIL	15/12/2010 -	.5 ml	Vomiting	15/12/2010		Recovered/r		
					2.22.121						esolved		
2011-003319	12/04/2011	14 Years	Female	Prophylaxis	GARDASIL	15/12/2010 -		Injection site swelling	15/12/2010		Recovered/r		
								Injection site induration	15/12/2010		esolved		
								Swelling face Erythema	15/12/2010 15/12/2010				
								Erythema	15/12/2010				
2011-003324	12/04/2011	14 Years	Female	Prophylaxis	GARDASIL	01/04/2011 - 01/04/2011		Pain in extremity	01/04/2011		Recovered/r		
				. ,				Injection site pain	01/04/2011		esolved		
0044 000045	40/04/004	40.5	F	David da '	OARDAS"	44/00/0044 44/00/05::		News	4.4/00/2011		D		
2011-003347	13/04/2011	12.5 Years	Female	Prophylaxis	GARDASIL	14/03/2011 - 14/03/2011		Nausea	14/03/2011		Recovered/r esolved		
2011-003351	13/04/2011	14 Years	Female	Prophylaxis	GARDASIL	06/04/2011 -	.5 ml	Epistaxis	06/04/2011		Recovered/r		
								,			esolved		
2011-003353	13/04/2011	12 Years	Female	Prophylaxis	GARDASIL	14/03/2011 -		Dizziness	14/03/2011		Recovered/r		
								Nausea	14/03/2011		esolved		
2011-003354	13/04/2011	14 Years	Female		GARDASIL	14/03/2011 -		Dizziness	14/03/2011		Recovered/r		Asthma
								Dyspnoea	14/03/2011		esolved		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2011-003355	13/04/2011	13 Years	Female	Prophylaxis	GARDASIL	14/03/2011 -		Dizziness Dyspnoea	14/03/2011 14/03/2011		Recovered/r esolved	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/r esolved		
2011-003360	13/04/2011	13 Years	Female	Prophylaxis	GARDASIL	14/03/2011 -		Nausea Dizziness	14/03/2011 14/03/2011		Recovered/r esolved		
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/r esolved		
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/r esolved		
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/r esolved		
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/r esolved		
2011-003708	06/05/2011	13 Years	Female	Prophylaxis	GARDASIL	03/05/2011 -		Cellulitis	04/05/2011		Not recovered at time of reporting		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2011-003711	06/05/2011	14 Years	Female	Prophylaxis	GARDASIL	04/05/2011 -	.5 ml	Syncope	04/05/2011		Recovered/r		
								Pulse absent Pallor	04/05/2011 04/05/2011		esolved		
									04/05/2011				
2011-003712	06/05/2011	13 Years	Female	Prophylaxis	GARDASIL	03/05/2011 - 03/05/2011	.5 ml	Anaphylactic reaction Hypoaesthesia	03/05/2011		Recovered/r		
2011-003712	00/03/2011	15 Teals	lemale	Tophylaxis	GANDASIL	03/03/2011 - 03/03/2011	.5 1111	Peripheral coldness	03/05/2011		esolved		
								. Griprioral Goldingo	00/00/2011				
2011-003825	11/05/2011	13 Years	Female		GARDASIL	03/05/2011 - 03/05/2011		Pyrexia	04/05/2011		Recovered/r		
i								Malaise	04/05/2011		esolved		
								Asthenia					
2011-003901	13/05/2011	14 Years	Female	Prophylaxis	GARDASIL	03/05/2011 -	.5 ml	Influenza like illness	05/05/2011		Recovered/r		
											esolved		
2011-003902	13/05/2011	13 Years	Female	Prophylaxis	GARDASIL	10/05/2011 -	.5 ml	Presyncope	10/05/2011		Recovered/r		
											esolved		
2011-004036	19/05/2011	13 Years	Female	Prophylaxis	GARDASIL	03/05/2011 -	.5 ml	Injection site pain	04/05/2011		Recovered/r		
											esolved		
2011-004131	25/05/2011	13 Years	Female	Prophylaxis	GARDASIL	09/02/2011 - 09/02/2011	.5 ml	Hypersensitivity	09/02/2011		Recovered/r		
								Swelling face	09/02/2011		esolved		
								Rash	09/02/2011				
			_		2.22.20								
2011-004196	27/05/2011	13 Years	Female	Prophylaxis	GARDASIL	06/10/2010 - 29/03/2011 17/12/2010 -		Headache	12/04/2011		Not		Tonsillectomy
						29/03/2011 -		Abdominal pain	12/04/2011 12/04/2011		recovered at time of		
						29/03/2011 -		Alopecia Pollakiuria	12/04/2011		reporting		
								1 Ollakiulia	12/04/2011		roporting		
2011-004222	26/05/2011	13 Years	Female	Prophylaxis	GARDASIL	30/09/2010 -		Lower respiratory tract	11/2010		Unknown		
						06/12/2010 -		infection					
						28/03/2011 -		Tonsillitis	11/2010				
								Herpes zoster	02/2011				
								Tooth infection	03/2011				
								Candidiasis					
								Fatigue					
								Lethargy					
2011-004420	08/06/2011	13 Years	Female	Prophylaxis	GARDASIL	01/12/2010 -	.5 ml	Eye swelling	01/12/2010		Recovered/r		
								Eye pruritus	01/12/2010		esolved		
			_		2.22.20			Rash pruritic					
2011-004460	13/06/2011	14 Years	Female	Prophylaxis	GARDASIL	16/09/2010 -		Fatigue	16/09/2010		Not		
						18/11/2010 -		Headache	16/09/2010		recovered at time of		
											reporting		
2011 001100	14/06/2014	10 V	Fom-!-	Drophyloric	GARDASIL	22/00/2010	E m!	Fruthama	22/00/2042	-			
2011-004480	14/06/2011	12 Years	remaie	Prophylaxis	GARDASIL	23/09/2010 - 13/12/2010 -	.5 ml .5 ml	Erythema Pain in extremity	23/09/2010 23/09/2010		Recovered/r esolved		
						13/12/2010 -	.5 1111	Injection site pruritus	23/09/2010		esuiveu		
								injection site pruntus	23/09/2010				
2011-004491	14/06/2011	12 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -	.5 ml	Erythema	15/09/2010	<u> </u>	Not		Dry skin
						16/12/2010 -	.5 ml	Pruritus	15/09/2010		recovered at		
								Eczema	15/09/2010		time of		
											reporting		



	Data of first									Described.			
	Date of first notification	Patient	Patient					Adverse Reaction(s)	Reaction	Reaction Cessation		Concomitant	Medical History
IPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comn
2011-004591	17/06/2011	14 Years		Prophylaxis	GARDASIL	13/12/2010 -		Henoch-Schonlein purpura Joint swelling			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/r esolved		
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/r esolved		
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/r esolved		
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 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/r esolved		
2011-005133	07/07/2011	14 Years	Female	Prophylaxis	GARDASIL	31/03/2011 -	.5 ml	Headache	31/03/2011		Recovered/r esolved		
011-005134	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/r esolved		
2011-005137	07/07/2011	13 Years	Female	Prophylaxis	GARDASIL	28/03/2011 -	.5 ml	Dizziness	28/03/2011		Recovered/r esolved		
011-005138	07/07/2011	14 Years	Female	Prophylaxis	GARDASIL	31/03/2011 -	.5 ml	Dizziness	31/03/2011		Recovered/r esolved		
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/r esolved		
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/r esolved		
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



	Date of first	_	_							Reaction			
LIDDAID	notification	Patient	Patient	La Parataux	2	T		Adverse Reaction(s)	Reaction	Cessation	0	Concomitant	Medical History
HPRA ID 2011-006753	to HPRA 12/09/2011	Age 16 Years	Sex	Indications Prophylaxis	Suspect Drug(s) GARDASIL	Therapy Dates 12/09/2011 -	.5 ml	(MedDRA PT) Abdominal pain	Onset Date 12/09/2011	Date	Outcome Recovered/r	Medication(s)	(MedDRA PT)/Comment
2011-006/53	12/09/2011	16 Years	Female	Propriylaxis	GARDASIL	12/09/2011 -	im c.	Nausea	12/09/2011		esolved		
								Hyperhidrosis	12/09/2011		COOIVCG		
								Hypotension	12/09/2011				
								Erythema	12/09/2011				
								Heart rate increased	12/09/2011				
								Tachycardia	12/09/2011				
2011-006780	14/09/2011	12 Years	Female	Prophylaxis	GARDASIL	13/09/2011 - 13/09/2011	.5 ml	Headache	13/09/2011		Recovered/r		
								Abdominal pain	13/09/2011		esolved		
								Urticaria	13/09/2011				
2011-006840	16/09/2011	12 Years	Female	Prophylaxis	GARDASIL	13/09/2011 -	.5 ml	Angioedema	13/09/2011		Recovered/r		
								Eye oedema	13/09/2011		esolved		
								Nausea	13/09/2011				
								Pain Abdominal pain upper	13/09/2011 13/09/2011				
								Abdominai pain upper	13/09/2011				
2011-006847	17/09/2011	14 Years	Female	Prophylaxis	GARDASIL	04/10/2010 -		Petit mal epilepsy	19/10/2011		Unknown	SERETIDE	Asthma
								Complex partial seizures	19/10/2011			SINGULAIR	Seasonal allergy
								Myoclonic epilepsy	19/10/2011			SALBUTAMOL	
								Epilepsy	19/10/2011				Comment-Investigations are on-going
2011-006869	19/09/2011	13 Years	Female	Prophylaxis	GARDASIL	19/09/2011 -		Dizziness	19/09/2011	-	Recovered/r		are on-going
2011 000003	13/03/2011	10 Tours	Terriale	Tophylaxis	CARBAGIL	13/03/2011		DIZZIIICSS	13/03/2011		esolved		
2011-006874	19/09/2011	13 Years	Female	Prophylaxis	GARDASIL	21/09/2010 -	.5 ml	Headache	22/09/2010		Recovered/r		Migraine
								Dizziness	22/09/2010		esolved		
2011-006876	19/09/2011	13 Years	Female	Prophylaxis	GARDASIL	16/11/2010 -	.5 ml	Headache	17/11/2010		Recovered/r		Migraine
								Dizziness	17/11/2010		esolved		
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	20/09/2011		Recovered/r esolved		Syncope
								Malaise	20/09/2011		esoived		
2011-006916	21/09/2011	16 Years	Female	Prophylaxis	GARDASIL	13/09/2011 -	.5 ml	Urticaria	14/09/2011		Recovered/r		
								Periorbital oedema	14/09/2011		esolved		
2011-006924	21/09/2011	13 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -		Cough	21/09/2011		Not		Cough
1								Throat tightness	21/09/2011		recovered at		Nasopharyngitis
											time of reporting		
2011-006925	21/09/2011	12 Years	Female	Prophylaxis	GARDASIL	20/09/2011 - 20/09/2011		Cough	20/09/2011		Recovered/r		
				' '				Throat tightness	20/09/2011		esolved		
								, and the second					
			•	•	•	•	*	•	•		•	•	•



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
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/r esolved		
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/r esolved		
2011-006985	23/09/2011	16 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -	.5 ml	Vomiting	21/09/2011		Recovered/r esolved		
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/r esolved		
2011-006995	22/09/2011	16 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -	.5 ml	Headache Nausea	21/09/2011 21/09/2011		Recovered/r esolved		
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/r esolved		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/r esolved		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/r esolved		
2011-007096	28/09/2011	12 Years	Female	Prophylaxis	GARDASIL	22/09/2011 -	.5 ml	Vomiting	22/09/2011		Recovered/r esolved		
2011-007097	28/09/2011	12 Years	Female	Prophylaxis	GARDASIL	27/09/2011 -	.5 ml	Panic attack	27/09/2011		Recovered/r esolved		Panic attack



