

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 |
|-------------|-------------------|---------|-----|---|---|
| 152361 | 4/05/2000 | Female | 30 | Varilrix (live varicella vaccine) - Suspect (5 days) | Varicella |
| 154227 | 28/06/2000 | Female | 31 | Varilrix (live varicella vaccine) - Suspect (4 days) | Rectal haemorrhage |
| 154378 | 28/06/2000 | Male | 1 | Varilrix (live varicella vaccine) - Suspect (8 days) | Rectal haemorrhage |
| 160389 | 4/01/2001 | Unknown | 34 | Varilrix (live varicella vaccine) - Suspect (0 days) | Hyperventilation ; Syncope |
| 164636 | 18/05/2001 | Male | 6 | Varilrix (live varicella vaccine) - Suspect (-) | Varicella |
| 164926 | 28/05/2001 | Female | 53 | Trade Name Not Specified (Tamoxifen citrate) - Concomitant (-); Varilrix (live varicella vaccine) - Suspect (1 days) | Headache ; Pyrexia ; Rash erythematous |
| 170098 | 19/11/2001 | Female | 22 | Varilrix (live varicella vaccine) - Suspect (2 days) | Eye pain ; Malaise ; Pyrexia ; Varicella |
| 178030 | 13/08/2002 | Male | 4 | Varilrix (live varicella vaccine) - Suspect (-) | Pyrexia ; Rash vesicular |
| 178527 | 28/08/2002 | Male | 44 | Varilrix (live varicella vaccine) - Suspect (-) | Visual impairment |
| 178554 | 29/08/2002 | Male | - | Varilrix (live varicella vaccine) - Suspect (-) | Optic neuritis |
| 189538 | 14/08/2003 | Female | 34 | Varilrix (live varicella vaccine) - Suspect (-) | Herpes zoster |
| 192779 | 2/12/2003 | Female | 36 | Trade Name Not Specified (Product not Coded) - Concomitant (-); Varilrix (live varicella vaccine) - Suspect (-) | Herpes zoster |
| 193574 | 6/01/2004 | Male | 1 | DTPa Vaccine (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Tetanus toxoid) - Suspect (-); Varilrix (live varicella vaccine) - Suspect (-) | Diabetic ketosis |
| 196914 | 29/04/2004 | Male | 4 | Varilrix (live varicella vaccine) - Suspect (-) | Cough ; Eye haemorrhage ; Pyrexia ; Rash macular ; Stevens-Johnson syndrome |
| 208274 | 30/05/2005 | Male | 1 | Varilrix (live varicella vaccine) - Suspect (-) | Body temperature increased ; Hypoacusis |
| 208376 | 1/06/2005 | Female | - | Varilrix (live varicella vaccine) - Suspect (-) | Abortion |
| 222074 | 29/09/2006 | Female | 26 | Microlut (Norgestrel) - Concomitant (-); Varilrix (live varicella vaccine) - Suspect (13 days) | Rash papular |

