HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Summary details of suspected adverse reactions/events associated with the use of Gardasil
1st March 2014 - 31st March 2015

HPRA ID	Date of first notification to HPRA	Patient Age	Indications	Vaccine Name	Vaccination Date(s)	Dose	Adverse Reaction(s) (MedDRA PT)	Reaction Onset Date	Reaction Cessation Date	Outcome	Concomitant Medication(s)	Medical History/Case Comments
2014-019844	04/03/2014	13 Years	Prophylaxis	GARDASIL	04/12/2013		Nausea Headache Vomiting Asthenia Fatigue Decreased appetite	04/12/2013 04/12/2013 04/12/2013 04/12/2013 04/12/2013 04/12/2013	06/12/2013 06/12/2013 06/12/2013 06/12/2013 06/12/2013 06/12/2013	Recovered/ resolved	ONDANSETRON KWELLS	Cerebral haemorrhage in 2012
2014-020050	24/03/2014	13 Years	Prophylaxis	GARDASIL	20/03/2014		Disorientation Abnormal behaviour Transient memory impairment Fatigue Malaise Syncope	20/03/2014 20/03/2014 21/03/2014 21/03/2014 21/03/2014 21/03/2014		Recovered/ resolved	IPV-BOOSTRIX	
2014-020057	24/03/2014	13 Years	Prophylaxis	GARDASIL	20/03/2014		Nausea	20/03/2014		Recovered/ resolved		
2014-020058	24/03/2014		Prophylaxis	GARDASIL BOOSTRIX	20/03/2014 20/03/2014		Headache	20/03/2014		Recovered/ resolved		Headache
2014-020073	26/03/2014	13 Years	Prophylaxis	GARDASIL	13/09/2013 18/11/2013		Headache Dizziness Feeling cold Muscular weakness Lethargy Fatigue Pharyngitis	18/11/2013 18/11/2013 18/11/2013 18/11/2013 18/11/2013 18/11/2013		Not recovered at time of reporting		
2014-020190	07/04/2014		Prophylaxis	GARDASIL	27/01/2013	.5 ml	Trance-transient Muscle twitching Headache			Recovered/ resolved		
2014-020199	07/04/2014	13 Years	Prophylaxis	GARDASIL BOOSTRIX	31/03/2014 31/03/2014		Vomiting	31/03/2014		Recovered/ resolved		
2014-020200	07/04/2014		Prophylaxis	GARDASIL PRIORIX.	31/03/2014 31/03/2014		Vomiting Dizziness	31/03/2014 31/03/2014		Recovered/ resolved		
2014-020210	07/04/2014	13 Years	Prophylaxis	GARDASIL	04/04/2014		Sensation of heaviness Injection site streaking Skin hypopigmentation Acne	04/04/2014		Not recovered at time of reporting		
2014-020212	08/04/2014	12 Years	Prophylaxis	GARDASIL	02/04/2014	.5 ml	Psychomotor hyperactivity	02/04/2014		Recovered/ resolved		
2014-020218	08/04/2014	18 Years	Prophylaxis	GARDASIL	20/03/2014	.5 ml	Syncope	20/03/2014		Recovered/ resolved		

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2014-020224	08/04/2014	13 Years	Prophylaxis	GARDASIL BOOSTRIX	27/03/2014 27/03/2014		Asthenia Vomiting Pain in extremity Pyrexia Malaise	27/03/2014 27/03/2014 27/03/2014 27/03/2014 27/03/2014		Recovered/ resolved	MOVICOL	Constipation
2014-020231	09/04/2014	12 Years	Prophylaxis	GARDASIL BOOSTRIX	24/03/2014 24/03/2014		Headache	24/03/2014		Recovered/ resolved		
2014-020232	09/04/2014	13 Years	Prophylaxis	GARDASIL BOOSTRIX	08/04/2014 08/04/2014		Syncope Asthenia	08/04/2014 08/04/2014		Recovered/ resolved		
2014-020233	09/04/2014	12 Years	Prophylaxis	GARDASIL	27/09/2013 29/11/2013		Local swelling Tenderness Erythema			Recovered/ resolved		
2014-020234	09/04/2014	13 Years	Prophylaxis	GARDASIL BOOSTRIX	08/04/2014 08/04/2014		Syncope	08/04/2014		Recovered/ resolved		
2014-020235	09/04/2014	13 Years	Prophylaxis	GARDASIL	24/03/2014		Nausea	24/03/2014		Recovered/ resolved		
2014-020263	11/04/2014	13 Years	Prophylaxis	GARDASIL	03/04/2014		Pyrexia Vomiting Nausea Erythema Arthralgia	03/04/2014 03/04/2014 03/04/2014 03/04/2014 03/04/2014		Recovered/ resolved		
2014-020267	11/04/2014	13 Years	Prophylaxis	GARDASIL	16/09/2013		Syncope Headache Convulsion Hyperventilation Vision blurred Nausea Muscular weakness	11/2013 11/2013 11/2013 11/2013 11/2013 11/2013 11/2013		Not recovered at time of reporting		Abdominal migraine
2014-020397	28/04/2014	12 Years	Prophylaxis	GARDASIL	03/04/2014	.5 ml	Fatigue Dizziness Headache Abdominal pain Nausea Influenza like illness Feeling hot	03/04/2014 03/04/2014 03/04/2014 03/04/2014 03/04/2014 03/04/2014 03/04/2014		Recovered/ resolved		