	Date of first notification	Patient	Patient					Adverse Reaction(s)	Reaction	Reaction Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2011-007099	28/09/2011	12 Years		Prophylaxis	GARDASIL	23/09/2011 -	.5 ml	Urticaria	23/09/2011		Recovered/r esolved		
2011-007123	29/09/2011	12 Years	Female	Prophylaxis	GARDASIL	16/09/2011 - 16/09/2011		Asthenia	18/09/2011		Recovered/r esolved		
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 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 16/09/2011		Recovered/r esolved		
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/r esolved		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/r esolved		
2011-007211	04/10/2011	12 Years	Female	Prophylaxis	GARDASIL	29/09/2011 -		Headache	29/09/2011		Recovered/r esolved		
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/r esolved	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/r esolved		
2011-007242	05/10/2011	14 Years	Female	Prophylaxis	GARDASIL	27/09/2011 -	.5 ml	Medication error			Recovered/r esolved		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 23/11/2010		Recovered/r esolved		
2011-007294	07/10/2011	12 Years	Female	Prophylaxis	GARDASIL	05/10/2011 -		Syncope	05/10/2011		Recovered/r esolved		



	Date of Cont												
	Date of first notification	Patient	Patient					Adverse Reaction(s)	Reaction	Reaction Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2011-007323	10/10/2011	12 Years	Female	Prophylaxis	GARDASIL	20/09/2011 -	.5 ml	Vomiting	20/09/2011		Recovered/r esolved		
2011-007384	12/10/2011	18 Years	Female	Prophylaxis	GARDASIL	20/09/2011 -	.5 ml	Maternal exposure during pregnancy			Recovered/r esolved		
								No adverse event					
2011-007389	12/10/2011	16 Years	Female	Prophylaxis	GARDASIL	03/10/2011 -	.5 ml	Syncope	03/10/2011		Recovered/r esolved		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 Museular weekness	07/10/2011		Not recovered at		
0044.007554	10/10/0044	10.1/			0.455.404	00/00/00/4		Muscular weakness	07/10/2011		time of		
2011-007551	18/10/2011	18 Years	Female	Prophylaxis	GARDASIL	26/09/2011 -		Pyrexia Chills			Recovered/r esolved		
								Fatigue Sinusitis					
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		
								John Swelling	20/09/2011		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/r esolved		
2011-008002	09/11/2011	17 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -	.5 ml	Guttate psoriasis	24/09/2011		Recovered/r		
											esolved		
		17 Years	Female	Prophylaxis	GARDASIL	15/09/2011 -		Headache	18/09/2011	24/10/2011	Recovered/r esolved		
2011-008131	15/11/2011	18 Years	Female	Prophylaxis	GARDASIL	13/09/2011 -	.5 ml	Fatigue Asthenia	13/09/2011 13/09/2011		Recovered/r esolved		
2011-008133	15/11/2011	12 Years	Female	Prophylaxis	GARDASIL	15/09/2011 -	.5 ml	Asthenia	15/09/2011		Recovered/r		Asthma
								Vision blurred Headache	15/09/2011 15/09/2011		esolved		
								Cough	15/09/2011				
								Cold sweat	15/09/2011				
								Flushing Wheezing	15/09/2011 15/09/2011				
2011-008301	23/11/2011	17 Years	Female	Prophylaxis	GARDASIL	14/11/2011 -		Urticaria	14/11/2011		Not		Asthma
											recovered at time of reporting		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/r esolved		



	Date of first notification	Patient	Patient					Adverse Reaction(s)	Reaction	Reaction Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2011-008394	25/11/2011	11 Years		Prophylaxis	GARDASIL	21/11/2011 -	.5 ml	Syncope	21/11/2011	Date	Recovered/r esolved	medication(3)	Syncope
2011-008409	28/11/2011	16 Years	Female	Prophylaxis	GARDASIL	21/11/2011 -	.5 ml	Panic attack	21/11/2011		Recovered/r esolved		
2011-008410	28/11/2011	13 Years	Female	Prophylaxis	GARDASIL	15/09/2010 -		Rash			Recovered/r esolved		
2011-008412	28/11/2011	13 Years	Female	Prophylaxis	GARDASIL	20/12/2010 -		Rash			Recovered/r esolved		
2011-008414	28/11/2011	13 Years	Female	Prophylaxis	GARDASIL	18/04/2011 -		Erythema nodosum			Recovered/r esolved		
2011-008416	28/11/2011	12 Years	Female	Prophylaxis	GARDASIL	21/11/2011 -	.5 ml	Headache	21/11/2011		Recovered/r esolved		
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/r esolved		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/r esolved		
2011-008466	29/11/2011	16 Years	Female	Prophylaxis	GARDASIL	29/09/2011 -	.5 ml	Maternal exposure during pregnancy No adverse event			Recovered/r esolved		
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/r esolved		
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/r esolved		
2011-008582	05/12/2011	17 Years	Female	Prophylaxis	GARDASIL	16/11/2011 -	.5 ml	Urticaria	19/11/2011		Recovered/r esolved		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 18/11/2011		Recovered/r esolved		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Commen
2011-008597	06/12/2011	17 Years	Female	Prophylaxis	GARDASIL	01/12/2011 -	.5 ml	Syncope	01/12/2011		Recovered/r esolved		
								Tremor Vision blurred	01/12/2011 01/12/2011		esoived		
								Hypopnoea	01/12/2011				
								Chest discomfort	01/12/2011				
								Muscular weakness	01/12/2011				
								Wasculai Weakiess					
2011-008601	06/12/2011	16 Years	Female	Prophylaxis	GARDASIL	10/10/2011 -	.5 ml	Urticaria	10/10/2011		Recovered/r		Asthma
								Chest discomfort	10/10/2011		esolved		
2011-008614	07/12/2011	13 Years	Female	Prophylaxis	GARDASIL	26/09/2011 -	.5 ml	Injection site pain	26/09/2011		Recovered/r		
				, ,				Injection site erythema	26/09/2011		esolved		
								Injection site oedema	26/09/2011				
2011-008616	07/12/2011	13 Years	Female	Prophylaxis	GARDASIL	05/12/2011 -	.5 ml	Rash maculo-papular	05/12/2011		Recovered/r esolved		
								Pruritus	05/12/2011		esolved		
2011-008617	07/12/2011	12 Years	Female	Prophylaxis	GARDASIL	20/09/2011 -	.5 ml	Headache	20/09/2011		Recovered/r		
											esolved		
2011-008690	09/12/2011	12 Years	Female	Prophylaxis	GARDASIL	23/09/2011 -		Urticaria	24/09/2011		Recovered/r esolved		
2011-008692	09/12/2011	13 Years	Female	Prophylaxis	GARDASIL	29/09/2011 -	.5 ml	Urticaria	30/09/2011		Recovered/r		
2011-000092	09/12/2011	15 Teals	l emale	Τοριιγιαλίο	GANDASIL	29/09/2011 -	.5 1111	Officaria	30/03/2011		esolved		
2011-008702	12/12/2011	13 Years	Female	Prophylaxis	GARDASIL	16/09/2011 -	.5 ml	Urticaria	16/09/2011		Recovered/r		
											esolved		
2011-008704	12/12/2011	16 Years	Female	Prophylaxis	GARDASIL	17/10/2011 -	.5 ml	Abortion spontaneous	18/10/2011		Recovered/r		
2011-008725	13/12/2011	13 Years	Famala	Drophylovia	GARDASIL	24/11/2011 -	.5 ml	Fotigue			esolved		
2011-008725	13/12/2011	13 Years	Female	Prophylaxis	GARDASIL	24/11/2011 -	im c.	Fatigue Cough	24/11/2011		Recovered/r esolved		
								Cougii	24/11/2011		esoiveu		
2011-008812	16/12/2011	17 Years	Female	Prophylaxis	GARDASIL	06/10/2011 -	.5 ml	Headache	06/10/2011		Recovered/r		
											esolved		
2011-008833	19/12/2011	17 Years	Female	Prophylaxis	GARDASIL	30/09/2011 -	.5 ml	maternal exposure during pregnancy			Recovered/r esolved		
								, , ,			esoived		
								No adverse event					
2011-008836	19/12/2011	18 Years	Female	Prophylaxis	GARDASIL	10/10/2011 -		maternal exposure during			Recovered/r		
				•				pregnancy			esolved		
								No adverse event					
2044 00222	40/40/0044	40.1/	F	December de l'	CADDAGU	00/40/0044	F!	Data ta autor - 20	00/40/0044		D		
2011-008837	19/12/2011	12 Years	Female	Prophylaxis	GARDASIL	03/10/2011 -	.5 ml	Pain in extremity	03/10/2011		Recovered/r esolved		
2011-008841	19/12/2011	12 Years	Female	Prophylaxis	GARDASIL	03/10/2011 -	.5 ml	Vomiting	03/10/2011		Recovered/r	+	
2011 0000 11	.5/12/2011		. omaio		O, III D, IOIE	50/10/2011	1.0 1111	· Similing	03/10/2011		esolved		
2011-008845	19/12/2011	12 Years	Female	Prophylaxis	GARDASIL	29/09/2011 -	.5 ml	Panic attack	29/09/2011		Recovered/r		Panic attack
								Stress	29/09/2011		esolved		
1								Dyspnoea	29/09/2011			1	



	Date of first notification	Patient	Patient					Adverse Reaction(s)	Reaction	Reaction Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2011-008848	19/12/2011	16 Years	Female	Prophylaxis	GARDASIL	25/11/2011 -	.5 ml	Pruritus	25/11/2011		Recovered/r esolved		
2011-008895	21/12/2011	17 Years	Female	Prophylaxis	GARDASIL	30/09/2011 -	.5 ml	Urticaria			Recovered/r esolved		
2011-008899	21/12/2011	16 Years	Female	Prophylaxis	GARDASIL	30/09/2011 -	.5 ml	Urticaria	30/09/2011		Recovered/r esolved		
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/r esolved		
2012-009098	05/01/2012		Female	Prophylaxis	GARDASIL		.5 ml	Nausea Abdominal pain Headache			Recovered/r esolved		
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/r esolved		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/r esolved		Urticaria
2012-010407	13/03/2012	18 Years	Female	Prophylaxis	GARDASIL	22/11/2011 -	.5 ml	Fatigue Lip blister Headache	22/11/2011		Recovered/r esolved	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		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2012-010428	14/03/2012	18 Years		Prophylaxis	GARDASIL	20/09/2011 -	.5 ml	Maternal exposure during			Recovered/r	()	
2012 010 120	, 00, 2012	10 10010	· omaio	. ropnylanio	07.11.27.10.2	23/11/2011 -	.5 ml	pregnancy			esolved		
								No adverse event					
								no adverse event					
2012-010434	14/03/2012	17 Years	Female	Prophylaxis	GARDASIL	25/11/2011 -	.5 ml	Rash macular	25/11/2011		Not		
								Fatigue			recovered at		
								Local swelling			time of		
								Dermatitis allergic			reporting		
2012-010461	15/03/2012	24 Years	Female	Prophylaxis	GARDASIL	30/01/2012 -	.5 ml	Arthralgia	04/02/2012		Not		
2012-010401	13/03/2012	24 1 Cais	lemale	Τοριιγιαλίδ	GANDASIE	30/01/2012 -	.5 1111	Aitilaigia	04/02/2012		recovered at		
											time of		
											reporting		
2012-010467	15/03/2012	16 Years	Female	Prophylaxis	GARDASIL	14/09/2011 -		Maternal exposure during			Recovered/r	CONTRACEPTIVE PILL	
						16/11/2011 -		pregnancy			esolved		
								No adverse event					
								No adverse event					
2012-010527	20/03/2012	12 Years	Female	Prophylaxis	GARDASIL	13/03/2012 -	.5 ml	Headache	13/03/2012		Recovered/r		
								Vomiting	13/03/2012		esolved		
2012-010617	23/03/2012	17 Years	Female	Prophylaxis	GARDASIL	14/11/2011 -	.5 ml	Nausea	14/11/2011		Not		
								Lethargy	14/11/2011		recovered at		
								Weight decreased	14/11/2011		time of		
								Amnesia	14/11/2011		reporting		
								Chest pain	14/11/2011				
								Headache	14/11/2011				
								Syncope	14/11/2011				
2012-010694	28/03/2012	12 Years	Female	Prophylaxis	GARDASIL	24/11/2011 -	.5 ml	Vomiting	24/11/2011		Recovered/r		
2012 010001	20/00/2012	12 100.0	· omaio	. ropnylanio	07.11.27.10.2	2 1, 1 1, 20 1 1		Rash	24/11/2011		esolved		
								T COST	2 .,, 20		000.100		
2012-010695	28/03/2012	12 Years	Female	Prophylaxis	GARDASIL	23/09/2011 -	.5 ml	Pyrexia	28/11/2011		Recovered/r		
						28/11/2011 -	.5 ml	Nausea	23/09/2011		esolved		
								Injection site pain	23/09/2011				
								Pallor	23/09/2011				
2012-010735	29/03/2012	13 Years	Female	Prophylaxis	GARDASIL	20/03/2012 -	.5 ml	Asthenia	20/03/2012		Not		Urinary tract infection
2012-010/33	23/03/2012	13 TealS	i emale	ι τοριτγιαλίο	GARDASIL	26/09/2011 -	.5 ml	Pallor	20/03/2012		recovered at		Officery tract infection
						02/12/2011 -	.5 ml	Pyrexia	20/03/2012		time of		
						02/12/2011	1.5 1111	Nausea	20/03/2012		reporting		
								Decreased appetite	20/03/2012		609		
	1							Socioassa appoints	20,00,2012				
2012-010745	30/03/2012	17 Years	Female	Prophylaxis	GARDASIL	28/11/2011 -	.5 ml	maternal exposure during			Recovered/r		
				' '				pregnancy			esolved		
								No adverse event					