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|-------------|-------------------|--------|-----|---|---|
| 222169 | 5/10/2006 | Female | 21 | Varivax II (live varicella vaccine) - Suspect (0 days) | Urticaria |
| 224378 | 4/01/2007 | Male | 1 | Varilrix (live varicella vaccine) - Suspect (0 days) | Malaise ; Pyrexia |
| 225159 | 29/01/2007 | Female | 4 | Varivax Refrigerated (live varicella vaccine) - Suspect (-) | Rash vesicular |
| 230728 | 2/02/2007 | Male | 1 | Varilrix (live varicella vaccine) - Suspect (0 days) | Injection site reaction |
| 234242 | 11/10/2007 | Female | 24 | Varivax Refrigerated (live varicella vaccine) - Suspect (10 days) | Varicella post vaccine |
| 234846 | 25/10/2007 | Male | 1 | Fluvax (Influenza virus haemagglutinin) - Suspect (-); Varivax Refrigerated (live varicella vaccine) - Suspect (-) | Death |
| 235560 | 22/11/2007 | Male | 5 | Varilrix (live varicella vaccine) - Suspect (10 days) | Varicella zoster virus infection |
| 239468 | 1/04/2008 | Male | 1 | Varilrix (live varicella vaccine) - Suspect (9 days) | Bone marrow failure ; Contusion ; Haemorrhage ; Haemorrhage intracranial ; Hepatic function abnormal ; Thrombocytopenia |
| 243036 | 18/07/2008 | Female | 27 | Varilrix (live varicella vaccine) - Suspect (21 days) | Abortion induced |
| 247059 | 10/12/2008 | Female | 1 | Varivax Refrigerated (live varicella vaccine) - Suspect (2 days) | Abdominal pain ; Diarrhoea ; Irritability ; Pyrexia ; Vomiting |
| 259192 | 2/11/2009 | Male | 1 | Varilrix (live varicella vaccine) - Suspect (2 days) | Rash vesicular |
| 265208 | 21/04/2010 | Male | 1 | Fluvax (Influenza virus haemagglutinin) - Suspect (0 days); Varilrix (live varicella vaccine) - Suspect (0 days) | Seizure |
| 265214 | 21/04/2010 | Female | 1 | Panvax H1N1 influenza vaccine (Influenza virus haemagglutinin) - Suspect (0 days); Varilrix (live varicella vaccine) - Suspect (0 days) | Coma scale abnormal ; Febrile convulsion |
| 266295 | 3/05/2010 | Male | 1 | Fluvax (Influenza virus haemagglutinin) - Suspect (0 days); Varilrix (live varicella vaccine) - Suspect (0 days) | Pyrexia ; Seizure ; Vomiting |
| 269431 | 18/06/2010 | Male | 1 | Varivax Refrigerated (live varicella vaccine) - Suspect (51 days) | Herpes zoster |
| 273607 | 21/09/2010 | Male | 5 | Infanrix-IPV (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Poliovirus ; | Extensive swelling of vaccinated limb ; Injection site reaction |

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| | | | | Tetanus toxoid) - Suspect (1 days); Varilrix (live varicella vaccine) - Suspect (1 days) | |
| 274827 | 25/10/2010 | Male | 2 | Hepatitis A Vaccine (Hepatitis a virus antigen) - Suspect (0 days); Pneumovax 23 (Pneumococcal purified capsular polysaccharides) - Suspect (0 days); Varilrix (live varicella vaccine) - Suspect (0 days) | Cough ; Urticaria |
| 279520 | 7/03/2011 | 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); Varilrix (live varicella vaccine) - Suspect (0 days) | Dyspnoea ; Rash ; Urticaria ; Vomiting |
| 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 |
| 281315 | 13/04/2011 | Male | 1 | Varilrix (live varicella vaccine) - Suspect (2 days) | Rash maculo-papular |
| 287265 | 11/08/2011 | Male | 7 | Varilrix (live varicella vaccine) - Suspect (1 days) | Abdominal pain ; Abdominal pain ; Diarrhoea |
| 288764 | 12/09/2011 | Male | 1 | Varilrix (live varicella vaccine) - Suspect (10 days) | Hypersensitivity ; Nail discolouration ; Rash vesicular ; Urinary tract infection |
| 295402 | 4/02/2012 | Male | 1 | Varilrix (live varicella vaccine) - Suspect (1 days) | Herpes simplex ; Polymerase chain reaction ; Rash vesicular |
| 297033 | 7/03/2012 | Male | 12 | Varilrix (live varicella vaccine) - Suspect (11 days) | Herpes simplex test positive ; Rash |
| 297605 | 20/03/2012 | Male | 1 | Varilrix (live varicella vaccine) - Suspect (3 days) | Pruritus ; Rash papular |
| 298402 | 3/04/2012 | Male | 12 | Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - | Varicella |

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|-------------|-------------------|--------|-----|--|---|
| | | | | Concomitant (12 days); Varilrix (live varicella vaccine) - Suspect (12 days) | |
| 300595 | 18/05/2012 | Female | 1 | Varilrix (live varicella vaccine) - Suspect (12 days) | Encephalitis |
| 303272 | 9/07/2012 | Female | 1 | Hiberix (Haemophilus influenza type B polyribose ribitol phosphate ; Tetanus toxoid) - Concomitant (0 days); Priorix (Measles virus ; Mumps virus ; Rubella virus) - Concomitant (0 days); Varilrix (live varicella vaccine) - Suspect (0 days) | No adverse event ; Vaccination error |
| 304701 | 3/08/2012 | Female | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Varilrix (live varicella vaccine) - Suspect (0 days) | Presyncope |
| 307309 | 24/09/2012 | Male | 1 | Varivax Refrigerated (live varicella vaccine) - Suspect (-) | Facial paralysis |
| 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 |
| 314789 | 28/02/2013 | Male | 1 | Varilrix (live varicella vaccine) - Suspect (0 days) | Injection site reaction ; Petechiae |
| 314791 | 28/02/2013 | Male | 1 | Varilrix (live varicella vaccine) - Suspect (2 days) | Varicella |

