

The information provided in these tables 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). While most reports received by TGA are published in the DAEN, not all reports are included. Those excluded 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 be a duplicate of a case included in the DAEN.

**Table 1 – Cases in Adverse Event Management System that do not appear on the DAEN, and are not duplicate reports of cases in the DAEN**

| Case number | Report entry date | Gender  | Age (yrs) | Medicines reported as being taken  | MedDRA Reaction terms  |
|-------------|-------------------|---------|-----------|--|--|
| 229162      | 31/05/2007        | Female  | 17        | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days)   | Headache ; Oropharyngeal pain                                  |
| 229409      | 6/06/2007         | Female  | 17        | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Seizure ; Syncope  |
| 230281      | 28/06/2007        | Female  | 15        | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (14 days)  | Rash pruritic  |
| 230813      | 10/07/2007        | Unknown | -         | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Seizure  |
| 232963      | 4/09/2007         | Female  | 20        | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Anaphylactic reaction ; Chest discomfort ; Dyspnoea ; Flushing |
| 232966      | 4/09/2007         | Female  | 20        | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Lymphadenopathy  |
| 233635      | 20/09/2007        | Female  | 26        | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Injection site mass  |
| 233733      | 21/09/2007        | Female  | 77        | Albalon (Naphazoline hydrochloride) - Concomitant (-); Arimidex (Anastrozole) - Concomitant (-); Cervarix (HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein) - Suspect (-); Norspan 10 (Buprenorphine) - Concomitant (-); Panamax (Paracetamol) - Concomitant (-); Pravachol (pravastatin sodium) - Concomitant (-) | Cough ; Lacrimation increased ; Malaise ; Nasal congestion     |
| 233744      | 24/09/2007        | Female  | -         | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Carcinoma in situ  |
| 234104      | 8/10/2007         | Female  | 14        | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV  | Nephritis  |

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|        |            |         |    |   |  |
|--------|------------|---------|----|---|--|
|        |            |         |    | Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (14 days)   |  |
| 234611 | 19/10/2007 | Female  | 25 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days)  | Vulvovaginal discomfort  |
| 236310 | 14/12/2007 | Female  | 20 | Brevinor (ethinyloestradiol ; Norethisterone) - Concomitant (-); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Chest discomfort ; Dyspnoea ; Flushing ; Injection site reaction ; Lymphadenopathy |
| 238012 | 18/02/2008 | Female  | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Hallucination ; Malaise ; Muscular weakness  |
| 239061 | 18/03/2008 | Female  | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Paralysis  |
| 243268 | 29/07/2008 | Female  | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Gait disturbance   |
| 243270 | 29/07/2008 | Female  | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Influenza like illness   |
| 244157 | 26/08/2008 | Unknown | <1 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (197 days)  | Death neonatal   |
| 244739 | 19/09/2008 | Female  | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Concomitant (176 days); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Concomitant (270 days); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Concomitant (311 days); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-) | Caesarean section  |
| 244745 | 19/09/2008 | Female  | 19 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Abdominal distension ; Cervix carcinoma ; Vaginal discharge ; Vaginal haemorrhage  |
| 248134 | 29/01/2009 | Female  | 18 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Sepsis neonatal  |

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|--------|------------|--------|----|---|--|
| 248445 | 10/02/2009 | Female | 14 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Multiple sclerosis   |
| 250015 | 8/04/2009  | Female | 23 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Death ; Hypertrophic cardiomyopathy                                |
| 250188 | 15/04/2009 | Female | 19 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (5 days)  | Aphasia ; Meningitis ; Paralysis                                   |
| 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  |
| 250964 | 13/05/2009 | Female | 49 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (2 days)  | Inappropriate schedule of drug administration ; Oropharyngeal pain |
| 251437 | 25/05/2009 | Female | 22 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Abortion induced ; Exposure during pregnancy                       |
| 252796 | 29/06/2009 | Female | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (41 days)   | Ovarian cancer   |
| 254216 | 20/07/2009 | Female | 20 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Meningitis   |
| 254974 | 5/08/2009  | Female | 21 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Cervix carcinoma   |
| 257194 | 24/09/2009 | Female | 21 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Headache ; Oropharyngeal pain ; Pyrexia                            |
| 264916 | 14/04/2010 | Female | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Nervous system disorder  |
| 272233 | 16/08/2010 | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Pancreatitis   |
| 277148 | 23/12/2010 | Female | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Concomitant (-)   | Dizziness ; Headache ; Malaise ; Nausea ; Seizure ; Syncope        |

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|--------|------------|--------|----|---|---|
| 279838 | 15/03/2011 | Female | 15 | Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Concomitant (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)  | Presyncope ; Rash ; Urticaria                   |
| 284113 | 10/06/2011 | Female | 2  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Foetal exposure during pregnancy                |
| 292061 | 18/11/2011 | Female | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Guillain-Barre syndrome                         |
| 293483 | 18/12/2011 | Female | 28 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Multiple sclerosis                              |
| 293906 | 26/12/2011 | Female | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Still's disease                                 |
| 294094 | 3/01/2012  | Female | 22 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-); Trade Name Not Specified (Product not Coded) - Concomitant (-)   | Cervical dysplasia                              |
| 294310 | 6/01/2012  | Female | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Vaccination complication                        |
| 299930 | 7/05/2012  | Female | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (35 days); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (35 days)  | Lymphadenitis                                   |
| 305200 | 13/08/2012 | Female | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Complex regional pain syndrome                  |
| 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 | Headache ; Lethargy ; Syncope ; Viral infection |

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|        |            |        |    |  |  |
|--------|------------|--------|----|--|--|
|        |            |        |    | 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) |  |
| 314333 | 20/02/2013 | 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)   | Syncope  |
| 319840 | 17/05/2013 | Female | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days)   | Urticaria  |
| 320589 | 30/05/2013 | Female | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Paraesthesia   |
| 326038 | 30/08/2013 | 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); H-B-Vax II Vaccine Adult (Hepatitis B surface antigen recombinant) - Concomitant (-245 days)             | Anaphylactic reaction ; Ovarian cyst   |
| 326133 | 4/09/2013  | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Balance disorder ; Dysphagia ; Emotional distress ; Muscular weakness ; Paralysis ; Parosmia ; Pyrexia   |
| 326208 | 4/09/2013  | Male   | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Rash   |
| 330073 | 5/11/2013  | Female | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | No adverse event   |
| 333842 | 21/01/2014 | Female | 46 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Alcohol abuse ; Blood bilirubin increased ; Drug abuse ; Infertility female ; Limb injury ; Muscle injury ; Nerve injury ; Spinal deformity ; Stent placement ; Tobacco user |
| 334994 | 13/02/2014 | Male   | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (28 days)  | Facial paralysis ; Leukaemic infiltration  |