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
2012-010746	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 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/r esolved		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/r esolved		
2012-010792	02/04/2012	12 Years	Female	Prophylaxis	GARDASIL	24/11/2011 -	.5 ml	Pain in extremity	25/11/2011		Recovered/r esolved		
2012-010793	30/03/2012	13 Years	Female	Prophylaxis	GARDASIL	23/11/2011 -	.5 ml	Pruritus Erythema	23/11/2011 23/11/2011		Recovered/r esolved		
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/r esolved		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/r esolved		
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/r esolved		
2012-010840	04/04/2012	17 Years	Female	Prophylaxis	GARDASIL	15/09/2011 - 17/11/2011 -	.5 ml .5 ml	Paraesthesia			Recovered/r esolved		
2012-010878	04/04/2012	13 Years	Female	Prophylaxis	GARDASIL	29/11/2011 - 27/09/2011 -		VIIth nerve paralysis	03/2012		Recovered/r esolved		



HPRA ID	Date of first notification to HPRA	Patient	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
2012-011007	12/04/2012	13 Years		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 15/03/2012 27/03/2012 28/03/2012 30/03/2012 30/03/2012 28/03/2012 28/03/2012	Date	Not recovered at time of reporting	medication(s)	(MedDKA P1)/Comment
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/r esolved		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/r esolved		
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/r esolved		
2012-011329	01/05/2012	17 Years	Female	Prophylaxis	GARDASIL	17/04/2012 -		Syncope	18/04/2012		Recovered/r esolved		
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/r esolved		
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/r esolved		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID				Indications	Suspect Drug(s)	Therapy Dates	Dose				Outcome		
HPRA ID 2012-011384	to HPRA 03/05/2012	Age 13 Years	Sex Female	Indications Prophylaxis	Suspect Drug(s) GARDASIL BOOSTRIX	Therapy Dates 26/03/2012 - 26/03/2012 26/03/2012 - 26/03/2012	Jose J.5 ml J.5 ml	(MedDRA PT) Psychogenic seizure Epilepsy Loss of consciousness Syncope Drop attacks Head injury Fall Eye movement disorder Headache Dizziness Nausea Malaise Body temperature Chills Pallor Fatigue	27/03/2012 27/03/2012 27/03/2012 27/03/2012 27/03/2012 26/03/2012 27/03/2012 27/03/2012 27/03/2012 27/03/2012	Date	Outcome Unknown	Medication(s)	(MedDRA PT)/Comment
								Somnolence Fatigue Headache Injection site reaction	27/03/2012 27/03/2012 27/03/2012				
2012-011458	08/05/2012	17 Years	Female	Prophylaxis	GARDASIL	20/09/2011 -	.5 ml	Pityriasis rosea Oropharyngeal pain	20/09/2011		Recovered/r esolved		
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/r esolved		
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/r esolved		
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/r esolved		
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		



	Date of first									Desetion			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Reaction Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2012-012043	12/06/2012	13 Years	Female	Prophylaxis	GARDASIL	16/04/2012 -	.5 ml	Dizziness	16/04/2012	Date	Recovered/r	wedication(s)	(WedDKA FT)/Comment
2012-012043	12/00/2012	13 Teals	remale	Fiopilylaxis	BOOSTRIX	16/04/2012 -	.5 ml	Pallor	16/04/2012		esolved		
					Beeenax	10/04/2012	.0 1111	Talloi	10/04/2012		COOIVCG		
2012-012050	12/06/2012	17 Years	Female	Prophylaxis	GARDASIL	07/12/2011 -	.5 ml	Nausea	08/12/2011		Recovered/r		
							1.0	Decreased appetite	08/12/2011		esolved		
								, , , , , , , , , , , , , , , , , , , ,					
2012-012128	15/06/2012	18 Years	Female	Acne	GARDASIL	2011 - 2011		Pulmonary embolism	30/01/2012		Recovered/r		Acne
				Prophylaxis	YASMIN			Upper respiratory tract	13/01/2012		esolved		Prophylaxis
				Prophylaxis				infection					
								Cough	30/01/2012				
								Chest discomfort	30/01/2012				
2042 042252	00/00/0040	40 V	Famala	Deservation	CARRACII	04/06/0040	F1	I beneau a a sisteris e	04/00/0040		December 11:		
2012-012353	29/06/2012	18 Years	Female	Prophylaxis	GARDASIL	21/06/2012 -	.5 ml	Hypersensitivity Rash pruritic	21/06/2012 21/06/2012		Recovered/r esolved		
								Erythema	21/06/2012		esoiveu		
								Swollen tongue	21/06/2012				
								Swelling face	21/06/2012				
								Cwoming race	21/00/2012				
2012-012879	24/07/2012	13 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -	.5 ml	Fatigue			Not		
						23/11/2011 -	.5 ml	Lethargy			recovered at		
								Somnolence			time of		
											reporting		
2012-012935	25/07/2012	18 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -	.5 ml	Fatigue	12/2011		Not		
						23/11/2011 -		Pain	12/2011		recovered at		
								Epistaxis	12/2011		time of reporting		
								Headache	12/2011		reporting		
2012-013357	08/08/2012	17 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -	.5 ml	Maternal exposure prior to			Recovered/r		
				. ,				pregnancy			esolved		
								No adverse event					
2012-013360	08/08/2012	16 Years	Female	Prophylaxis	GARDASIL	21/09/2011 -	.5 ml	Maternal exposure during			Recovered/r		
2012 013300	00/00/2012	10 Tours	Cinaic	Tophylaxis	GARBAGIE	23/11/2011 -	.5 1111	pregnancy			esolved		
						20/ 1 1/2011		No adverse event			000.104		
								No auverse event					
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	23/08/2012		Recovered/r		Pityriasis rosea
				1				Rash papular	23/08/2012		esolved		
2012-013856	30/08/2012	16 Years	Female	Prophylaxis	GARDASIL	18/04/2012 -		Maternal exposure during			Recovered/r		
						08/12/2011 -		pregnancy			esolved		
								No adverse event					
2042 044242	40/00/0040	40 V	Famala	Drambulania	CARRACII	44/00/0040	F!	Manaitia a	44/00/0040		December 11:		
2012-014348	12/09/2012	12 Years	Female	Prophylaxis	GARDASIL	11/09/2012 -	.5 ml	Vomiting	11/09/2012		Recovered/r esolved		
											esoiveu		



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	Date of first notification	Patient	Patient					Adverse Reaction(s)	Reaction	Reaction Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
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/r esolved		
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/r esolved		
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/r esolved		
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/r esolved		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		Recovered/r esolved		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/r esolved		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/r esolved		
2012-014520	19/09/2012	17 Years	Female	Prophylaxis	GARDASIL	18/09/2012 -	.5 ml	Syncope	18/09/2012		Recovered/r esolved		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Commen
2012-014545	19/09/2012	13 Years		Prophylaxis	GARDASIL	19/09/2012 -	.5 ml	Throat tightness	19/09/2012		Recovered/r	YASMIN	Dysmenorrhoea
								Dysphagia	19/09/2012		esolved		
								Dyspnoea	19/09/2012				
2012-014546	19/09/2012	17 Years	Female	Prophylaxis	GARDASIL	19/09/2012 -	.5 ml	Rash erythematous	19/09/2012		Recovered/r		
								Feeling hot	19/09/2012		esolved		
								Rash pruritic	19/09/2012				
								Dizziness	19/09/2012				
2012-014587	20/09/2012	18 Years	Female	Prophylaxis	GARDASIL	06/12/2011 -	.5 ml	Epilepsy	03/2012	1	Not		Hypersensitivity
2012 014001	20/00/2012	10 Touro	Tomaio	Горпушлю	O/ II (D/ IOIE	00/12/2011	.0 1111	Ернороу	00/2012		recovered at		i typersonality ty
2012-014588	20/09/2012	14 Years	Female	Prophylaxis	GARDASIL	12/09/2011 -	.5 ml	Abdominal pain	09/2011	1	Unknown		Familial risk factor
				., ,				Thyroid function test	09/2011				
								abnormal					
2012-014589	20/09/2012	15 Years	Female	Prophylaxis	GARDASIL	09/05/2011 -	.5 ml	Vestibulitis	09/10/2011		Not		
						01/10/2010 -	.5 ml				recovered at		
2012-014591	20/09/2012	13 Years	Female	Prophylaxis	GARDASIL	12/09/2011 -	.5 ml	Convulsion	11/2011		Unknown		
						09/12/2011 -	.5 ml						
2012-014594	20/09/2012	15 Years		Prophylaxis	GARDASIL	18/01/2011 -	.5 ml	Malaise	10/2011		Not		Gluten free diet
						07/12/2011 -	.5 ml	Oropharyngeal pain	10/2011		recovered at		Food intolerance
								Rash	10/2011		time of		
								Abdominal pain	10/2011		reporting		
								Flushing	10/2011				
2012-014719	25/09/2012	17 Years	Female	Prophylaxis	GARDASIL	12/09/2012 -		Lower respiratory tract	13/09/2012	1	Recovered/r		
20.2 0	20/00/2012		· omaio	. ropinyiaxio	0, 11, 12, 10, 12	12/00/2012		infection	1.070072012		esolved		
2012-014752	25/09/2012	13 Years	Female	Prophylaxis	GARDASIL	14/09/2012 -	.5 ml	Asthenia	14/09/2012		Recovered/r		
				' '				Vomiting	14/09/2012		esolved		
								Headache	14/09/2012				
								Rash	14/09/2012				
											1		
2012-014766	26/09/2012	17 Years	Female	Prophylaxis	GARDASIL	12/09/2012 -		Headache	12/09/2012		Not		
											recovered at		
											time of reporting		
											reporting		
2012-014809	27/09/2012	12 Years	Female	Prophylaxis	GARDASIL	17/09/2012 -	.5 ml	Syncope	17/09/2012		Recovered/r		
											esolved		
2012-014824	27/09/2012	12 Years	Female	Prophylaxis	GARDASIL	18/09/2012 -	.5 ml	Syncope	18/09/2012		Recovered/r		
											esolved		
2012-014825	27/09/2012	17 Years	Female	Prophylaxis	GARDASIL	19/09/2012 -	.5 ml	Syncope	19/09/2012		Recovered/r		
								Myoclonus	19/09/2012		esolved		
2012-014832	27/09/2012	17 Years	Fomale	Prophylaxis	GARDASIL	20/09/2012 -	.5 ml	Synoono	20/09/2012		Recovered/r		
2012-014032	21/09/2012	i/ rears	remale	гторпутахіѕ	GARDASIL	20/09/2012 -	.5 IIII	Syncope	20/09/2012		esolved		
2012-014840	28/09/2012	17 Years	Fomolo	Prophylavic	GARDASIL	21/09/2012 -	.5 ml	Dizziness	21/09/2012	-			
2012-014840	20/09/2012	i/ rears	remaie	Prophylaxis	GAKDASIL	21/09/2012 -	ım c.				Recovered/r		
		1	I		ĺ	1		Syncope	21/09/2012		esolved		



