

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database) but not included in the Database of Adverse Event Notifications (DAEN). Reports readily identified as duplicates of cases in the DAEN are indicated by blue shading. The reports that do not appear in the DAEN may have insufficient information and/or no reasonable temporal association and/or the relationship between the medicine/vaccine and the adverse event appears to not be related as judged by a health professional and/or the report may have been received by the TGA within the last 90 days and/or the report may be a duplicate of a case included in the DAEN

Case Number	Report Entry Date	Gender	Age	Medicine (Onset Time)	Reaction
250246	17/04/2009	Female	13	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Concomitant (-); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (-)	Seizure ; Syncope
266810	10/05/2010	Female	12	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (-)	Syncope
271964	10/08/2010	Male	12	H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days)	Headache ; Malaise ; Pain in extremity ; Pyrexia
272242	16/08/2010	Female	11	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (7 days); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (7 days)	Arthralgia ; C-reactive protein increased ; Hyporeflexia ; Joint swelling ; Red blood cell sedimentation rate increased
274700	20/10/2010	Female	12	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); H-B-Vax II (Hepatitis B surface antigen recombinant) - Concomitant (0 days)	Rash erythematous ; Urticaria
277292	5/01/2011	Male	-	Engerix B (Hepatitis B surface antigen recombinant) - Concomitant (-); Fluvax (Influenza virus haemagglutinin) - Suspect (50 days)	Guillain-Barre syndrome
279517	7/03/2011	Female	59	Engerix B (Hepatitis B surface antigen recombinant) - Suspect (3 days)	Headache ; Hyperhidrosis ; Lethargy ; Nausea ; Pain ; Pyrexia
280661	31/03/2011	Female	14	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days)	Abdominal discomfort ; Malaise ; Nausea ; Rash
280766	1/04/2011	Female	12	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days); Varilrix (live varicella vaccine) - Suspect (0 days)	Pain ; Pyrexia ; Vomiting
294281	6/01/2012	Female	53	Engerix B (Hepatitis B surface antigen recombinant) - Suspect (2 days); Vivaxim (Hepatitis a virus antigen ; Salmonella typhi Vi polysaccharide) -	Pruritus ; Urticaria

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				Suspect (0 days)	
295502	6/02/2012	Female	-	Engerix B (Hepatitis B surface antigen recombinant) - Suspect (-)	Guillain-Barre syndrome
300468	16/05/2012	Female	12	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (12 days); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (12 days)	Hemiplegic migraine ; Lethargy ; Syncope
302800	27/06/2012	Male	12	H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days)	Erythema ; Pruritus ; Swelling face
305842	24/08/2012	Male	55	Engerix B (Hepatitis B surface antigen recombinant) - Concomitant (-); Trade Name Not Specified (hepatitis B immunoglobulin) - Suspect (-)	Hepatitis C ; Suspected transmission of an infectious agent via product
308233	11/10/2012	Female	14	Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (523 days); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (349 days); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (564 days); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (-); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (349 days); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (475 days); Varilrix (live varicella vaccine) - Suspect (564 days)	Headache ; Lethargy ; Syncope ; Viral infection
309390	5/11/2012	Male	13	Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (0 days); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days)	Presyncope
313229	1/02/2013	Female	25	H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days)	Presyncope
314461	22/02/2013	Female	12	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days)	Dizziness
314784	28/02/2013	Female	13	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18	Syncope ; Vomiting

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				L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days)	
317316	9/04/2013	Female	12	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (-)	Syncope
317639	12/04/2013	Male	13	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (-)	Syncope
320724	31/05/2013	Female	12	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days)	Syncope
327295	18/09/2013	Male	-	Engerix B (Hepatitis B surface antigen recombinant) - Suspect (-)	Hepatitis C
347941	25/09/2014	Female	67	Engerix B (Hepatitis B surface antigen recombinant) - Suspect (4 days); Vivaxim (Hepatitis a virus antigen ; Salmonella typhi Vi polysaccharide) - Suspect (4 days)	Postoperative wound infection
355327	2/03/2015	Female	12	Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-); H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (-)	Anaphylactic reaction
355342	2/03/2015	Male	13	H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (-)	Anaphylactic reaction
355346	2/03/2015	Female	13	H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (-)	Anaphylactic reaction
371098	20/11/2015	Female	2	H-B-Vax II Vaccine Paediatric (Hepatitis B surface antigen recombinant) - Suspect (0 days); M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days)	Syncope
377831	22/03/2016	Unknown	-	H-B-Vax II Vaccine Paediatric (Hepatitis B surface antigen recombinant) - Suspect (0 days)	Product quality issue
387385	4/05/2016	Male	10	Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (0 days); H-	Pruritus ; Rash

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				B-Vax II Vaccine Paediatric (Hepatitis B surface antigen recombinant) - Suspect (0 days); Neisvac-C (aluminium hydroxide hydrate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (0 days); Proquad (live varicella vaccine ; Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days)	
391385	8/07/2016	Male	12	H-B-Vax II Vaccine Paediatric (Hepatitis B surface antigen recombinant) - Suspect (1 days); Menitorix (Haemophilus influenza type B polyribose ribitol phosphate ; Meningococcal polysaccharide group C ; Tetanus toxoid) - Suspect (1 days)	Febrile convulsion ; Viral infection
394208	30/08/2016	Female	<1	H-B-Vax II Vaccine Paediatric (Hepatitis B surface antigen recombinant) - Suspect (0 days); Vitamin K (Phytomenadione) - Concomitant (0 days)	Injection site abscess
396488	6/10/2016	Male	-	Engerix B (Hepatitis B surface antigen recombinant) - Suspect (1 days)	Anaphylactic reaction
397677	26/10/2016	Male	28	Engerix B (Hepatitis B surface antigen recombinant) - Suspect (0 days)	Anaphylactic reaction
426022	24/01/2018	Male	34	Engerix-B Paediatric Dose (Hepatitis B surface antigen recombinant) - Suspect (0 days)	Accidental overdose