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|        |            |         |    |  |  |
|--------|------------|---------|----|--|--|
| 337816 | 2/04/2014  | Female  | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-);<br>Varicella Vaccine (live varicella vaccine) - Suspect (-)   | No adverse event   |
| 348014 | 29/09/2014 | Female  | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Cervix neoplasm ; Vaccination failure  |
| 348157 | 1/10/2014  | Male    | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Disability   |
| 348221 | 1/10/2014  | Female  | 14 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (428 days)   | Polyneuropathy   |
| 355321 | 2/03/2015  | Female  | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Anaphylactic reaction  |
| 355323 | 2/03/2015  | Female  | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Anaphylactic reaction  |
| 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  |
| 356297 | 18/03/2015 | Female  | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Abdominal pain upper ; Arthralgia ;<br>Dizziness ; Headache ; Lethargy ;<br>Seizure ; Vision blurred |
| 356519 | 23/03/2015 | Unknown | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Gait disturbance ; Hallucination ; Pain<br>in extremity ; Seizure                                    |
| 356665 | 25/03/2015 | Female  | 13 | 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) | Nausea ; Paraesthesia oral   |
| 357694 | 16/04/2015 | Male    | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (38 days)  | Concomitant disease progression  |
| 361065 | 9/06/2015  | Female  | -  | Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1  | Anogenital warts ; Vaccination failure   |

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|        |            |         |    |  |   |
|--------|------------|---------|----|--|---|
|        |            |         |    | Protein ; HPV Type 6 L1 Protein) - Suspect (-)   |   |
| 363587 | 9/07/2015  | Male    | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (80 days)  | Hypersensitivity  |
| 376805 | 3/03/2016  | Male    | 12 | 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) | Extensive swelling of vaccinated limb ; Lymphadenopathy ; Pain in extremity |
| 377294 | 11/03/2016 | Unknown | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Device breakage   |
| 377295 | 11/03/2016 | Unknown | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Device breakage   |
| 385097 | 24/03/2016 | Female  | 13 | 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) | Throat tightness  |
| 385692 | 4/04/2016  | Female  | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Premature menopause   |
| 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                  |
| 387535 | 6/05/2016  | Male    | 12 | 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) | Eye swelling  |
| 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   |

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| 388545 | 23/05/2016 | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (266 days)  | Disease progression ; Motor neurone disease                              |
| 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);<br>Varivax (live varicella vaccine) - Suspect (0 days)  | Syncope  |
| 390226 | 17/06/2016 | Female | 14 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days)  | Cough ; Dizziness ; Malaise ; Nausea ; Pyrexia                           |
| 394209 | 30/08/2016 | 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)  | Rash pruritic  |
| 394426 | 2/09/2016  | Male   | 13 | Adacel (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis fimbriae 2 + 3 ; Pertussis toxoid ; Poliovirus ; 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)                | Headache ; Injection site reaction ; Lymphadenopathy ; Myalgia ; Pyrexia |
| 395269 | 15/09/2016 | 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)  | Pharyngeal oedema  |
| 397384 | 21/10/2016 | 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)  | Presyncope   |
| 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  |
| 410426 | 24/05/2017 | Female | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Death  |
| 411833 | 14/06/2017 | 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)  | Cough ; Throat irritation  |



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|--------|------------|---------|----|--|--|
| 413247 | 4/07/2017  | Female  | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days)   | Dizziness ; Feeling of body temperature change ; Headache ; Lethargy ; Malaise ; Myalgia   |
| 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);<br>Varivax (live varicella vaccine) - Suspect (0 days) | Headache ; Injection site swelling ; Rash  |
| 413939 | 12/07/2017 | Unknown | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Pancreatitis   |
| 415527 | 7/08/2017  | Female  | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Pruritus ; Rash  |
| 416488 | 18/08/2017 | Female  | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Ovarian cancer   |
| 416984 | 28/08/2017 | Female  | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Injury   |
| 419475 | 6/10/2017  | Female  | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Abdominal pain upper ; Anxiety ; Areflexia ; Arthralgia ; Autonomic nervous system imbalance ; Bed rest ; Blood disorder ; Cardiac disorder ; Central pain syndrome ; Complex regional pain syndrome ; Conversion disorder ; Diarrhoea ; Diplopia ; Dizziness ; Dysaesthesia ; Dyspnoea ; Fatigue ; Food allergy ; Food intolerance ; Gait disturbance ; Gait inability ; Herpes zoster ; Lethargy ; Loss of consciousness ; Malaise ; Muscular weakness ; Nausea ; Neuralgia ; Pain in extremity ; Paraesthesia ; Rash macular ; Rehabilitation therapy ; Vision blurred ; Vomiting |

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|        |            |         |    |   |   |
|--------|------------|---------|----|---|---|
| 420290 | 20/10/2017 | Male    | 12 | Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (14 days); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (14 days)  | Concomitant disease progression ; Seizure |
| 420721 | 26/10/2017 | 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)  | Anaphylactic reaction                     |
| 420785 | 27/10/2017 | Unknown | -  | Cervarix (HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein) - Suspect (-); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Brain injury                              |
| 421159 | 2/11/2017  | 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)  | Anaphylactic reaction                     |
| 421166 | 2/11/2017  | 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)  | Muscle twitching                          |
| 426932 | 7/02/2018  | 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)  | Complex regional pain syndrome            |
| 429039 | 13/03/2018 | Male    | 12 | Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (0 days); Gardasil 9 (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 31 L1 Protein ; HPV Type 33 L1 Protein ; HPV Type 45 L1 Protein ; HPV Type 52 L1 Protein ; HPV Type 58 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days) | Anaphylactic reaction                     |
| 439596 | 3/08/2018  | Female  | 12 | Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (-); Gardasil 9 (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 31 L1 Protein ; HPV Type 33 L1 Protein ; HPV Type 45 L1 Protein ; HPV Type 52 L1 Protein ; HPV Type 58 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)           | Unevaluable event                         |
| 449183 | 30/10/2018 | Female  | 30 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV   | Vaccination failure                       |

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|        |            |        |   |   |  |
|--------|------------|--------|---|---|--|
|        |            |        |   | Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   |  |
| 450890 | 20/11/2018 | Female | - | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-) | Cervix carcinoma ; Vaccination failure |
| 454073 | 1/01/2019  | Female | - | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-) | Cervix carcinoma                       |

**Table 2 Cases in the Adverse Event Management System that do not appear on the DAEN as they are duplicate reports of cases in the DAEN**

| Case number | Report entry date | Gender | Age (yrs) | Medicines reported as being taken  | MedDRA Reaction terms                                    |
|-------------|-------------------|--------|-----------|--|--|
| 0229108     | 30/05/2007        | Female | 17        | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Joint swelling   |
| 0229127     | 31/05/2007        | Female | 17        | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Syncope  |
| 0229141     | 31/05/2007        | Female | 15        | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Injection site pain                                      |
| 0229152     | 31/05/2007        | Female | 17        | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days);<br>Naprogenic (naproxen sodium) - Concomitant (0 days)                     | Dysphagia ; Swollen tongue                               |
| 0229197     | 1/06/2007         | 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);<br>H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days) | Dizziness ; Malaise ; Myalgia                            |
| 0229203     | 1/06/2007         | Female | 15        | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Abdominal pain upper ; Nausea ;<br>Rash ; Vision blurred |
| 0229212     | 1/06/2007         | Female | 16        | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Abdominal pain ; Dizziness ;<br>Headache                 |