HPRA ID to	Date of first notification	Patient								Bernellen.			the state of the s
HPRA ID to		Patient								Reaction			
			Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
	28/09/2012	12 Years	Female	Prophylaxis	GARDASIL	24/09/2012 -		Lymphadenopathy	26/09/2012		Recovered/r		
								Face oedema	26/09/2012		esolved		
								Local reaction	26/09/2012				
								2550. 1505	20/00/2012				
2012-014874 01	01/10/2012	16 Years	Female	Prophylaxis	GARDASIL	19/09/2012 -	.5 ml	Syncope	19/09/2012		Recovered/r		Syncope
											esolved		3, 33, 3
2012-014907 02	02/10/2012	12 Years	Female	Prophylaxis	GARDASIL	24/09/2012 -	.5 ml	Panic attack	24/09/2012		Recovered/r		Anxiety disorder
20.2 0.1001	02/10/2012	12 . 00.10	· omaio	i ropinyianao	07 11 127 10.12	2 1/00/2012		r ame attack	2 1/00/2012		esolved		r abacty discrete
2012-014915 02	02/10/2012	12 Years	Female	Prophylaxis	GARDASIL	11/09/2012 -	.5 ml	Pain in extremity	11/09/2012		Recovered/r		
				' '				Injection site pain	11/09/2012		esolved		
2012-014992 03	03/10/2012	17 Years	Female	Prophylaxis	GARDASIL	28/09/2012 -	.5 ml	Purpura	28/09/2012		Recovered/r		
				., ,			_	Chest discomfort	28/09/2012		esolved		
2012-015012 04	04/10/2012	13 Years	Female	Prophylaxis	GARDASIL	28/09/2012 -		Erythema nodosum	30/09/2012		Not		
				., ,		23/03/2012 -		,			recovered at		
						21/11/2011 -					time of		
											reporting		
2012-015026 05	05/10/2012	12 Years	Female	Prophylaxis	GARDASIL	24/09/2012 -	.5 ml	Syncope	24/09/2012		Recovered/r		
2012-013020	03/10/2012	12 Tears	lemale	Τοριιγιαλίδ	GANDASIL	24/09/2012 -	.5 1111	Зупсоре	24/03/2012		esolved		
0040 045007	05/40/0040	40.1/	E	Daniel Landa	0.4.00.4.011	04/40/0040	F1	Dii	04/40/0040		1		Davis alled
2012-015027 05	05/10/2012	12 Years	remale	Prophylaxis	GARDASIL	01/10/2012 -	.5 ml	Dizziness	01/10/2012		Recovered/r		Panic attack
								Hyperventilation	01/10/2012		esolved		
2012-015031 05	05/10/2012	13 Years	Female	Prophylaxis	GARDASIL	04/10/2012 -	.5 ml	Syncope	04/10/2012		Recovered/r		
2012 013031	03/10/2012	10 Tours	Cinaic	Tophylaxis	GARBAGIE	04/10/2012	.5 1111	Tonic clonic movements	04/10/2012		esolved		
								Torne ciorne movements	04/10/2012		CSOIVCG		
2012-015041 08	08/10/2012	12 Years	Female	Prophylaxis	GARDASIL	28/09/2012 -	.5 ml	Pallor	28/09/2012		Recovered/r		
20.2 0.00	00/10/2012	12 10010	· omaio	1 1001111101110	0,11,12,10,12	26/06/2012		Asthenia	28/09/2012		esolved		
								Headache	28/09/2012		COOIVCG		
								Vomiting	28/09/2012				
								Vollitarig	26/09/2012				
2012-015042 08	08/10/2012	13 Years	Female	Prophylaxis	GARDASIL	25/09/2012 -	.5 ml	Pallor	25/09/2012		Not		Coeliac disease
2012 010012	00/10/2012	10 10010	i omaio	Γιοριτγιαλίο	O/ II (B) (O)E	20/00/2012	1.0 1111	Asthenia	25/09/2012		recovered at		Asthma
								Disorientation	25/09/2012		time of		Cardiac murmur
								Dyskinesia	25/09/2012		reporting		Cardiac mumui
								,	25/09/2012		reporting		
								Fatigue					
								Muscle twitching					
2012-015051 10	10/10/2012	16 Years	Female	Prophylaxis	GARDASIL	13/09/2012 -	.5 ml	Abdominal pain	14/09/2012		Recovered/r		
2012-013031	10/10/2012	10 16415	i Gillale	Γιοριιγιαλίο	GANDAGIL	13/03/2012 -	.5 1111	Diarrhoea	14/09/2012		esolved		
		1	1								CSUIVEU		
								Pyrexia	14/09/2012				
2012-015057 10	10/10/2012	17 Years	Female	Prophylaxis	GARDASIL	10/10/2012 -	.5 ml	Hypersensitivity	10/10/2012		Recovered/r		Food allergy
	,,				S	.0,.0,2012		Pain in extremity	10/10/2012		esolved		. 554 45.97
						1		Agitation	10/10/2012		COOIVCU		
						1		Flushing	10/10/2012				
						1		i idaliliy	10/10/2012				



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(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/r esolved		
2012-015245	25/10/2012	17 Years	Female	Prophylaxis	GARDASIL	10/10/2012 -	.5 ml	VIIth nerve paralysis	16/10/2012		Recovered/r esolved		
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/r esolved		
2012-015454	10/11/2012	12 Years	Female	Prophylaxis	GARDASIL	11/09/2012 -	.5 ml	Headache	11/09/2012		Recovered/r esolved		
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/r esolved		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/r esolved		Overweight
2012-015459	11/11/2012	16 Years	Female	Prophylaxis	GARDASIL	13/09/2012 -	.5 ml	Headache	13/09/2012		Recovered/r esolved		
2012-015460	11/11/2012	12 Years	Female	Prophylaxis	GARDASIL	14/09/2012 -	.5 ml	Vomiting	14/09/2012		Recovered/r esolved		
2012-015461	12/11/2012	19 Years	Female	Prophylaxis	GARDASIL	07/11/2012 -	.5 ml	Anaphylactic reaction	07/11/2012		Recovered/r esolved		
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/r esolved		
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/r esolved		
2012-015486	13/11/2012	16 Years	Female	Prophylaxis	GARDASIL	18/09/2012 -	.5 ml	Urticaria	18/09/2012		Recovered/r esolved		Food allergy
2012-015487	13/11/2012	17 Years	Female	Prophylaxis	GARDASIL	18/09/2012 -	.5 ml	Injection site pain	13/11/2012		Recovering/r esolving		
2012-015488	13/11/2012	17 Years	Female	Prophylaxis	GARDASIL	13/11/2012 -	.5 ml	Syncope	13/11/2012		Recovered/r esolved		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2012-015526	15/11/2012	17 Years	Female	Prophylaxis	GARDASIL	03/10/2011 - 16/04/2012 -	1 Dosage forms	Alopecia	02/2012		Recovering/r esolving		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/r esolved		
2012-015531	15/11/2012	17 Years	Female	Prophylaxis	GARDASIL	21/09/2012 -	.5 ml	Oral mucosal blistering	21/09/2012		Recovered/r esolved		
2012-015532	15/11/2012	16 Years	Female	Prophylaxis	GARDASIL	21/09/2012 -	.5 ml	Injection site pain	21/09/2012		Recovered/r esolved		
2012-015536	15/11/2012	12 Years	Female	Prophylaxis	GARDASIL	15/11/2012 - 15/11/2012	.5 ml	Asthma	15/11/2012		Recovered/r esolved		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/r esolved		
2012-015603	23/11/2012	16 Years	Female	Prophylaxis	GARDASIL	25/09/2012 -	.5 ml	Headache	25/09/2012		Recovered/r esolved		
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/r esolved		Lymphadenopathy
2012-015609	23/11/2012	16 Years	Female	Prophylaxis	GARDASIL	05/09/2012 -		maternal exposure during pregnancy No adverse event			Recovered/r esolved		
2012-015610	23/11/2012	12 Years	Female	Prophylaxis	GARDASIL	19/09/2012 -	.5 ml	Headache	19/09/2012		Recovered/r esolved		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2012-015649	28/11/2012	17 Years	Female	Prophylaxis	GARDASIL	14/11/2012 -	.5 ml	Pain in extremity	14/11/2012		Recovering/r		
						09/09/2012 -		Injection site erythema	14/11/2012		esolving		
								Injection site warmth	14/11/2012				
								Injection site pain	14/11/2012				
								Insomnia	14/11/2012				
								Monoplegia					
2012-015659	29/11/2012	17 Years	Female	Prophylaxis	GARDASIL	19/09/2012 -	.5 ml	Maternal exposure during			Recovered/r		
								pregnancy			esolved		
								No adverse event					
2012-015662	28/11/2012		Female	Prophylaxis	GARDASIL			Extensive swelling of			Unknown		
			ļ					vaccinated limb					
2012-015694	03/12/2012	12 Years	Female	Prophylaxis	GARDASIL	30/11/2012 -		Presyncope	30/11/2012		Recovered/r		
								Loss of consciousness	30/11/2012		esolved		
2012-015695	03/12/2012	13 Years	Female	Prophylaxis	GARDASIL	15/11/2012 -		Pain in extremity	15/11/2012		Not		
								Muscular weakness	15/11/2012		recovered at		
								Sensory disturbance	15/11/2012		time of		
								Neuralgia			reporting		
2012-015700	03/12/2012	17 Years	Female	Prophylaxis	GARDASIL	22/11/2012 -	.5 ml	Eye irritation	23/11/2012		Not		
								Hallucination	23/11/2012		recovered at		
								Eye swelling	23/11/2012		time of		
								Chest discomfort	23/11/2012		reporting		
2012-015718	05/12/2012	12 Years	Female	Prophylaxis	GARDASIL	29/11/2012 -		Anaphylactic reaction	29/11/2012		Recovered/r		
					BOOSTRIX	27/09/2012 -		Dyspnoea	29/11/2012		esolved		
						29/11/2012 -		Pallor	29/11/2012				
								Cough	29/11/2012				
								Tachycardia	29/11/2012				
2012-015720	05/12/2012	18 Years	Female	Prophylaxis	GARDASIL	10/10/2012 -	.5 ml	Urticaria	11/10/2012		Recovered/r		
								Eyelid oedema	11/10/2012		esolved		
2012-015799	13/12/2012	17 Years	Female	Prophylaxis	GARDASIL	26/11/2012 -		Urticaria			Not		
											recovered at		
											time of reporting		
2012-015805	2-015805 13/12/2012 13	13 Years	Female	Prophylaxis	GARDASIL	03/12/2012 -		Feeling hot	03/12/2012		Recovered/r		
								Hypoaesthesia	03/12/2012		esolved		
								Dizziness	03/12/2012		1		
								Disorientation	03/12/2012				
								Decreased appetite			1		
	1							Pallor			1		
								Hyperhidrosis					
								Somnolence					
	1	<u> </u>											