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2014-020434	41760		Acne Prophylaxis	GARDASIL DIANETTE	20/09/2013 19/11/2013 03/2013		Thrombosis	03/2014		Recovered/ resolved		Acne Comment-Thrombosis considered most likely associated with Dianette
2014-020488	07/05/2014	32 Years		GARDASIL	19/12/2013		Blister Rash	19/12/2013	21/12/2013	Recovered/ resolved		
2014-020513	09/05/2014	17 Years	Prophylaxis	GARDASIL	24/04/2014		Sensation of foreign body Dysphagia Cough Dry mouth	24/04/2014 24/04/2014 24/04/2014 24/04/2014		Recovered/ resolved		
2014-020540	13/05/2014	13 Years	Prophylaxis	GARDASIL PRIORIX.	12/05/2014 12/05/2014		Pyrexia Lethargy	12/05/2014 12/05/2014		Recovered/ resolved		
2014-020602	18/05/2014	18 Years	Prophylaxis	GARDASIL	02/05/2014		Hypoaesthesia Panic attack Hyperventilation	02/05/2014 02/05/2014 02/05/2014		Recovered/ resolved	OXYTETRACYCLINE	Panic attack
2014-020603	18/05/2014	17 Years	Prophylaxis	GARDASIL	06/12/2013		Injection site erythema Injection site pain	06/12/2013 06/12/2013		Recovered/ resolved		
2014-020606	18/05/2014	18 Years	Prophylaxis	GARDASIL	12/09/2013 14/11/2013 02/05/2014		Nausea			Recovered/ resolved		
2014-020607	18/05/2014	18 Years	Prophylaxis	GARDASIL	14/11/2013		Urticaria	14/11/2013		Recovered/ resolved		
2014-020821	10/06/2014	13 Years	Prophylaxis	GARDASIL BOOSTRIX	13/05/2014 13/05/2014		Dizziness Flushing Decreased appetite Fatigue	14/05/2014 14/05/2014 14/05/2014 14/05/2014		Recovered/ resolved		
2014-021036	25/06/2014	19 Years	Prophylaxis	GARDASIL			Papilloma viral infection			Not recovered at time of reporting		Comment- The patients screen was negative for HPV genotypes 16 & 18
2014-021042	02/07/2014	14 Years	Prophylaxis	GARDASIL	01/07/2014		Syncope	01/07/2014		Recovered/ resolved		
2014-021212	25/07/2014	13 Years	Prophylaxis	GARDASIL	12/05/2014	.5 ml	Headache Asthenia Confusional state Otitis media Body temperature increased	12/05/2014 12/05/2014 12/05/2014 12/05/2014 12/05/2014	17/05/2014 17/05/2014 17/05/2014 17/05/2014 17/05/2014	Recovered/ resolved		

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

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2014-021779	01/10/2014	14 Years	Prophylaxis	GARDASIL	25/03/2011 26/11/2010 24/09/2010		Local swelling Pain in extremity Hodgkin's disease	 06/2011		Recovered/ resolved		Familial risk factor
2014-021799	02/10/2014	12 Years	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	Immunisation	GARDASIL TETRAVAC	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	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	Prophylaxis	GARDASIL	10/09/2014	.5 ml	Medication error Emotional distress Fatigue	10/09/2014		Recovered/ resolved		Comment- Patient received two Gardasil vaccines on the same day in error.
2014-022438	16/12/2014	12 Years	Prophylaxis	GARDASIL	19/09/2011 09/12/2011 22/03/2012	.5 ml .5 ml .5 ml	Fatigue Pain Headache Somnolence Pyrexia			Not recovered at time of reporting	OVRANETTE	Hypermobility syndrome Meier-Gorlin syndrome High arched palate Syncope Facial bones fracture Tremor Dizziness Palpitations Loss of consciousness Multiple allergies Abdominal distension Menstruation irregular Disturbance in attention Memory impairment Stress urinary incontinence Comment-Investigations ongoing

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2014-022442	17/12/2014	12 Years	Prophylaxis	GARDASIL BOOSTRIX	22/09/2014 22/09/2014	.5 ml .5 ml	Asthenia Dysstasia Asphasia (transient)	22/09/2014 22/09/2014 22/09/2014		Recovered/ resolved		
2015-022601	13/01/2015	13 Years	Prophylaxis	BOOSTRIX GARDASIL	28/04/2014 28/04/2014		Pyrexia Chills Hallucination	29/04/2014 29/04/2014 29/04/2014		Recovered/ resolved		
2015-022720	28/01/2015		Prophylaxis	GARDASIL	27/09/2010 17/10/2010 14/03/2011		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 Eye pain Transient blindness Amenorrhoea Abdominal pain lower Injection site mass Visual field defect Chronic fatigue syndrome	14/03/2011 14/03/2011 2011 2011 2011 2011 10/2011 10/2011 01/2012 01/2012 2012 2012 2012 2012 2012 2012 2012 2012 2012 01/2015 14/03/2011 09/2014 03/2013		Not recovered at time of reporting		Comment-Investigations ongoing

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STATEMENT TO ACCOMPANY
ADVERSE REACTION DATA RELEASED BY THE HPRA

Introduction

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

Spontaneous Adverse Reaction Reports

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

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

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

Adverse Reaction Listings

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

Lists reactions for a specific drug substance irrespective of whether the reporter provided the approved drug substance name or a brand name of that substance. Brand names are included in the listing if they have been provided.

- 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.

- 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.