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|         |            |        |    |  |  |
|---------|------------|--------|----|--|--|
| 0229217 | 1/06/2007  | 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) | Asthenia ; Hypoaesthesia ; Muscular weakness   |
| 0229313 | 5/06/2007  | Female | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days) | Aphasia ; Muscular weakness ; Neuropathy peripheral  |
| 0229344 | 5/06/2007  | Female | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days) | Asthenia ; Circulatory collapse ; Consciousness fluctuating ; Dizziness ; Lethargy ; Malaise ; Palpitations ; Vomiting |
| 0229406 | 6/06/2007  | Female | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days) | Complex regional pain syndrome ; Fatigue ; Hemiparesis ; Hypoaesthesia ; Injection site reaction ; Pain                |
| 0229407 | 6/06/2007  | Female | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days) | Hemiparesis ; Neck pain ; Throat lesion  |
| 0229411 | 6/06/2007  | Female | 18 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (9 days) | Epilepsy ; Ill-defined disorder ; Spinal fracture  |
| 0229514 | 7/06/2007  | Female | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days) | Axillary pain ; Injection site pain  |
| 0229519 | 7/06/2007  | Female | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days) | Back pain ; Injection site pain  |
| 0229536 | 8/06/2007  | Female | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days) | Dyspnoea ; Erythema ; Nausea ; Urticaria   |
| 0229971 | 20/06/2007 | Female | 18 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days) | Nausea ; Throat irritation ; Urticaria   |
| 0230062 | 22/06/2007 | 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) | Dizziness ; Hypoaesthesia  |
| 0230074 | 22/06/2007 | Female | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days) | Aphasia ; Muscular weakness ; Neuropathy peripheral  |
| 0230318 | 28/06/2007 | Female | 18 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV  | Seizure  |

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|         |            |        |    |   |  |
|---------|------------|--------|----|---|--|
|         |            |        |    | Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (9 days)  |  |
| 0230393 | 29/06/2007 | Female | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Emotional distress ; Paraesthesia  |
| 0230579 | 4/07/2007  | Female | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Guttate psoriasis  |
| 0230793 | 10/07/2007 | Female | 18 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Malaise ; Oropharyngeal pain ; Urticaria                                     |
| 0230794 | 10/07/2007 | Female | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Injection site reaction  |
| 0230795 | 10/07/2007 | Female | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Headache ; Malaise ; Urticaria   |
| 0231299 | 27/07/2007 | Female | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Anaphylactic reaction ; Chest discomfort ; Dyspnoea ; Flushing               |
| 0231506 | 3/08/2007  | Female | 25 | Bricanyl Turbuhaler (Terbutaline sulfate) - Concomitant (-); Diane-35 ED (cyproterone acetate ; ethinylestradiol) - Concomitant (-); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Sigmacort (Hydrocortisone acetate) - Concomitant (-); Zoton (Lansoprazole) - Concomitant (-) | Anaphylactic reaction  |
| 0232655 | 28/08/2007 | Female | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Dizziness ; Malaise  |
| 0232823 | 31/08/2007 | Female | 24 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Chest discomfort ; Lymphadenopathy ; Pharyngeal oedema ; Pyrexia ; Urticaria |
| 0234535 | 18/10/2007 | Female | 19 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (2 days)  | Dry skin ; Exfoliative rash ; Headache ; Nausea ; Pruritus ; Rash macular    |
| 0234728 | 23/10/2007 | Female | 26 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Fatigue ; Hyperhidrosis ; Loss of consciousness ; Rash ; Vomiting            |

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|         |            |        |    |  |   |
|---------|------------|--------|----|--|---|
| 0234903 | 31/10/2007 | Female | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Dizziness ; Headache ; Lethargy ; Pruritus ; Rash   |
| 0235236 | 13/11/2007 | Female | 19 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Headache ; Urticaria  |
| 0235391 | 19/11/2007 | Female | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (2 days)   | Vulval disorder ; Vulvovaginal inflammation   |
| 0235452 | 20/11/2007 | Female | 22 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Joint swelling ; Rheumatoid arthritis   |
| 0235566 | 22/11/2007 | Female | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (123 days); Levlen ED (ethinylestradiol ; Levonorgestrel) - Concomitant (468 days)   | Malaise ; Mood swings ; Nausea ; Pain ; Vomiting  |
| 0235666 | 26/11/2007 | Female | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days)   | Headache ; Injection site rash ; Urticaria  |
| 0235706 | 27/11/2007 | Female | 14 | Diane-35 ED (cyproterone acetate ; ethinylestradiol) - Concomitant (-); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Zoloft (Sertraline hydrochloride) - Concomitant (-)  | Chest discomfort ; Dizziness ; Gait disturbance ; Headache ; Heart rate increased ; Pyrexia |
| 0235882 | 4/12/2007  | Female | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days)   | Diarrhoea ; Nausea ; Pyrexia ; Vomiting   |
| 0236304 | 14/12/2007 | Female | 23 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Logynon ED (ethinylestradiol ; Levonorgestrel) - Concomitant (-); Seretide 125/25 MDI (fluticasone propionate ; Salmeterol xinafoate) - Concomitant (-); Ventolin (Salbutamol) - Concomitant (-) | Oedema peripheral ; Pruritus ; Rash morbilliform  |
| 0236314 | 14/12/2007 | Female | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Hypotension ; Syncope   |

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|         |            |        |    |  |   |
|---------|------------|--------|----|--|---|
| 0236448 | 20/12/2007 | 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);<br>H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days) | Dyspnoea ; Fatigue ; Headache ;<br>Nausea   |
| 0236529 | 24/12/2007 | Female | 23 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days)   | Oedema peripheral ; Pruritus  |
| 0237001 | 16/01/2008 | Female | 20 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Urticaria   |
| 0237044 | 17/01/2008 | Female | 25 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Anaphylactic reaction   |
| 0237060 | 17/01/2008 | Female | 24 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Injection site mass ; Injection site<br>pain  |
| 0237061 | 17/01/2008 | Female | 25 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Fatigue ; Headache ; Malaise  |
| 0237079 | 18/01/2008 | Female | 22 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-); Trade<br>Name Not Specified (Prednisolone) - Concomitant (-)                    | Rheumatoid arthritis  |
| 0237279 | 24/01/2008 | Female | 23 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Insomnia ; Mood altered   |
| 0237689 | 7/02/2008  | Female | 19 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Hypoaesthesia   |
| 0237820 | 12/02/2008 | Female | 25 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Pruritus ; Urticaria  |
| 0237956 | 15/02/2008 | Female | 26 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Dizziness ; Influenza like illness ;<br>Injection site reaction ; Nausea ;<br>Pyrexia |
| 0238402 | 28/02/2008 | Female | 20 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Dysgeusia   |