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2012-015824	14/12/2012	13 Years	Female	Prophylaxis	GARDASIL	26/11/2012 -	.5 ml	Rash erythematous	27/11/2012		Recovered/r	BOOSTRIX	
								Swelling face	27/11/2012		esolved		
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	05/12/2012 -		Pyrexia	07/12/2012		Recovered/r		
					PRIORIX.	01/10/2012 -		Oropharyngeal pain	07/12/2012		esolved		
						05/12/2012 -		Malaise	07/12/2012				
								Asthenia	07/12/2012				
								Pain	07/12/2012				
2013-015918	02/01/2013	13 Years	Female	Prophylaxis	BOOSTRIX	05/12/2012 -	.5 ml	Personality change	05/12/2012		Recovered/r		
				' '	GARDASIL	05/12/2012 -	.5 ml	Inappropriate affect	05/12/2012		esolved		
								Somnolence	05/12/2012				
								Dysarthria					
2013-015940	02/01/2013	17 Years	Female	Prophylaxis	GARDASIL	05/11/2012 -	1 Dosage	Pyrexia	05/11/2012		Recovered/r	YASMINELLE	
2010 010010	02/01/2010		· omaio	. ropinjianio	0, 11, 12, 10, 12	00/11/2012	forms	Vomiting	05/11/2012		esolved	.,	
							1011110	Headache	05/11/2012		COOIVCG		
								Abdominal pain	05/11/2012				
								Muscle spasms	05/11/2012				
								Muscle spasms	05/11/2012				
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	04/12/2012		Recovered/r		
								Chills	04/12/2012	05/12/2012	esolved		
								Arthralgia	04/12/2012	01/01/2013			
								Pyrexia	04/12/2012	06/12/2012			
								Headache	04/12/2012				
								Pain in extremity	04/12/2012	01/01/2013			
								Photophobia	04/12/2012	05/12/2012			
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	06/11/2012		Recovered/r		
								Headache	06/11/2012	1	esolved		
								Pain	06/11/2012	1			
								Pain in extremity	06/11/2012	21/11/2012			
2013-016024	11/01/2013	12 Years	Female	Prophylaxis	GARDASIL	05/12/2012 -	.5 ml	Medication error			Recovered/r		Comment-Patient received
											esolved		3rd dose early.
2013-016065	16/01/2013	12 Years	Female	Prophylaxis	GARDASIL	02/10/2012 -	.5 ml	Sneezing	02/10/2012	1	Recovered/r		
								Eye pruritus	02/10/2012	1	esolved		
								Influenza like illness	02/10/2012	1			



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
2013-016066	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/r esolved		
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 15/10/2012		Recovered/r esolved	BECLAZONE VENTOLIN SINGULAIR	Asthma Hyperventilation
2013-016280	07/02/2013	12 Years	Female	Prophylaxis	GARDASIL	13/09/2012 - 14/11/2012 -	.5 ml	Dizziness Influenza like illness Nausea Somnolence Fatigue Headache Narcolepsy Hypersomnia	14/09/2012 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/r esolved		
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/r esolved		
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/r esolved		
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 12/03/2013		Unknown	MEFAC	



	Date of first									Bereiten			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Reaction Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
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 VIIth nerve paralysis	07/12/2012 07/12/2012 07/12/2012 07/12/2012		Recovered/r esolved	GABAPENTIN PARACETAMOL/CODEIN E	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 11/03/2013		Recovered/r esolved		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/r esolved		
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/r esolved		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/r esolved		
2013-016723	25/03/2013	17 Years	Female	Prophylaxis	GARDASIL	08/11/2012 - 08/11/2012		Pain in extremity			Recovered/r esolved		
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 19/03/2013		Recovered/r esolved		
2013-016803	25/03/2013	17 Years	Female	Prophylaxis	GARDASIL	08/11/2012 -		Pain in extremity	08/11/2012		Recovered/r esolved		
2013-016853	08/04/2013	17 Years	Female	Prophylaxis	GARDASIL	22/11/2012 -		Pain in extremity Tenderness	22/11/2012 22/11/2012		Recovered/r esolved		
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/r esolved		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID 1	to HPRA 10/04/2013	Age 18 Years	Sex Female	Indications Prophylaxis	Suspect Drug(s) GARDASIL	Therapy Dates 01/10/2012 - 01/10/2012	Dose	(MedDRA PT) Postural orthostatic	Onset Date 08/11/2012	Date	Outcome Not	Medication(s)	(MedDRA PT)/Comment
2013-010009	10/04/2013	io reais	remale	Propriyiaxis	GARDASIL	01/10/2012 - 01/10/2012		tachycardia syndrome	06/11/2012		recovered at		
								Palpitations	08/11/2012		time of		
								1 alpitations	00/11/2012		reporting		
2013-016871	10/04/2013	12 Years	Female	Prophylaxis	BOOSTRIX	09/04/2013 -	1 Dosage	Feeling hot	09/04/2013		Recovered/r	ELTROXIN	Hypothyroidism
				. ,	GARDASIL	09/04/2013 -	forms	Dizziness	09/04/2013		esolved		
						20/11/2012 -	1 Dosage	Malaise	09/04/2013				
						18/09/2012 -	forms	Dysphagia	09/04/2013				
							1 Dosage forms	Flushing	09/04/2013				
							1011113	Urticaria Throat tightness	09/04/2013 09/04/2013				
								Hypersensitivity	09/04/2013				
								Пурстосполичку	03/04/2013				
2013-016877	11/04/2013	13 Years	Female	Prophylaxis	BOOSTRIX	09/04/2013 -	1 Dosage	Headache	09/04/2013		Recovered/r		
					GARDASIL	09/04/2013 -	forms	Feeling hot	09/04/2013		esolved		
							1 Dosage forms	Flushing	09/04/2013				
							IOIIIIS	Urticaria Dysphagia	09/04/2013 09/04/2013				
								Hypersensitivity	09/04/2013				
2013-016890	12/04/2013		Female	Prophylaxis	GARDASIL	08/11/2012 -	1 Dosage	Oedema peripheral	03/04/2013		Unknown		
							forms	, ,					
2013-016896	12/04/2013	13 Years	Female	Prophylaxis	GARDASIL	05/12/2012 -		Nausea	05/12/2012		Recovered/r		Epistaxis
2013-016907	15/04/2013	12 Vaara	Famala	Drophylovia	GARDASIL	01/10/2012 -	.5 ml	Urtigaria	11/04/2013		esolved		
2013-016907	15/04/2013	13 Years	Female	Prophylaxis	BOOSTRIX	11/04/2013 -	.5 ml	Urticaria	11/04/2013		Recovered/r esolved		
					BOOGINIX	11/04/2013	.5 1111	Pruritus	11/04/2013		CSOIVCG		
								Truntus	11/04/2013				
2013-016909	15/04/2013	19 Years	Female	Prophylaxis	GARDASIL	10/04/2013 -		Rash erythematous	10/04/2013		Recovered/r		
						03/12/2012 -		Urticaria	10/04/2013		esolved		
0040 040000	10/01/0010	40.1/	F	December 1 - 2 -	0.4.00.4.011	03/10/2012 -		1.5	44/00/0040		NI.		
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		
								Musculoskeletal stillless	11/03/2013		time of		
											reporting		
2013-016974	19/04/2013	19 Years	Female	Prophylaxis	GARDASIL	14/11/2012 -	.5 ml	Maternal exposure during			Unknown		Comment-No further
					PRIORIX.	19/09/2012 -		pregnancy					information provided
						14/11/2012 -							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 -	.5 ml	Headache	20/11/2012		Recovered/r		
2042 04222	00/04/0040	40 V	F1-	Deschided:	CARRACII	25/09/2012 -		Material and according			esolved		Commant No Costonia
2013-016993	22/04/2013	16 Years	Female	Prophylaxis	GARDASIL	17/12/2012 -		Maternal exposure during			Unknown		Comment-No further
								pregnancy	1		1		information provided regarding impact of
													exposure to vaccine in
									1		1		pregnancy.



