

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). 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	Medicines reported as being taken	MedDRA Reaction terms
156049	10/08/2000	Female	17	Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (58 days)	Hepatitis; Malaise
178230	15/08/2002	Female	51	Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Concomitant (3 days); Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Concomitant (43 days); Typherix (Salmonella typhi Vi polysaccharide) - Suspect (3 days); Typherix (Salmonella typhi Vi polysaccharide) - Suspect (43 days)	Injection site reaction
214084	07/12/2005	Female	34	Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (0 days)	Asthenia; Chest discomfort; Cold sweat; Dizziness; Dyspnoea; Lethargy; Pallor; Photophobia; Tremor
220339	25/07/2006	Female	44	Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (-)	Injection site reaction
231094	20/07/2007	Male	51	Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (4 days)	Facial paralysis
232214	20/08/2007	Female	46	Havrix 1440 (Hepatitis a virus antigen) - Suspect (-)	Cough; Oral candidiasis; Vulvovaginal candidiasis
234529	17/10/2007	Male	1	Menjugate (Corynebacterium diphtheriae ; Neisseria meningitidis group C oligosaccharide) - Suspect (10 days); Pedvaxhib (Haemophilus type B polysaccharide ; Neisseria meningitidis outer	Generalised oedema; Rash; Tongue oedema

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). 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	Medicines reported as being taken	MedDRA Reaction terms
				membrane protein complex) - Suspect (10 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (10 days); VAQTa Hepatitis A Vaccine Inactivated (Hepatitis a virus antigen) - Suspect (10 days)	
247060	10/12/2008	Female	4	Havrix Junior (Hepatitis a virus antigen) - Suspect (21 days); Typhim VI (Salmonella typhi Vi polysaccharide) - Suspect (21 days)	Facial paralysis
271119	22/07/2010	Male	23	Dukoral (Vibrio cholerae) - Suspect (-); Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Concomitant (-); Typhim VI (Salmonella typhi Vi polysaccharide) - Concomitant (-)	Vomiting
272525	23/08/2010	Female	44	Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (-); Yellow Fever Vaccine (Yellow fever virus) - Concomitant (-)	Pneumonia
274553	15/10/2010	Male	23	Dukoral (Vibrio cholerae) - Suspect (0 days); Trade Name Not Specified (Prednisolone) - Suspect (-); Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (0 days); Typhoid Vaccine (Salmonella typhi) - Suspect (0 days)	Abdominal pain; Diarrhoea; Gastritis; Vomiting
274765	21/10/2010	Female	29	Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (0 days)	Blood pressure increased; Dizziness; Headache; Rash; Swelling face; Taste disorder

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). 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	Medicines reported as being taken	MedDRA Reaction terms
274906	26/10/2010	Female	29	Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (0 days)	Dizziness; Hypersensitivity; Lip swelling; Periorbital oedema; Rash; Taste disorder
278955	21/02/2011	Male	22	Jespect (Japanese encephalitis virus) - Concomitant (0 days); Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (0 days)	Dizziness; Dystonia; Loss of consciousness
281948	28/04/2011	Male	1	Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Suspect (1 days); Meningococcal C Vaccine (Corynebacterium diphtheriae ; Neisseria meningitidis group C oligosaccharide) - Suspect (1 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (1 days); VAQTa Hepatitis A Vaccine Inactivated (Hepatitis a virus antigen) - Suspect (1 days)	Diarrhoea; Pyrexia; Rash; Vomiting
282462	06/05/2011	Female	35	Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (5 days); Stamaril (Yellow fever virus) - Suspect (5 days); Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (5 days); Typhoid Vaccine (Salmonella typhi) - Suspect (5 days)	Influenza like illness
282676	12/05/2011	Male	35	Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (5 days); Stamaril (Yellow fever virus) - Suspect (5 days); Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (5 days); Typhim VI (Salmonella typhi Vi polysaccharide) - Suspect (5 days)	Headache; Influenza like illness; Nausea

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). 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	Medicines reported as being taken	MedDRA Reaction terms
289086	16/09/2011	Male	37	Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (24 days)	Chest pain; Headache; Nausea
294847	23/01/2012	Female	2	Havrix Junior (Hepatitis a virus antigen) - Suspect (2 days); Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspect (2 days); Typhim VI (Salmonella typhi Vi polysaccharide) - Suspect (2 days)	Hypoglycaemic seizure
314693	27/02/2013	Female	48	Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (1 days)	Arthralgia; Dizziness; Hyperhidrosis; Myalgia; Nausea
320235	24/05/2013	Female	30	ADT Booster (Diphtheria toxoid ; Tetanus toxoid) - Suspect (3 days); Rabipur (Rabies virus) - Suspect (3 days); Stamaril (Yellow fever virus) - Suspect (3 days); Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (3 days)	Stasis dermatitis
322559	02/07/2013	Male	21	Twinrix Adult 720/20 Formulation (Hepatitis a virus antigen ; Hepatitis B surface antigen recombinant) - Suspect (0 days)	Hyperhidrosis; Pyrexia; Syncope
326173	04/09/2013	Female	77	Havrix 1440 (Hepatitis a virus antigen) - Suspect (0 days); Typhim VI (Salmonella typhi Vi polysaccharide) - Suspect (0 days)	Angioedema; Urticaria
332469	12/12/2013	Female	18	Havrix 1440 (Hepatitis a virus antigen) - Suspect (0 days); Typhim VI (Salmonella typhi Vi polysaccharide) - Suspect (0 days)	Bradycardia; Dizziness; Feeling hot; Hyperhidrosis; Hypotension; Nausea

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). 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	Medicines reported as being taken	MedDRA Reaction terms
358600	01/05/2015	Female	6	Fluvax (Influenza virus haemagglutinin) - Suspect (0 days); Havrix Junior (Hepatitis a virus antigen) - Suspect (0 days); Typhim VI (Salmonella typhi Vi polysaccharide) - Suspect (0 days)	Hypersensitivity
358784	04/05/2015	Female	6	Fluvax (Influenza virus haemagglutinin) - Suspect (0 days); Havrix Junior (Hepatitis a virus antigen) - Suspect (0 days); Typhim VI (Salmonella typhi Vi polysaccharide) - Suspect (0 days)	Anaphylactic reaction
395266	15/09/2016	Male	40	Havrix 1440 (Hepatitis a virus antigen) - Suspect (-); Typhim VI (Salmonella typhi Vi polysaccharide) - Suspect (-)	Acute disseminated encephalomyelitis
415455	04/08/2017	Female	37	FluQuadri Vaccine (Influenza virus haemagglutinin) - Suspect (1 days); Havrix 1440 (Hepatitis a virus antigen) - Suspect (1 days); Pneumovax 23 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days)	Pruritus; Rash