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|         |            |        |    |  |   |
|---------|------------|--------|----|--|---|
| 0238802 | 11/03/2008 | Female | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Incoherent ; Logorrhoea ; Mania ; Pressure of speech ; Psychotic disorder |
| 0239779 | 10/04/2008 | Female | 26 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Injection site reaction   |
| 0240037 | 16/04/2008 | Female | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Pruritus ; Rash   |
| 0240337 | 23/04/2008 | Female | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Injection site reaction ; Rash  |
| 0240361 | 24/04/2008 | Female | 24 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (2 days)   | Erythema ; Injection site reaction ; Injection site vesicles ; Pruritus   |
| 0240716 | 8/05/2008  | Female | 15 | 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) | Urticaria   |
| 0241431 | 2/06/2008  | 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)   | Dizziness ; Nausea  |
| 0241770 | 11/06/2008 | Female | 20 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Abdominal pain upper ; Headache ; Injection site pain ; Presyncope        |
| 0242464 | 1/07/2008  | Female | -  | 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) | Injection site reaction ; Rash erythematous                               |
| 0242754 | 9/07/2008  | 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)   | Rash  |



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|         |            |        |    |  |  |
|---------|------------|--------|----|--|--|
| 0243546 | 6/08/2008  | Female | 25 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days)   | Asthenia ; Chest pain ; Coordination abnormal ; Dizziness ; Dyspnoea ; Muscle spasms ; Syncope                               |
| 0244129 | 25/08/2008 | Female | 14 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (6 days)   | Dizziness ; Headache ; Lethargy ; Malaise  |
| 0244130 | 25/08/2008 | 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)   | Headache ; Hypoaesthesia ; Injected limb mobility decreased ; Injection site pain ; Menstrual disorder                       |
| 0244616 | 15/09/2008 | Female | 14 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days)   | Hepatitis  |
| 0244738 | 19/09/2008 | Female | 26 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Oral herpes ; Urticaria  |
| 0244873 | 25/09/2008 | Female | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Alopecia   |
| 0245062 | 2/10/2008  | 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)   | Pruritus ; Urticaria   |
| 0245224 | 7/10/2008  | 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)   | Arthralgia ; Decreased appetite ; Feeling hot ; Headache ; Lethargy ; Nasopharyngitis ; Nausea ; Pallor ; Pyrexia ; Vomiting |
| 0247559 | 8/01/2009  | Female | 25 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (4 days);<br>Microgynon (ethinylloestradiol ; Levonorgestrel) - Concomitant (-)  | Malaise ; Pyrexia ; Rash generalised ; Serum sickness  |
| 0247741 | 16/01/2009 | Female | 25 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (104 days);<br>Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (17 days) | Multiple sclerosis   |

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|         |            |        |    |   |   |
|---------|------------|--------|----|---|---|
| 0248770 | 19/02/2009 | Female | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Erythema ; Pruritus ; Urticaria   |
| 0249155 | 11/03/2009 | Female | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (6 days)  | Rheumatoid arthritis  |
| 0249906 | 3/04/2009  | Female | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Atrioventricular septal defect ; Congenital anomaly ; Exposure during pregnancy   |
| 0250215 | 16/04/2009 | Female | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Generalised tonic-clonic seizure  |
| 0250694 | 5/05/2009  | Female | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Generalised tonic-clonic seizure  |
| 0251308 | 22/05/2009 | Female | 25 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (123 days)  | Ataxia ; Dyskinesia ; Eye disorder ; Gait disturbance   |
| 0251643 | 28/05/2009 | Female | 11 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (4 days); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (4 days); Varicella Vaccine (live varicella vaccine) - Suspect (4 days) | Peripheral swelling ; Rash erythematous   |
| 0252031 | 9/06/2009  | Female | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Mydriasis ; Seizure   |
| 0253656 | 13/07/2009 | Female | 24 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days)  | Asthenia ; Balance disorder ; Disturbance in attention ; Headache ; Neck pain   |
| 0253785 | 15/07/2009 | Female | 18 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (28 days)   | Abdominal pain upper ; Chest discomfort ; Chills ; Dyspnoea ; Headache ; Hypopnoea ; Insomnia ; Palpitations ; Seizure ; Syncope ; Vomiting |
| 0253874 | 16/07/2009 | Female | -  | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Pancreatitis chronic  |

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|         |            |        |    |  |  |
|---------|------------|--------|----|--|--|
| 0253877 | 16/07/2009 | Female | 26 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Nerve injury ; Pleurisy viral                                    |
| 0254243 | 20/07/2009 | Female | 21 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Injection site extravasation ; Subcutaneous emphysema            |
| 0254881 | 3/08/2009  | Female | 24 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (2 days)   | Chest pain ; Injection site reaction ; Lymphadenopathy           |
| 0256901 | 18/09/2009 | 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)   | Seizure  |
| 0256908 | 18/09/2009 | Female | 11 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days)   | Cough ; Erythema ; Oropharyngeal pain ; Pruritus ; Swelling face |
| 0256941 | 21/09/2009 | 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); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days) | Syncope  |
| 0256943 | 21/09/2009 | Female | 11 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days) | Syncope  |
| 0256947 | 21/09/2009 | 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); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days) | Injection site pain  |
| 0256949 | 21/09/2009 | 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)   | Erythema ; Headache ; Paraesthesia                               |
| 0257340 | 30/09/2009 | 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)   | Seizure  |
| 0257342 | 30/09/2009 | 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)   | Headache ; Loss of consciousness ; Tonic clonic movements        |

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|         |            |        |    |  |   |
|---------|------------|--------|----|--|---|
| 0257593 | 6/10/2009  | Female | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Abdominal pain lower ; Decreased appetite ; Lethargy ; Pallor ; Vomiting  |
| 0260385 | 26/11/2009 | Female | 27 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Alopecia  |
| 0261238 | 19/12/2009 | Female | 23 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Disturbance in attention ; Pelvic pain  |
| 0262217 | 26/01/2010 | Female | 23 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Furuncle  |
| 0263994 | 19/03/2010 | Female | 26 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Concomitant (-); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (130 days); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (31 days) | Nervous system disorder   |
| 0264517 | 31/03/2010 | Female | 40 | Cervarix (HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein) - Suspect (0 days)  | Musculoskeletal discomfort ; Rash ; Wheezing  |
| 0266810 | 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   |
| 0270361 | 7/07/2010  | Female | 23 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Erythema ; Pruritus ; Urticaria   |
| 0270444 | 8/07/2010  | Female | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Urticaria   |
| 0272242 | 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 |

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|         |            |        |    |   |   |
|---------|------------|--------|----|---|---|
| 0274700 | 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);<br>H-B-Vax II (Hepatitis B surface antigen recombinant) - Concomitant (0 days)  | Rash erythematous ; Urticaria   |
| 0275559 | 12/11/2010 | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Dizziness ; Extensive swelling of vaccinated limb ; Fatigue ; Injection site pain ; Skin discolouration |
| 0279520 | 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);<br>Varilrix (live varicella vaccine) - Suspect (0 days)   | Dyspnoea ; Rash ; Urticaria ; Vomiting  |
| 0280156 | 22/03/2011 | 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)  | Dyspnoea  |
| 0280329 | 25/03/2011 | Female | 12 | Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days); Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)       | Syncope   |
| 0280337 | 25/03/2011 | Female | 12 | Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days); Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)       | Presyncope  |
| 0280661 | 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);<br>H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days)  | Abdominal discomfort ; Malaise ; Nausea ; Rash  |
| 0280766 | 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);<br>H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days);<br>Varilrix (live varicella vaccine) - Suspect (0 days) | Pain ; Pyrexia ; Vomiting   |