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



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2013-017358	04/06/2013	18 Years	Female	Prophylaxis	GARDASIL	14/05/2013 -		Influenza like illness	27/05/2013		Recovered/r	DIANETTE	
								Pain	27/05/2013		esolved		
								Body temperature	27/05/2013				
								Headache	27/05/2013				
								Oropharyngeal pain	27/05/2013				
								Musculoskeletal stiffness	27/05/2013				
2013-017433	12/06/2013	17 Years	Female	Prophylaxis	GARDASIL	11/04/2013 -		Nausea	11/04/2013		Recovered/r	TRIMETHOPRIM	
						03/12/2012 -		Headache	11/04/2013		esolved	DIFFERIN	
						04/10/2012 -		Body temperature	11/04/2013			MICROLITE	
								Face oedema	11/04/2013				
								Dysphagia	11/04/2013				
2013-017446	13/06/2013	18 Years	Female	Prophylaxis	GARDASIL	29/04/2013 -	.5 ml	Fatigue	29/04/2013		Recovered/r	YASMIN	
				1 ' '				Lymphadenopathy	29/04/2013		esolved		
								Pyrexia	29/04/2013				
2013-017672	08/07/2013	17 Years	Female	Prophylaxis	GARDASIL	12/03/2013 -	.5 ml	Injection site pain	12/03/2013		Not		
				1 ' '							recovered at		
											time of		
											reporting		
2013-017770	17/07/2013	13 Years	Female	Prophylaxis	GARDASIL	19/04/2013 -	1 Dosage	No adverse event			Recovered/r	BOOSTRIX	Asthma
2010 011110	1170172010		· omaio		0, 11, 12, 10,12	15/03/2013 -	forms	Inappropriate schedule of			esolved	2000111111	7.63
						20/09/2012 -	1 Dosage	drug administration			COOIVCG		
2013-017835	24/07/2013	14 Years	Female	Prophylaxis	GARDASIL	14/03/2013 -	. Doodgo	Pallor	14/03/2013		Recovered/r		
2010 017000	24/01/2013	14 Tours	Tomaic	Tophylaxis	BOOSTRIX	14/03/2013 -		Cold sweat	14/03/2013		esolved		
					BOOSTRIA	14/03/2013 -		Hypotension	14/03/2013		esoiveu		
								riypoterision	14/03/2013				
2013-017837	24/07/2013	17 Years	Female	Prophylaxis	GARDASIL	06/11/2012 -		Syncope	06/11/2012		Recovered/r		
2010 017007	2 1/01/2010	17 10010	Tomalo	Tophylaxio	G/ II (B/ (G)E	00/11/2012		Супосре	00/11/2012		esolved		
2013-017839	24/07/2013	17 Years	Fomale	Prophylaxis	GARDASIL	11/09/2012 -		Presyncope	11/09/2012		Recovered/r		Syncope
2013-017639	24/01/2013	17 Tears	remale	Fiophylaxis	GARDASIL	11/09/2012 -			11/09/2012		esolved		Зупсоре
								Syncope	11/09/2012		esoiveu		
2013-017840	24/07/2013	12 Years	Fomale	Prophylaxis	GARDASIL	13/09/2012 -		Syncope	13/09/2012		Recovered/r		
2013 017040	24/01/2013	12 10013	Tomaic	Tophylaxis	GARBAGIE	13/03/2012		Hypotension	13/09/2012		esolved		
								Typoterision	13/03/2012		esoiveu		
2013-018105	26/08/2013	17 Years	Female	Prophylaxis	PANDEMRIX	25/02/2010 -		Fatigue	01/2011	1	Recovering/r	FYBOGEL	Dermatillomania
_0.0001000	_0,00,2010	1., 10013	· omaic	oprijianio	GARDASIL	06/10/2010 -		Somnolence	101/2011		esolving	SANOMIGRAN	Impetigo
					GARDAGIE	02/12/2010 -		Headache			CSOIVING	TERBINAFINE	Impeligo
						15/03/2011 -		Dizziness				TETRALYSAL	
						13/03/2011						TETTALIOAL	
								Chronic fatigue syndrome					
2013-018229	09/09/2013	18 Years	Female	Prophylaxis	GARDASIL	09/09/2013 -		Dizziness	09/09/2013	1	Recovered/r		
2013-010229	03/03/2013	10 16015	cinale	Ιοριιγιαλίο	GANDAGIL	03/03/2013 -		Nausea	09/09/2013		esolved		
								Ivausea	03/03/2013		CSOIVCG		
2013-018254	11/09/2013	12 Years	Female	Prophylaxis	GARDASIL	10/09/2013 -		Nausea	10/09/2013	 	Recovered/r		
2013-010234	11/09/2013	12 16415	i emale	ι ιυριιγιαλίο	GARDASIL	10/09/2013 -		Ivausea	10/09/2013		esolved		
	1	1	ļ	ļ					ļ	<u> </u>	coulved		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Commen
2013-018275	13/09/2013	13 Years	Female	Prophylaxis	GARDASIL	13/09/2013 -		Sensation of foreign body	13/09/2013		Unknown		
				, ,				Rash erythematous	13/09/2013				
								Tachycardia	13/09/2013				
								Headache	13/09/2013				
								. roadaone	10/00/2010				
2013-018284	13/09/2013	12 Years	Female	Prophylaxis	GARDASIL	09/09/2013 -		Malaise	10/09/2013		Recovering/r		
20.000.020.	10,00,2010	12 100.0	· omaio		67 11 127 1612	00/00/2010		Pyrexia	09/09/2013		esolving		
								Oropharyngeal pain	11/09/2013		ccciving		
								Oedema peripheral	11/09/2013				
								Ocacina periprierar	11/03/2013				
2013-018290	16/09/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Syncope	12/09/2013	12/09/2013	Recovered/r		
2013 010230	10/03/2013	12 TCais	Ciliaic	Τοριιγιαλίο	GANDAGIE	12/03/2013		Супсорс	12/03/2013	12/03/2013	esolved		
2013-018292	16/09/2013	12 Years	Famala	Drophylovia	GARDASIL	12/09/2013 -		Cymanna	12/09/2013				
2013-018292	16/09/2013	12 Years	remaie	Prophylaxis	GARDASIL	12/09/2013 -		Syncope	12/09/2013		Recovered/r esolved		
								_	.				
2013-018296	16/09/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Syncope	12/09/2013		Recovered/r		
											esolved		
2013-018297	16/09/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Panic attack	12/09/2013		Recovered/r		
											esolved		
2013-018299	16/09/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Syncope	12/09/2013		Recovered/r		
				, ,							esolved		
2013-018309	17/09/2013	12 Years	Female	Prophylaxis	GARDASIL	16/09/2013 -		Body temperature	16/09/2013		Not		
2010 010000	11700/2010	12 Tours	Tomalo	Порпушлю	G/11/B/10/E	16/00/2010		increased	10/00/2010		recovered at		
								inoroacoa			time of		
											reporting		
2013-018316	18/09/2013	18 Years	Female	Prophylaxis	GARDASIL	17/09/2013 -		Headache	17/09/2013		Recovered/r	GALFER	Anaemia
								Stress	17/09/2013		esolved		
								Dizziness	17/09/2013				
								Panic attack	17/09/2013				
2013-018317	18/09/2013	16 Years	Female	Prophylaxis	GARDASIL	17/09/2013 -		Headache	17/09/2013		Recovered/r		
								Amnesia	17/09/2013		esolved		
								Syncope	17/09/2013				
								Fall	17/09/2013				
2013-018318	18/09/2013	12 Years	Female	Prophylaxis	GARDASIL	18/09/2013 -	.5 ml	Rash	18/09/2013		Recovered/r		Asthma
								Hypersensitivity	18/09/2013		esolved		
2013-018319	18/09/2013	12 Years	Female	Prophylaxis	GARDASIL	18/09/2013 -	.5 ml	Hypersensitivity	18/09/2013		Recovered/r		
				. ,				1			esolved		
								Rash pruritic	18/09/2013				
								Taon prantio	13/03/2013				
2013-018320	18/09/2013	12 Years	Female	Prophylaxis	GARDASIL	18/09/2013 -	.5 ml	Hypersensitivity	18/09/2013	1	Not		Eczema
2010 010020	10/03/2013	12 10015	Cinale	ι τοριτγιαλίο	OARDAGIL	10/03/2013 -	.5 1111	Rash pruritic	18/09/2013		recovered at		Psoriasis
	1							Rash plantic	10/03/2013		time of		1 30110313
											reporting		
									<u> </u>		reporting		
2013-018321	18/09/2013	12 Years	Female	Prophylaxis	GARDASIL	18/09/2013 -	.5 ml	Hypersensitivity	18/09/2013		Recovered/r		
	1							Rash	18/09/2013		esolved		
1	1							Nausea	18/09/2013		1		
	1	1	1	1	1		1	I	1	1	1	I	



	Date of first	Detions	Detient					Adverse Beestien(s)	Donation	Reaction		Concernitors	Madical Listons
HPRA ID	notification to HPRA	Patient Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Cessation Date	Outcome	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment
2013-018323	18/09/2013	12 Years		Prophylaxis	GARDASIL	18/09/2013 -	.5 ml	Hypersensitivity	18/09/2013	Date	Recovered/r	mediodion(s)	(modbrott tyrodininone
								Rash pruritic	18/09/2013		esolved		
								Nausea	18/09/2013				
2013-018339	20/09/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -	+	Pain in extremity	16/09/2013		Unknown		
20.00.0000	20,00,2010	12 10010	· omaio	. ropinyiaxio	0,(5, 10.12	12/00/2010		Headache	16/09/2013		0		
								Pyrexia	16/09/2013				
								Asthenia	16/09/2013				
								Fatigue	16/09/2013				
								Injection site warmth	16/09/2013				
2013-018349	23/09/2013	16 Years	Female	Prophylaxis	GARDASIL	18/09/2013 -	.5 ml	Incorrect dose	18/09/2013		Recovered/r		
						05/10/2010 -	.5 ml	administered			esolved		
						09/12/2010 -	.5 ml	No adverse event					
						06/04/2011 -	.5 ml						
2013-018354	23/09/2013	12 Years	Female	Prophylaxis	GARDASIL	23/09/2013 -		Syncope	23/09/2013		Recovered/r esolved		Asthma
								Dizziness	23/09/2013		000.704		
								5.22000	20,00,20.0				
2013-018355	23/09/2013	12 Years	Female	Prophylaxis	GARDASIL	23/09/2013 -		Nausea	23/09/2013		Recovered/r		
											esolved		
2013-018357	23/09/2013	18 Years	Female	Prophylaxis	GARDASIL	16/09/2013 -	.5 ml	Asthenia Pain in extremity	16/09/2013 16/09/2013		Not recovered at		Asthma
								Asthma	09/2013		time of		
								Body temperature	16/09/2013		reporting		
								increased					
2013-018363	23/09/2013	14 Years	Female	Prophylaxis	GARDASIL	18/01/2011 -		Fatigue	02/2011		Not		
						18/02/2011 - 20/05/2011 -					recovered at time of		
						20/05/2011 -					reporting		
2013-018377	25/09/2013	12 Years	Female	Prophylaxis	GARDASIL	24/09/2013 -		Vomiting	24/09/2013		Recovered/r		
				., ,				3			esolved		
2013-018378	25/09/2013	12 Years	Female	Prophylaxis	GARDASIL	24/09/2013 -		Syncope	24/09/2013		Recovered/r		Syncope
0040 040070	05/00/0040		E I.	December 1 or 2 or	OARRAGII	0.4/0.0/0.04.0		He de de de	0.4/0.0/0.04.0	0.4/0.0/0.04.0	esolved		Han an area for to a store t
2013-018379	25/09/2013		Female	Prophylaxis	GARDASIL	24/09/2013 -		Headache	24/09/2013	24/09/2013	Recovered/r esolved		Upper respiratory tract infection
2013-018386	25/09/2013	12 Years	Female	Prophylaxis	GARDASIL	17/09/2013 -	.5 ml	Vomiting	17/09/2013		Not		
								Retching	18/09/2013		recovered at		
								Syncope	17/09/2013		time of		
								Headache	18/09/2013		reporting		
2013-018389	25/09/2013	17 Years	Female	Prophylaxis	GARDASIL	10/09/2013 -	.5 ml	Erythema nodosum	11/09/2013		Unknown		Hiatus hernia
				' '				Oropharyngeal pain	11/09/2013				Lymphadenopathy
								Fatigue	11/09/2013	09/2013			
2013-018391	26/09/2013	12 Years	Female	Prophylaxis	GARDASIL	24/09/2013 -	.5 ml	Nasal congestion	24/09/2013		Not		
					S	2.700,2010		Eye swelling	24/09/2013		recovered at		
								7			time of		
											reporting		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2013-018415	30/09/2013	18 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -	.5 ml	Rash erythematous	12/09/2013		Recovered/r esolved		
2013-018416	30/09/2013	13 Years	Female	Prophylaxis	GARDASIL	27/09/2013 -	.5 ml	Rash macular Dizziness Butterfly rash Pallor			Recovered/r esolved		
2013-018448	02/10/2013	12 Years	Female	Prophylaxis	GARDASIL	01/10/2013 -		Syncope	01/10/2013		Recovered/r esolved		
2013-018450	02/10/2013	13 Years	Female	Prophylaxis	GARDASIL	25/09/2013 -		Urticaria	25/09/2013		Recovered/r esolved		
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		Recovered/r esolved	IMPLANON YASMIN	
2013-018464	03/10/2013	17 Years	Female	Prophylaxis	GARDASIL	03/10/2013 -		Syncope	03/10/2013		Recovered/r esolved		
2013-018465	03/10/2013	13 Years	Female	Prophylaxis	GARDASIL	03/10/2013 -		Dizziness	03/10/2013		Recovered/r esolved		
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/r esolved		
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/r esolved		
2013-018481	04/10/2013	17 Years	Female	Prophylaxis	GARDASIL	03/10/2013 -		Syncope	03/10/2013		Recovered/r esolved		
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	