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| 319385 | 9/05/2013 | 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); Varilrix (live varicella vaccine) - Suspect (0 days) | Presyncope |
| 319890 | 20/05/2013 | Male | 1 | Varilrix (live varicella vaccine) - Suspect (0 days) | Injection site mass ; Injection site swelling |
| 328280 | 8/10/2013 | Female | 24 | Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (25 days); Priorix-Tetra (live varicella vaccine ; Measles virus ; Mumps virus ; Rubella virus) - Suspect (0 days); Varilrix (live varicella vaccine) - Suspect (42 days) | No adverse event |
| 329693 | 31/10/2013 | 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 Vaccine Adult (Hepatitis B surface antigen recombinant) - Concomitant (0 days); Varilrix (live varicella vaccine) - Concomitant (0 days) | Syncope |
| 329887 | 4/11/2013 | Female | 7 | Priorix (Measles virus ; Mumps virus ; Rubella virus) - Suspect (-); Varilrix (live varicella vaccine) - Suspect (-) | Vaccine breakthrough infection |
| 332223 | 9/12/2013 | Male | 31 | Varilrix (live varicella vaccine) - Suspect (0 days) | Incorrect route of drug administration |
| 337743 | 2/04/2014 | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-); Varilrix (live varicella vaccine) - Suspect (-) | Hypersensitivity |
| 341618 | 4/06/2014 | Male | 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); Varivax Refrigerated (live varicella vaccine) - Suspect (0 days) | Syncope |

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| 342132 | 16/06/2014 | Male | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Varilrix (live varicella vaccine) - Suspect (0 days) | Head injury ; Seizure ; Syncope |
| 342245 | 17/06/2014 | Male | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Varivax Refrigerated (live varicella vaccine) - Suspect (0 days) | Dizziness ; Headache ; Hypoaesthesia ; Nausea ; Retching ; Syncope |
| 346198 | 20/08/2014 | Male | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Varivax Refrigerated (live varicella vaccine) - Suspect (0 days) | Urticaria |
| 356584 | 24/03/2015 | Male | 14 | Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (1 days); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days); Pneumovax 23 (Pneumococcal purified capsular polysaccharides) - Suspect (1 days); Varilrix (live varicella vaccine) - Suspect (1 days) | Headache ; Hypoaesthesia ; Pain in extremity |
| 358747 | 4/05/2015 | Male | 14 | Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (0 days); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Varilrix (live varicella vaccine) - Suspect (0 days) | Injection site cellulitis |
| 387063 | 28/04/2016 | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Varivax (live varicella vaccine) - Suspect (0 days) | Chest discomfort ; Lip pruritus ; Lip swelling ; Urticaria |

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| 388347 | 19/05/2016 | 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); Varivax (live varicella vaccine) - Suspect (0 days) | Syncope |
| 389086 | 31/05/2016 | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Varivax (live varicella vaccine) - Suspect (0 days) | Syncope |
| 390331 | 20/06/2016 | Female | 36 | Varivax Refrigerated (live varicella vaccine) - Suspect (0 days) | Injection site reaction |
| 398006 | 1/11/2016 | Male | 14 | Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (0 days); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Varivax (live varicella vaccine) - Suspect (0 days) | Syncope |
| 400135 | 5/12/2016 | Male | 5 | Varivax Refrigerated (live varicella vaccine) - Suspect (0 days) | Hypersensitivity |
| 413713 | 10/07/2017 | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Varivax (live varicella vaccine) - Suspect (0 days) | Headache ; Injection site swelling ; Rash |
| 418309 | 18/09/2017 | Female | - | BCG Vaccine (Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain)) - Suspect (-); M-M-R II (Measles virus ; Mumps virus ; Rubella virus) - Suspect (-); Sabin Vaccine (Poliovirus) - Suspect (-); Trade Name Not Specified (Product not Coded) - Suspect (-); Typhim VI (Salmonella typhi Vi polysaccharide) - Suspect (-); Varivax (live varicella vaccine) - Suspect (-) | Corynebacterium infection |