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|         |            |        |    |  |  |
|---------|------------|--------|----|--|--|
| 0287390 | 15/08/2011 | 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)   | Lymphadenopathy ; Varicella  |
| 0288909 | 14/09/2011 | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Premature menopause  |
| 0291611 | 10/11/2011 | Female | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Amnesia ; Blindness transient ; Deafness ; Depression ; Disturbance in attention ; Fatigue ; Incontinence ; Pain ; Seizure |
| 0300468 | 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   |
| 0304701 | 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   |
| 0305196 | 13/08/2012 | Female | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Complex regional pain syndrome   |
| 0313775 | 12/02/2013 | Female | 24 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days)   | Nausea ; Oral mucosal blistering ; Vomiting  |
| 0314461 | 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  |
| 0314545 | 25/02/2013 | Male   | 12 | 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) | Syncope  |
| 0314784 | 28/02/2013 | 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);  | Syncope ; Vomiting   |

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|         |            |        |    |   |   |
|---------|------------|--------|----|---|---|
|         |            |        |    | H-B-Vax II (Hepatitis B surface antigen recombinant) - Suspect (0 days)   |   |
| 0316050 | 22/03/2013 | 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)  | Syncope   |
| 0316158 | 25/03/2013 | Male   | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days);<br>Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days)   | Arthralgia ; Headache ; Pyrexia   |
| 0316956 | 4/04/2013  | Female | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Syncope   |
| 0317281 | 8/04/2013  | Male   | 12 | Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (2 days)   | C-reactive protein increased ;<br>Lymphadenopathy ; Pyrexia ;<br>Vomiting |
| 0317316 | 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   |
| 0317458 | 10/04/2013 | 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)  | Syncope   |
| 0317533 | 10/04/2013 | Male   | 12 | Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Syncope   |
| 0317558 | 11/04/2013 | Male   | 14 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Facial paralysis  |
| 0317598 | 11/04/2013 | Male   | 14 | Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days); Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days) | Syncope   |
| 0317639 | 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   |

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|         |            |        |    |   |  |
|---------|------------|--------|----|---|--|
| 0317783 | 15/04/2013 | Female | 13 | Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days); Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Rash ; Syncope                             |
| 0317868 | 16/04/2013 | Male   | 15 | Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (1 days); Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days) | Hypersensitivity ; Injection site reaction |
| 0317973 | 16/04/2013 | Male   | 13 | Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days); Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Syncope                                    |
| 0317975 | 16/04/2013 | Male   | 15 | Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Syncope                                    |
| 0318000 | 17/04/2013 | Male   | 12 | Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days); Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Syncope                                    |
| 0318016 | 17/04/2013 | 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)  | Abdominal discomfort ; Syncope             |
| 0318245 | 19/04/2013 | Male   | 13 | Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days); Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Syncope                                    |



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|         |            |        |    |  |  |
|---------|------------|--------|----|--|--|
| 0318366 | 22/04/2013 | Male   | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Syncope  |
| 0318498 | 23/04/2013 | Female | 12 | Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Varicella Vaccine (live varicella vaccine) - Suspect (0 days)                                   | Syncope  |
| 0318778 | 29/04/2013 | Female | 12 | Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Urticaria  |
| 0318911 | 2/05/2013  | Male   | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (3 days)   | Lymphadenopathy  |
| 0319148 | 6/05/2013  | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days); Varicella Vaccine (live varicella vaccine) - Suspect (1 days)  | Abdominal pain ; Injection site reaction ; Rash pruritic |
| 0319152 | 6/05/2013  | 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); Varicella Vaccine (live varicella vaccine) - Suspect (0 days)  | Syncope  |
| 0319359 | 9/05/2013  | Male   | 12 | Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days); Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)                | Syncope  |
| 0319385 | 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   |
| 0319462 | 10/05/2013 | Male   | 12 | Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Concomitant (12 days); Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (12 days) | Neuropathy peripheral                                    |
| 0319726 | 15/05/2013 | Male   | 13 | Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV   | Syncope  |

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|         |            |        |    |  |                         |
|---------|------------|--------|----|--|-------------------------|
|         |            |        |    | Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days); Varicella Vaccine (live varicella vaccine) - Suspect (0 days)  |                         |
| 0319893 | 20/05/2013 | 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); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days)   | Syncope                 |
| 0319895 | 20/05/2013 | Male   | 15 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Syncope                 |
| 0320180 | 23/05/2013 | Female | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-); Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (-)   | Syncope                 |
| 0320618 | 30/05/2013 | Female | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (446 days)   | Urticaria               |
| 0320708 | 31/05/2013 | Male   | 17 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (3 days)   | Injection site reaction |
| 0320724 | 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                 |
| 0320749 | 3/06/2013  | 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) | Syncope                 |
| 0320926 | 4/06/2013  | 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); Varicella Vaccine (live varicella vaccine) - Suspect (0 days)  | Syncope                 |
| 0321260 | 11/06/2013 | Female | 12 | Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days); Human Papillomavirus Recombinant Vaccine   | Syncope                 |

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|         |            |        |    |  |                               |
|---------|------------|--------|----|--|-------------------------------|
|         |            |        |    | Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   |                               |
| 0321438 | 13/06/2013 | Male   | 13 | Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Syncope                       |
| 0321818 | 20/06/2013 | Male   | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Rash pruritic                 |
| 0322335 | 28/06/2013 | Male   | 12 | Human Papillomavirus Recombinant Vaccine Quadrivalent (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Nausea ; Pallor               |
| 0325636 | 26/08/2013 | Male   | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Syncope                       |
| 0326195 | 4/09/2013  | 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)   | Injection site pain ; Malaise |
| 0328939 | 21/10/2013 | 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);<br>Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days)  | Syncope                       |
| 0329693 | 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);<br>H-B-Vax II Vaccine Adult (Hepatitis B surface antigen recombinant) - Concomitant (0 days); Varilrix (live varicella vaccine) - Concomitant (0 days) | Syncope                       |
| 0329764 | 1/11/2013  | 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);<br>Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) - Suspect (0 days)  | Presyncope                    |
| 0330372 | 7/11/2013  | 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)   | Syncope                       |
| 0330387 | 7/11/2013  | 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)   | Syncope                       |

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|         |            |        |    |   |                                      |
|---------|------------|--------|----|---|--------------------------------------|
|         |            |        |    | Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days);<br>Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) -<br>Suspect (0 days)  |                                      |
| 0330389 | 7/11/2013  | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV<br>Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days);<br>Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) -<br>Suspect (0 days) | Syncope                              |
| 0330557 | 11/11/2013 | Male   | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV<br>Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Syncope                              |
| 0330990 | 14/11/2013 | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV<br>Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Syncope                              |
| 0331870 | 2/12/2013  | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV<br>Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days);<br>Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) -<br>Suspect (0 days) | Syncope                              |
| 0331879 | 2/12/2013  | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV<br>Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days);<br>Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) -<br>Suspect (0 days) | Syncope                              |
| 0332966 | 24/12/2013 | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV<br>Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (87 days)  | Anaphylactic reaction ; Ovarian cyst |
| 0333394 | 8/01/2014  | Female | 18 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV<br>Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-);<br>Hepatitis B Vaccine (Hepatitis B surface antigen recombinant) -<br>Suspect (-)           | Premature menopause                  |
| 0333613 | 14/01/2014 | Female | 22 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV<br>Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (14 days)  | Myalgia ; Pain in extremity          |
| 0337093 | 24/03/2014 | Male   | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV<br>Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Vomiting                             |