	Date of first	Barriana.	Bartland.					A book Bracklands	Bernetten	Reaction			Market Harris
LIDDAID	notification	Patient	Patient	to Paretters	0	Th		Adverse Reaction(s)	Reaction	Cessation	0.11	Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2013-018525	09/10/2013	12 Years	remaie	Prophylaxis	GARDASIL	26/09/2013 -		Dizziness	26/09/2013		Recovered/r		
								Pallor	26/09/2013		esolved		
								Asthenia	26/09/2013				
								Cold sweat	26/09/2013				
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/r		
											esolved		
2013-018584	16/10/2013	13 Years	Female	Prophylaxis	GARDASIL	09/09/2013 -	.5 ml	Tachycardia	09/09/2013		Recovered/r		
								Headache	09/09/2013		esolved		
								Flushing	09/09/2013				
								Heart rate irregular	09/09/2013				
								Dizziness	09/09/2013				
2013-018751	04/11/2013	12 Years	Female	Prophylaxis	GARDASIL	03/10/2013 -		Herpes zoster	23/10/2013		Recovered/r		
				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				.,			esolved		
2013-018774	07/11/2013	13 Years	Female	Prophylaxis	GARDASIL	19/09/2011 -		Syncope	28/03/2012		Unknown		
					BOOSTRIX	21/03/2012 -		Post viral fatigue	28/03/2012				
						21/03/2012 -		syndrome					
								Pain					
2013-018788	08/11/2013	16 Years	Female	Prophylaxis	GARDASIL	24/09/2013 -	.5 ml	Incorrect dose	24/09/2013		Recovered/r		
2010 010700	00/11/2010	10 Touro	Tomalo	Торпушлю	0,1112,1012	24/05/2010	.0	administered	2-1/00/2010		esolved		
								No adverse event			0001100		
								no adverse event					
2013-018789	08/11/2013	16 Years	Female	Prophylaxis	GARDASIL	24/09/2013 -	.5 ml	Incorrect dose	24/09/2013		Recovered/r		
								administered			esolved		
								No adverse event					
2013-018829	13/11/2013	13 Years	Female	Prophylaxis	GARDASIL	13/11/2013 -		Pallor	13/11/2013		Recovered/r		
2010 010020	10,11,2010	10 10010	· omaio	. ropinylazao	0,11,0,10,12	10/11/2010			13/11/2010		esolved		
								Cold sweat	13/11/2013	1			
								Tremor	13/11/2013				
								Syncope	13/11/2013				
2013-018856	17/11/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Headache	14/09/2013		Recovered/r		
2013-010000	17/11/2013	12 16415	i ciliale	ι τυριτιγιαλίδ	GANDAGIL	12/03/2013 -		Dizziness	14/09/2013	1	esolved		
								Muscular weakness	14/09/2013		COUVEU		
									14/09/2013				
								Myalgia	14/03/2013				
2013-018857	17/11/2013	17 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -	1	Headache	12/09/2013	1	Recovered/r		
											esolved		
2013-018889	19/11/2013	12 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Headache	12/09/2013		Recovered/r		
										1	esolved		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2013-018890	19/11/2013	17 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Nausea	12/09/2013		Recovered/r esolved		
								5	40/00/0040		esoiveu		
								Dizziness	12/09/2013				
2013-018897	20/11/2013	12 Years	Fomolo	Prophyloxic	GARDASIL	19/09/2013 -		Headache	19/09/2013		Recovered/r		
2013-010091	20/11/2013	12 Teals	remale	Prophylaxis	GANDASIL	19/09/2013 -		Dizziness	19/09/2013		esolved		
								Dizziiicss	13/03/2013		COOLVCG		
2013-018899	20/11/2013	17 Years	Female	Prophylaxis	GARDASIL	19/09/2013 -		Vomiting	19/09/2013		Recovered/r		
				., ,							esolved		
2013-018929	22/11/2013	12 Years	Female	Prophylaxis	GARDASIL	19/09/2013 -		Local swelling	20/09/2013		Recovered/r		
				' '							esolved		
2013-018950	25/11/2013	13 Years	Female	Prophylaxis	GARDASIL	12/11/2013 -	.5 ml	Urticaria	12/11/2013		Recovered/r		Eczema
				. ,		10/09/2013 -					esolved		Food allergy
2013-018966	25/11/2013	13 Years	Female	Prophylaxis	GARDASIL	12/2010 -		Headache	12/2010		Not		Learning disability
						03/2011 -		Dizziness	2011		recovered at		Previous speech disorder
								Anxiety	2011		time of		Enuresis
								Depression	2011		reporting		
								Mood swings	2011				
								Quality of life decreased	2011				
								Vomiting	2011				
								Abnormal behaviour	2011				
								Memory impairment	2011				
								Confusional state Tremor	2011 2011				
								Tremoi	2011				
2013-018980	27/11/2013	17 Years	Female	Prophylaxis	GARDASIL	24/09/2013 -	.5 ml	Lip swelling	24/09/2013		Recovered/r		
						- "	1.0	Joint swelling	24/09/2013		esolved		
								Rash	24/09/2013				
								Throat tightness	24/09/2013				
2013-019017	29/11/2013	13 Years	Female	Prophylaxis	GARDASIL	26/09/2013 -	.5 ml	Injection site paraesthesia	13/10/2013		Recovered/r		
											esolved		
								Muscle spasms	13/10/2013				
								Dyspnoea	13/10/2013				
0040 040000	00/40/0040	40.1/	F I .	Donald India	0.455.4011	07/44/0040		Handark .	07/44/0040		D	NACOEAN	A second sections
2013-019028	02/12/2013	13 Years	remale	Prophylaxis	GARDASIL	27/11/2013 -		Headache	27/11/2013 27/11/2013		Recovered/r esolved	NASOFAN	Appendicectomy Constipation
								Dyspepsia	27/11/2013		esoived		Consupation
2013-019033	02/12/2013	17 Years	Female	Prophylaxis	GARDASIL	23/09/2013 -	.5 ml	Syncope	23/09/2013		Recovered/r		
_5.0 0.0000	52,12,2010	77 10013	· omaic	oprijianio	O/ IND/NOIL	20/00/2010		Headache	23/09/2013		esolved		
								Urticaria	23/09/2013				
								5 7 5 5 7					
2013-019103	10/12/2013	13 Years	Female	Prophylaxis	GARDASIL	02/10/2013 -		Headache	02/10/2013		Recovered/r		
								Dizziness	02/10/2013		esolved		
								Nausea	02/10/2013				
2013-019150	16/12/2013		Female	Prophylaxis	GARDASIL	20/10/2010 -		Drug prescribing error			Recovered/r		Syncope
						02/10/2013 -		No adverse event			esolved		
						04/12/2013 -							



	Date of first notification	Patient	Detient					Adverse Recetion(s)	Reaction	Reaction Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Patient Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	Adverse Reaction(s) (MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2013-019180	13/12/2013	12 Years		Prophylaxis	GARDASIL GARDASIL	25/11/2013 -	.5 ml	Cough	25/11/2013	Date	Recovered/r	SALBUTAMOL	Asthma
								Throat tightness	25/11/2013		esolved	VENTOLIN	
								Wheezing	25/11/2013				
											1		
2013-019223	23/12/2013	13 Years	Female	Prophylaxis	GARDASIL	30/09/2013 -	.5 ml	Idiopathic	07/11/2013		Not recovered at		
								thrombocytopenic purpura	07/44/0040		time of		
								Haemorrhage	07/11/2013		reporting		
2014-019231	30/12/2013	12 Years	Female	Prophylaxis	GARDASIL	09/09/2013 -	.5 ml	Platelet count decreased	28/12/2013		Unknown		
				. ,		04/11/2013 -	.5 ml	Mucosal haemorrhage	28/12/2013				
								Idiopathic	28/12/2013				
								thrombocytopenic purpura					
2014-019235	30/12/2013	12 Years	Female	Prophylaxis	GARDASIL	26/09/2013 -		Haemorrhage	30/12/2013		Not	BOOSTRIX	
								Contusion Thrombocytopenia	30/12/2013 30/12/2013		recovered at time of		
								Idiopathic	30/12/2013		reporting		
								thrombocytopenic purpura	30/12/2013		. oporang		
2014-019311	08/01/2014	13 Years	Female	Prophylaxis	GARDASIL	23/09/2013 -		Diarrhoea			Unknown		Asthma
								Colitis					
2014-019334	10/01/2014	18 Years	Female	Prophylaxis	GARDASIL	09/01/2014 -		Headache	09/01/2014		Recovered/r esolved		Headache
2014-019336	10/01/2014	18 Years	Famala	Prophylaxis	GARDASIL	09/01/2014 -		Headache	09/01/2014		Recovered/r		Systemic lupus
2014-019336	10/01/2014	io reais	remale	Propriyiaxis	GARDASIL	09/01/2014 -		Malaise	09/01/2014		esolved		erythematosus
								Walaise	03/01/2014		Coolved		ory the materials
2014-019345	13/01/2014	18 Years	Female	Prophylaxis	GARDASIL	09/01/2014 -		Nausea	09/01/2014	10/01/2014	Recovered/r		
								Dizziness	09/01/2014	10/01/2014	esolved		
0044 040000	10/01/0011	40.1/	F	Daniel de la	CARRAGII			I I a de de c			D		H I I.
2014-019368	10/01/2014	18 Years	remale	Prophylaxis	GARDASIL			Headache			Recovered/r esolved		Headache
2014-019429	23/01/2014	18 Years	Female	Prophylaxis	GARDASIL	16/09/2013 -	.5 ml	Periorbital oedema	17/09/2013		Recovered/r		Coeliac disease
				,,,,,,				Swelling face	17/09/2013		esolved		
								Vision blurred	17/09/2013				
								Local swelling	17/09/2013				
2014-019430	23/01/2014	17 Years	Famala	Prophylaxis	GARDASIL	10/09/2013 -	.5 ml	Local swelling	12/09/2013		Recovered/r		
2014-019430	23/01/2014	17 rears	remale	Propriyiaxis	GARDASIL	10/09/2013 -	.5 1111	Erythema	12/09/2013		esolved		
								Pruritus	12/09/2013		CSOIVCG		
								T Tantas	12/00/2010				
2014-019580	06/02/2014	12 Years	Female	Prophylaxis	GARDASIL	12/11/2013 -	.5 ml	Headache	15/11/2013		Recovered/r		
								Pyrexia	15/11/2013	1	esolved	1	
								Rash papular	15/11/2013				
2014-019586	06/02/2014	12 Years	Female	Prophylaxis	GARDASIL	11/2013 -		Migraine with aura			Not		Familial risk factor
	30,02,2014				SS. 101E	125.5		Asthenia			recovered at		. aa. non idotoi
								Amnesia			time of		
								Aphasia		1	reporting	1	
								Headache					



	Date of first									Reaction			
UDDAID	notification	Patient	Patient	to Paretona	Out of Day (a)	The same Desired		Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2014-019844	04/03/2014	13 Years	Female	Prophylaxis	GARDASIL	04/12/2013 -		Nausea	04/12/2013	06/12/2013	Recovered/r esolved	ONDANSETRON KWELLS	Cerebral haemorrhage
								Headache	04/12/2013	06/12/2013	esoived	KVVELLS	
								Vomiting	04/12/2013	06/12/2013			
								Asthenia	04/12/2013	06/12/2013			
								Fatigue	04/12/2013	06/12/2013			
								Decreased appetite	04/12/2013	06/12/2013			
2014-019893	07/03/2014	18 Years	Female	Prophylaxis	GARDASIL	26/09/2012 -		Incorrect dose	26/09/2012		Recovered/r		Asthma
								administered			esolved		
								No adverse event					
2014-020050	24/03/2014	13 Years	Female	Prophylaxis	GARDASIL	20/03/2014 -		Disorientation	20/03/2014		Recovered/r	IPV-BOOSTRIX	
				' '				Abnormal behaviour	20/03/2014		esolved		
								Memory impairment	21/03/2014				
								Fatigue	21/03/2014				
								Malaise	21/03/2014				
								Syncope	21/03/2014				
								•					
2014-020057	24/03/2014	13 Years	Female	Prophylaxis	GARDASIL	20/03/2014 -		Nausea	20/03/2014		Recovered/r esolved		
0044.000050	24/03/2014		E	Daniel I. danie	GARDASIL	20/03/2014 -		Harada da da	20/03/2014	1			Harden L.
2014-020058	24/03/2014		Female	Prophylaxis	BOOSTRIX	20/03/2014 -		Headache	20/03/2014		Recovered/r esolved		Headache
2014-020073	26/03/2014	13 Years	Female	Prophylaxis	GARDASIL	13/09/2013 -		Headache	18/11/2013		Not		
2011 020010	20/00/2011	10 10010	· omaio	1 1001111101110	0, 11, 12, 13, 12	18/11/2013 -		Dizziness	18/11/2013		recovered at		
						16,11,2010		Feeling cold	18/11/2013		time of		
								Muscular weakness	18/11/2013		reporting		
								Lethargy	18/11/2013				
								Fatigue	18/11/2013				
								Pharyngitis	10/11/2010				
								i naryngins					
2014-020190	07/04/2014		Female	Prophylaxis	GARDASIL	27/01/2013 -	.5 ml	Trance transient			Recovered/r		
								Muscle twitching			esolved		
								Headache					
2014-020199	07/04/2014	13 Years	Female	Prophylaxis	GARDASIL	31/03/2014 -		Vomiting	31/03/2014		Recovered/r		
					BOOSTRIX	31/03/2014 -					esolved		
2014-020200	07/04/2014		Female	Prophylaxis	GARDASIL	31/03/2014 -		Vomiting	31/03/2014		Recovered/r		
					PRIORIX.	31/03/2014 -		Dizziness	31/03/2014		esolved		
2014-020210	07/04/2014	13 Years	Female	Prophylaxis	GARDASIL	04/04/2014 -		Sensation of heaviness	04/04/2014		Not		
				-				Injection site streaking		1	recovered at		
1								Skin hypopigmentation		1	time of		
								Acne			reporting		
2014-020212	08/04/2014	12 Years	Female	Prophylaxis	GARDASIL	02/04/2014 -	.5 ml	Psychomotor hyperactivity	02/04/2014		Recovered/r		
2017 020212	00/04/2014	12 10013	Tomaic	1 Topinyianis	ONINDAGIL	02/04/2014	1.5 1111	- Sychomotor hyperactivity	02/07/2014		esolved		
2014-020218	08/04/2014	18 Years	Female	Prophylaxis	GARDASIL	20/03/2014 -	.5 ml	Syncope	20/03/2014		Recovered/r		
			1							I	esolved		



	Date of first									Reaction			
	notification	Patient	Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2014-020224	08/04/2014	13 Years	Female	Prophylaxis	GARDASIL	27/03/2014 -		Asthenia	27/03/2014		Recovered/r	MOVICOL	Constipation
					BOOSTRIX	27/03/2014 -		Vomiting	27/03/2014		esolved		
								Pain in extremity	27/03/2014				
								Pyrexia	27/03/2014				
0044 000004	00/04/0044	40.)/	F	December 1 - 1 - 1	OARDAOII	0.4/00/004.4		Malaise	27/03/2014		D		
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	08/04/2014 -		Syncope	08/04/2014		Recovered/r		
					BOOSTRIX	08/04/2014 -		Asthenia	08/04/2014		esolved		
2014-020233	09/04/2014	12 Years	Female	Prophylaxis	GARDASIL	27/09/2013 -		Local swelling			Recovered/r		
				1,7,		29/11/2013 -		Tenderness			esolved		
								Erythema					
2014-020234	09/04/2014	13 Years	Female	Prophylaxis	GARDASIL	08/04/2014 -		Syncope	08/04/2014		Recovered/r		
2011 02020 1	00,01,2011	10 10010	· omaio	, ,	BOOSTRIX	08/04/2014 -		Syllesps			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	03/04/2014		Recovered/r		
2014-020203	11/04/2014	15 Teals	Telliale	Τοριιγιαλίδ	GARDASIL	03/04/2014 -		Vomiting	03/04/2014		esolved		
								Nausea	03/04/2014		Coorroa		
								Erythema	03/04/2014				
								Arthralgia	03/04/2014				
2014-020267	11/04/2014	13 Years	Female	Prophylaxis	GARDASIL	16/09/2013 -		Syncope	11/2013		Not		Abdominal migraine
				1,7,				Headache	11/2013		recovered at		3
								Convulsion	11/2013		time of		
								Hyperventilation	11/2013		reporting		
								Vision blurred	11/2013				
								Nausea	11/2013				
								Muscular weakness	11/2013				
2014-020397	28/04/2014	12 Years	Female	Prophylaxis	GARDASIL	03/04/2014 -	.5 ml	Fatigue	03/04/2014		Recovered/r		
								Dizziness	03/04/2014		esolved		
								Headache	03/04/2014				
	1							Abdominal pain	03/04/2014				
	1							Nausea	03/04/2014				
								Influenza like illness	03/04/2014				
								Feeling hot	03/04/2014				
2014-020434	01/05/2014		Female	Acne	GARDASIL	20/09/2013 -		Thrombosis	03/2014		Recovered/r		Acne
2044 020402	07/05/0044	20 //	Famala	Prophylaxis	DIANETTE	19/11/2013 -		Distan	40/40/0040	04/40/0040	esolved		
2014-020488	07/05/2014	32 Years	remale		GARDASIL	19/12/2013 -		Blister	19/12/2013	21/12/2013	Recovered/r esolved		
								Rash					
											1		



	Date of first									Reaction			
	notification		Patient					Adverse Reaction(s)	Reaction	Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
2014-020513	09/05/2014	17 Years	Female	Prophylaxis	GARDASIL	24/04/2014 -		Sensation of foreign body	24/04/2014		Recovered/r		
								Dysphagia	24/04/2014		esolved		
								Cough	24/04/2014				
								Dry mouth	24/04/2014				
2014-020540	13/05/2014	13 Years	Female	Prophylaxis	GARDASIL	12/05/2014 -		Pyrexia	12/05/2014		Recovered/r		
					PRIORIX.	12/05/2014 -		Lethargy	12/05/2014		esolved		
2014-020602	18/05/2014	18 Years	Female	Prophylaxis	GARDASIL	02/05/2014 -		Hypoaesthesia	02/05/2014		Recovered/r	OXYTETRACYCLINE	Panic attack
								Panic attack	02/05/2014		esolved		
								Hyperventilation	02/05/2014				
2014-020603	18/05/2014	17 Years	Female	Prophylaxis	GARDASIL	06/12/2013 -		Injection site erythema	06/12/2013		Recovered/r		
								Injection site pain	06/12/2013		esolved		
2014-020606	18/05/2014	18 Years	Female	Prophylaxis	GARDASIL	12/09/2013 -		Nausea			Recovered/r		
						14/11/2013 -					esolved		
2014-020607	18/05/2014	18 Years	Female	Prophylaxis	GARDASIL	14/11/2013 -		Urticaria	14/11/2013		Recovered/r esolved		
2014-020821	10/06/2014	13 Years	Female	Prophylaxis	GARDASIL	13/05/2014 -		Dizziness	14/05/2014		Recovered/r		
					BOOSTRIX	13/05/2014 -		Flushing	14/05/2014		esolved		
								Decreased appetite	14/05/2014				
								Fatigue	14/05/2014				
2014-021036	25/06/2014	19 Years	Female	Prophylaxis	GARDASIL			Papilloma viral infection			Not		Comment-The patients
											recovered at		screen was negative for
											time of		HPV genotypes 16 & 18.
											reporting		
2014-021042	02/07/2014	14 Years	Female	Prophylaxis	GARDASIL	01/07/2014 -		Syncope	01/07/2014		Recovered/r esolved		
2011 2010:	05/05/004	40.14			0.100.100	10/05/0011			10/05/00/	47/05/00/			
2014-021212	25/07/2014	13 Years	remale	Prophylaxis	GARDASIL	12/05/2014 -	.5 ml	Headache	12/05/2014	17/05/2014	Recovered/r		
								Asthenia Confusional state	12/05/2014 12/05/2014	17/05/2014 17/05/2014	esolved		
								Otitis media	12/05/2014	17/05/2014			
ĺ								Body temperature	12/05/2014	17/05/2014			
ĺ								increased	12/03/2014	17/03/2014			
				ı		l		ilicicascu	1	l			1



Not recovitime	come A	Concomitant Medication(s) AMITRIPTYLINE MICROLITE	Medical History (MedDRA PT)/Comment
Not recovirine	come A overed at N e of	Medication(s) AMITRIPTYLINE	
Not recover time	overed at N	AMITRIPTYLINE	(MedDRA PT)/Comment
recov	overed at N		
time	e of	MICROLITE	
геро	orting		
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Reco	covering/r		
	· ·		
Reco	covered/r		
esol	lved		
Reco	covered/r		Syncope
			-,
1			Asthma
			Asuma
			<u> </u>
			Syncope
time	e of		
Reco	covered/r		
ocoli	lved		
	Recresso Recresso Not recretime	Recovering/r esolving Recovered/r esolved Recovered/r esolved Recovered/r esolved Not recovered at time of Recovered/r esolved	Recovered/r esolved Recovered/r esolved Recovered/r esolved Recovered/r esolved Not recovered at time of



HPRA ID 2014-021779	Date of first notification to HPRA 01/10/2014		Patient Sex Female	Indications Prophylaxis	Suspect Drug(s) GARDASIL	Therapy Dates 25/03/2011 - 26/11/2010 - 24/09/2010 -	Dose	Adverse Reaction(s) (MedDRA PT) Local swelling Pain in extremity Hodgkin's disease	Reaction Onset Date	Reaction Cessation Date	Outcome Recovered/r esolved	Concomitant Medication(s)	Medical History (MedDRA PT)/Comment 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/r esolved		Comment-Patient received two Gardasil injections on the same day in error.



HPRA ID 2014-022438	Date of first notification to HPRA 16/12/2014	Patient Age 12 Years	Patient Sex Female	Indications Prophylaxis	Suspect Drug(s) GARDASIL	Therapy Dates 19/09/2011 - 09/12/2011 - 22/03/2012 -	Dose .5 ml .5 ml .5 ml	Adverse Reaction(s) (MedDRA PT) Fatigue Pain Headache Somnolence Pyrexia	Reaction Onset Date	Reaction Cessation Date	Outcome Not recovered at time of reporting	Concomitant Medication(s) OVRANETTE	Medical History (MedDRA PT)/Comment 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/r esolved		
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/r esolved		



	Date of first notification	Patient	Patient					Adverse Reaction(s)	Reaction	Reaction Cessation		Concomitant	Medical History
HPRA ID	to HPRA	Age	Sex	Indications	Suspect Drug(s)	Therapy Dates	Dose	(MedDRA PT)	Onset Date	Date	Outcome	Medication(s)	(MedDRA PT)/Comment
HPRA ID 2015-022720	to HPRA 28/01/2015	Age	Sex Female	Indications Prophylaxis	Suspect Drug(s) GARDASIL	Therapy Dates 27/09/2010 - 17/10/2010 - 14/03/2011 -	Dose 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 2012	Date	Outcome Not recovered at time of reporting	Medication(s)	(MedDRA PT)/Comment
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/r esolved	BOOSTRIX	
2015-023382	20/04/2015	13 Years	Female	Prophylaxis	GARDASIL MENJUGATE KIT	23/03/2015 - 23/03/2015 -	.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/r esolving		
2015-023418		12 Years		Prophylaxis	GARDASIL BOOSTRIX	10/09/2014 - 10/09/2014 -	.5 ml .5 ml	Headache Fatigue	10/09/2014 10/09/2014	2014 2014	Recovered/r esolved		
2015-023478		13 Years		Prophylaxis	GARDASIL MENJUGATE KIT	16/04/2015 - 16/04/2015 -		Pyrexia			Recovered/r esolved		Influenza
2015-023576	11/05/2015	12 Years	Female	Prophylaxis	GARDASIL	29/09/2014 -	.5 ml	Alopecia	01/10/2014	10/2014	Recovered/r esolved	BOOSTRIX	



HPRA ID 2015-023577	Date of first notification to HPRA 11/05/2015	Patient Age 12 Years	Patient Sex Female	Indications Prophylaxis	Suspect Drug(s) GARDASIL	Therapy Dates 27/04/2015 -	Dose .5 ml	Adverse Reaction(s) (MedDRA PT) Alopecia	Reaction Onset Date 29/04/2015	Reaction Cessation Date	Outcome Not	Concomitant Medication(s) MENJUGATE KIT	Medical History (MedDRA PT)/Comment
						29/09/2014 -	.5 ml				recovered at time of reporting		
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/r esolving	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/r esolved		
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		



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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