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|         |            |        |    |   |   |
|---------|------------|--------|----|---|---|
| 0337350 | 27/03/2014 | 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)  | Eye pruritus ; Headache ; Nausea ; Ocular hyperaemia ; Periorbital oedema |
| 0337353 | 27/03/2014 | Male   | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (2 days)  | Dizziness ; Headache ; Nausea   |
| 0337743 | 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  |
| 0338289 | 9/04/2014  | 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)  | Dizziness ; Nausea  |
| 0338840 | 16/04/2014 | 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)  | Nausea ; Pallor ; Syncope   |
| 0339916 | 7/05/2014  | Male   | 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)  | Syncope   |
| 0341618 | 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);<br>Varivax Refrigerated (live varicella vaccine) - Suspect (0 days) | Syncope   |
| 0341656 | 5/06/2014  | Female | 24 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (6 days)  | Facial paralysis  |
| 0341769 | 10/06/2014 | Female | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Premature menopause   |
| 0342132 | 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);<br>Varilrix (live varicella vaccine) - Suspect (0 days)             | Head injury ; Seizure ; Syncope   |
| 0342245 | 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);<br>Varivax Refrigerated (live varicella vaccine) - Suspect (0 days) | Dizziness ; Headache ; Hypoaesthesia ; Nausea ; Retching ; Syncope        |
| 0343626 | 9/07/2014  | 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)  | Chest discomfort ; Dyspnoea ; Hypersensitivity ; Stridor ; Wheezing       |

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|         |            |        |    |  |   |
|---------|------------|--------|----|--|---|
| 0344434 | 18/07/2014 | Male   | 13 | 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)   | Generalised tonic-clonic seizure  |
| 0344841 | 25/07/2014 | Female | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Abnormal dreams ; Dizziness ; Headache ; Injection site pain ; Lethargy ; Muscular weakness ; Pyrexia |
| 0346198 | 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   |
| 0346286 | 22/08/2014 | 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)   | Serum sickness-like reaction  |
| 0355700 | 6/03/2015  | Female | 23 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Immune thrombocytopenic purpura ; Myelodysplastic syndrome ; Paroxysmal nocturnal haemoglobinuria     |
| 0356282 | 17/03/2015 | 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)   | Hypersensitivity  |
| 0356584 | 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  |
| 0356689 | 16/03/2015 | Female | 14 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (244 days)   | Abdominal pain ; Dizziness ; Headache   |
| 0358747 | 4/05/2015  | Male   | 14 | Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (0   | Injection site cellulitis   |

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|         |            |        |    |  |   |
|---------|------------|--------|----|--|---|
|         |            |        |    | 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)  |   |
| 0358948 | 6/05/2015  | 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)   | Chest pain ; Dizziness ; Malaise ; Paraesthesia ; Throat irritation |
| 0359898 | 22/05/2015 | Female | 12 | 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) | Urticaria   |
| 0360689 | 2/06/2015  | Male   | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)  | Syncope   |
| 0360988 | 5/06/2015  | 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); Varicella Vaccine (live varicella vaccine) - Suspect (0 days)  | Syncope   |
| 0368031 | 24/09/2015 | Female | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Headache ; Pyrexia ; Vomiting                                       |
| 0369997 | 3/11/2015  | 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); Varicella Vaccine (live varicella vaccine) - Suspect (0 days)  | Syncope   |
| 0371751 | 2/12/2015  | Male   | 12 | 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) | Injection site reaction ; Lethargy ; Pyrexia                        |
| 0375614 | 9/02/2016  | Female | 12 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (211 days)   | Fatigue   |
| 0388525 | 23/05/2016 | Female | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)   | Asthenia ; Athetosis ; Demyelination                                |

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|         |            |        |    |   |  |
|---------|------------|--------|----|---|--|
| 0388534 | 23/05/2016 | Female | 26 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (177 days)  | Multiple sclerosis   |
| 0388537 | 23/05/2016 | Female | 16 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Multiple sclerosis   |
| 0388549 | 23/05/2016 | Female | 25 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (103 days)  | Multiple sclerosis   |
| 0388553 | 23/05/2016 | Female | 21 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Multiple sclerosis relapse ; Optic neuritis  |
| 395293  | 15/09/2016 | Male   | 13 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (13 days)   | Acute disseminated encephalomyelitis   |
| 0430286 | 28/03/2018 | Male   | 11 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (0 days)  | Syncope  |
| 0439385 | 1/08/2018  | Male   | 13 | Boostrix (Diphtheria toxoid ; Pertactin ; Pertussis filamentous haemagglutinin ; Pertussis toxoid ; Tetanus toxoid) - Suspect (1 days); Gardasil 9 (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 31 L1 Protein ; HPV Type 33 L1 Protein ; HPV Type 45 L1 Protein ; HPV Type 52 L1 Protein ; HPV Type 58 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (1 days) | Injection site reaction  |
| 0448733 | 24/10/2018 | 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)  | Confusional state ; Gait disturbance ; Headache ; Hypoaesthesia ; Muscular weakness ; Neck pain ; Paraesthesia |
| 0449563 | 2/11/2018  | Female | 33 | Gardasil (HPV Type 11 L1 Protein ; HPV Type 16 L1 Protein ; HPV Type 18 L1 Protein ; HPV Type 6 L1 Protein) - Suspect (-)   | Vaccination failure  |



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The table on the following 26 pages lists reports that were entered into the previous internal database used by TGA. A new database was introduced in mid-2018, with data migrated from the old to the new database. While all reports were migrated, some reports had insufficient information coded for the medicine/vaccine name. These reports are currently being reviewed and manually updated to enter the coded medicine/vaccine name, which is required for the report to be published on the DAEN.

There are 227 reports listed in the following table. Of these 227 reports, 205 have previously been published in the DAEN, and will be available in the DAEN once the vaccine name has been updated. This process is expected to be completed in the coming weeks. There are 22 reports that will not be published on the DAEN as they either 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 be a duplicate of a report included in the DAEN. These reports can be identified by the highlighted case number. The reports which are duplicates (18) are identified in the table.

# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine  |   | Reaction   |
|----------|-------------|-----|-----|---|---|--|
| 238144   | 20/02/2008  | F   | 14  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 1 | Rash<br>Injection site reaction  |
| 238962   | 14/03/2008  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Headache<br>Hypotension<br>Dizziness<br>Injection site reaction<br>Vomiting<br>Syncope |
| 241072   | 22/05/2008  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Vomiting<br>Syncope  |
| 242529   | 02/07/2008  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Malaise<br>Headache<br>Injection site reaction<br>Pallor                               |
| 242553   | 03/07/2008  | F   | 14  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Nausea<br>Arthralgia<br>Vomiting<br>Lethargy<br>Decreased appetite                     |
| 242812   | 11/07/2008  | F   | 14  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Paraesthesia<br>Headache<br>Nausea<br>Dyspnoea<br>Dizziness<br>Pyrexia                 |



# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine  |     | Reaction   |
|----------|-------------|-----|-----|---|-----|--|
| 242997   | 17/07/2008  | F   | 23  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   | Hepatic failure<br>Acute kidney injury                       |
|          |             |     |     | Keppra (Levetiracetam) -Suspected                       | 154 |  |
|          |             |     |     | Tegretol (Carbamazepine) -Suspected                     |     |  |
|          |             |     |     | Benzodiazepine NOS -Other drug                          |     |  |
|          |             |     |     | Epilim (Sodium Valproate) -Other drug                   |     |  |
| 243863   | 15/08/2008  | F   | 22  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   | Chest pain<br>Nausea<br>Dizziness<br>Lethargy                |
| 245053   | 02/10/2008  | F   | 25  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   | Nausea<br>Dizziness<br>Swelling face                         |
| 245767   | 23/10/2008  | F   | 17  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 8   | Limb discomfort<br>Injection site pain                       |
| 245874   | 28/10/2008  | F   | 21  | Human Papillomavirus Recombinant Vaccine NOS -Suspected |     | Rash morbilliform<br>Pyrexia<br>Oedema<br>Nodule<br>Pruritus |
| 245875   | 28/10/2008  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   | Urticaria  |
| 245879   | 28/10/2008  | F   | 15  | DTPa-Hepatitis B (Dtpa-hepatitis B) -Suspected          | 0   | Throat tightness<br>Rash erythematous<br>Pruritus            |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected |     |  |
| 246547   | 25/11/2008  | F   | 23  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 15  | Demyelination  |

# DAEN Case Line Listing

Cases Count: 227

| Case No.  | Report Date | Sex | Age | Medicine  |   | Reaction   |
|-----------|-------------|-----|-----|---|---|--|
| 246558    | 25/11/2008  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Injection site reaction  |
|           |             |     |     | Hepatitis B Vaccine -Other drug                         | 0 |  |
| 246563    | 25/11/2008  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope<br>Syncope  |
| 247360    | 23/12/2008  | F   | 14  | Hepatitis B Vaccine -Suspected                          | 1 | Malaise  |
|           |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 1 | Nausea<br>Arthralgia<br>Pyrexia                                    |
| 249312    | 16/03/2009  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Headache   |
|           |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Malaise<br>Somnolence<br>Injection site hypoaesthesia<br>Dizziness |
| 250084    | 09/04/2009  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Nausea<br>Dizziness<br>Muscle contractions involuntary             |
| 255954    | 27/08/2009  | F   | 23  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Paraesthesia<br>Arthralgia<br>Myalgia                              |
| 259281    | 04/11/2009  | F   | 25  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Headache<br>Hypoaesthesia  |
| 261570    | 05/01/2010  | F   | ??  | Human Papillomavirus Recombinant Vaccine NOS -Suspected |   | Multiple sclerosis   |
| Duplicate |             |     |     |   |   |  |
| 261571    | 05/01/2010  | F   | ??  | Human Papillomavirus Recombinant Vaccine NOS -Suspected |   | Multiple sclerosis   |
| Duplicate |             |     |     |   |   |  |
| 261578    | 05/01/2010  | F   | ??  | Human Papillomavirus Recombinant Vaccine NOS -Suspected |   | Multiple sclerosis   |
| Duplicate |             |     |     |   |   |  |



# DAEN Case Line Listing

Cases Count: 227

| Case No.      | Report Date | Sex | Age | Medicine  |    | Reaction   |
|---------------|-------------|-----|-----|---|----|--|
| <b>261580</b> | 05/01/2010  | F   | ??  | Human Papillomavirus Recombinant Vaccine NOS -Suspected |    | Multiple sclerosis                                     |
| Duplicate     |             |     |     |   |    |  |
| <b>261582</b> | 05/01/2010  | F   | ??  | Human Papillomavirus Recombinant Vaccine NOS -Suspected |    | Multiple sclerosis                                     |
| Duplicate     |             |     |     |   |    |  |
| <b>273220</b> | 09/09/2010  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 63 | Headache<br>Depression<br>Nausea<br>Pyrexia<br>Fatigue |
| <b>273444</b> | 16/09/2010  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 1  | Chest pain<br>Abdominal pain                           |
|               |             |     |     | Varicella Vaccine -Suspected                            | 1  | Tachycardia<br>Hypertension                            |
| <b>273901</b> | 29/09/2010  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0  | Vomiting   |
| <b>274161</b> | 05/10/2010  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0  | Syncope<br>Pallor                                      |
| <b>274172</b> | 06/10/2010  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0  | Headache<br>Peripheral coldness                        |
|               |             |     |     | Varicella Vaccine -Suspected                            | 0  | Dizziness<br>Pallor                                    |
| <b>274819</b> | 22/10/2010  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0  | Presyncope   |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0  |  |
| <b>277690</b> | 18/01/2011  | F   | 27  | Human Papillomavirus Recombinant Vaccine NOS -Suspected |    | Alopecia areata  |

# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine  |   | Reaction   |
|----------|-------------|-----|-----|---|---|--|
| 277945   | 24/01/2011  | F   | 11  | Hepatitis B Vaccine -Suspected                          | 0 | Eye swelling   |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Swollen tongue<br>Seizure  |
| 278217   | 01/02/2011  | F   | 17  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Somnolence<br>Pain<br>Headache<br>Memory impairment<br>Rash<br>Dizziness |
| 279621   | 08/03/2011  | U   | 12  | Hepatitis B Vaccine -Suspected                          |   | Disturbance in attention   |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected |   | Fatigue<br>Lethargy  |
| 279881   | 15/03/2011  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope  |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| 280084   | 21/03/2011  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope  |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| 280085   | 21/03/2011  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope  |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| 280087   | 21/03/2011  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope  |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| 280088   | 21/03/2011  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope  |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |

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Cases Count: 227

| Case No.  | Report Date | Sex | Age | Medicine   |   | Reaction                                    |
|-----------|-------------|-----|-----|--|---|---|
| 280146    | 21/03/2011  | F   | ??  | Hepatitis B Vaccine -Suspected   | 0 | Presyncope                                  |
|           |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected  | 0 |   |
| 280360    | 25/03/2011  | F   | 13  | Hepatitis B Vaccine -Suspected   | 0 | Presyncope                                  |
| Duplicate |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected  | 0 |   |
| 280365    | 25/03/2011  | F   | 12  | Hepatitis B Vaccine -Suspected   | 0 | Skin abrasion<br>Presyncope                 |
| Duplicate |             |     |     | Human Papillomavirus Vaccine Bivalent (Human Papillomavirus Recombinant Vaccine Bivalent) -Suspected | 0 |   |
| 280597    | 30/03/2011  | F   | 12  | ADT Booster (Diphtheria And Tetanus Vaccine NOS) -Suspected  | 0 | Viral infection                             |
| Duplicate |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected  | 0 |   |
| 280806    | 04/04/2011  | F   | 13  | Hepatitis B Vaccine -Suspected   | 0 | Cold sweat<br>Vomiting<br>Syncope<br>Pallor |
|           |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected  | 0 |   |
| 281020    | 07/04/2011  | F   | 11  | Hepatitis B Vaccine -Suspected   | 0 | Urticaria<br>Pruritus                       |
|           |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected  | 0 |   |
|           |             |     |     | Cetirizine Hydrochloride -Other drug   |   |   |
| 281080    | 08/04/2011  | F   | 13  | Hepatitis B Vaccine -Suspected   | 0 | Rash<br>Swelling<br>Dyspnoea<br>Pyrexia     |
|           |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected  | 0 |   |
| 282357    | 05/05/2011  | F   | 12  | Hepatitis B Vaccine -Suspected   | 8 | Rash pruritic                               |
|           |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected  | 8 |   |

# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine  |   | Reaction  |
|----------|-------------|-----|-----|---|---|---|
| 283137   | 23/05/2011  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope  |
| 283368   | 27/05/2011  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Dizziness<br>Pallor<br>Diarrhoea                          |
| 283647   | 01/06/2011  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 1 | Rash erythematous   |
|          |             |     |     | Varilrix (Varicella Vaccine) -Suspected                 | 1 |   |
| 283866   | 07/06/2011  | F   | ??  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope  |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |   |
| 285420   | 05/07/2011  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected |   | Pain in jaw<br>Toothache<br>Facial pain                   |
|          |             |     |     | Varilrix (Varicella Vaccine) -Suspected                 |   |   |
| 285837   | 13/07/2011  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Muscular weakness<br>Paraesthesia<br>Anxiety<br>Dizziness |
| 287316   | 12/08/2011  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Eye pain<br>Eye swelling<br>Eye pruritus                  |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |   |
| 289243   | 20/09/2011  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope  |
| 289249   | 20/09/2011  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope  |
|          |             |     |     | Varicella Vaccine -Suspected                            | 0 |   |





# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine  |     | Reaction   |
|----------|-------------|-----|-----|---|-----|--|
| 291162   | 31/10/2011  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0   | Erythema   |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   | Gait disturbance   |
|          |             |     |     |   |     | Back pain<br>Injection site reaction<br>Pyrexia<br>Hyperhidrosis<br>Vomiting<br>Crying |
| 291549   | 08/11/2011  | F   | 13  | DTPa Vaccine (Dtpa Vaccine) -Suspected                  | 1   | Oropharyngeal pain   |
|          |             |     |     | Hepatitis B Vaccine -Suspected                          | 1   | Malaise  |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 1   | Headache   |
|          |             |     |     |   |     | Nausea<br>Pyrexia<br>Fatigue<br>Cough  |
| 293425   | 15/12/2011  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0   | Presyncope   |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   |  |
|          |             |     |     |   |     |  |
| 293862   | 23/12/2011  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0   | Presyncope   |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   |  |
|          |             |     |     |   |     |  |
| 294289   | 06/01/2012  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   | Nasopharyngitis<br>Headache<br>Injection site reaction<br>Fatigue                      |
|          |             |     |     |   |     |  |
| 294290   | 06/01/2012  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   | Nausea<br>Injection site reaction<br>Pyrexia   |
| 294291   | 06/01/2012  | F   | 26  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 730 | Vaccination failure  |

# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine  |        | Reaction   |
|----------|-------------|-----|-----|---|--------|--|
| 294296   | 06/01/2012  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected                                   | 310    | Skin reaction<br>Headache<br>Paraesthesia<br>Nausea<br>Constipation<br>Dizziness<br>Pyrexia<br>Abdominal pain upper<br>Diarrhoea |
| 294338   | 09/01/2012  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected                                   | 0      | Presyncope   |
| 294340   | 09/01/2012  | F   | 13  | Hepatitis B Vaccine -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0<br>0 | Syncope  |
| 294344   | 09/01/2012  | F   | 13  | Hepatitis B Vaccine -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0<br>0 | Tremor<br>Dizziness<br>Syncope   |
| 294345   | 09/01/2012  | F   | 13  | Hepatitis B Vaccine -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0<br>0 | Presyncope   |
| 296829   | 05/03/2012  | F   | 13  | Hepatitis B Vaccine -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0<br>0 | Skin exfoliation<br>Injection site reaction  |
| 297167   | 09/03/2012  | F   | 12  | Hepatitis B Vaccine -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0<br>0 | Presyncope   |
| 297459   | 16/03/2012  | F   | 19  | Human Papillomavirus Recombinant Vaccine NOS -Suspected                                   |        | Cervical dysplasia   |

# DAEN Case Line Listing

Cases Count: 227

| Case No.      | Report Date | Sex | Age | Medicine  |     | Reaction  |
|---------------|-------------|-----|-----|---|-----|---|
| <b>297511</b> | 19/03/2012  | F   | 27  | Human Papillomavirus Recombinant Vaccine NOS -Suspected |     | Cervix neoplasm   |
| <b>297810</b> | 23/03/2012  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0   | Presyncope  |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   |   |
| <b>297815</b> | 23/03/2012  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   | Lip pruritus<br>Eye movement disorder<br>Hypersensitivity<br>Decreased appetite |
| <b>297924</b> | 26/03/2012  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0   | Presyncope  |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   |   |
| <b>298116</b> | 28/03/2012  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0   | Rash<br>Injection site reaction   |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   |   |
| <b>298242</b> | 30/03/2012  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0   | Rash<br>Blister<br>Injection site reaction<br>Periorbital oedema                |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   |   |
| <b>298355</b> | 02/04/2012  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0   | Injection site reaction   |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   |   |
| <b>300451</b> | 16/05/2012  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0   | Paraesthesia  |
| <b>300463</b> | 16/05/2012  | F   | 14  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 414 | Hyperthyroidism   |

# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine  |   | Reaction         |
|----------|-------------|-----|-----|---|---|------------------|
| 300465   | 16/05/2012  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope          |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                  |
| 300487   | 16/05/2012  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope       |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                  |
| 301015   | 25/05/2012  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope          |
|          |             |     |     | Varicella Vaccine -Suspected                            | 0 |                  |
| 301024   | 25/05/2012  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope       |
|          |             |     |     | Varicella Vaccine -Suspected                            | 0 |                  |
| 301846   | 08/06/2012  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope       |
|          |             |     |     | Varicella Vaccine -Suspected                            | 0 |                  |
| 301864   | 08/06/2012  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope       |
| 301892   | 08/06/2012  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope          |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                  |
| 302806   | 27/06/2012  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 2 | Pityriasis rosea |
|          |             |     |     | Varicella Vaccine -Suspected                            | 2 |                  |
| 302835   | 28/06/2012  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope          |
|          |             |     |     | Varicella Vaccine -Suspected                            | 0 |                  |

# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine  |   | Reaction   |
|----------|-------------|-----|-----|---|---|--|
| 304309   | 27/07/2012  | F   | 14  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Malaise<br>Headache<br>Arthralgia<br>Heart rate increased<br>Dizziness<br>Myalgia<br>Vomiting<br>Photophobia |
| 310260   | 21/11/2012  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope   |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| 310549   | 27/11/2012  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope   |
| 310551   | 27/11/2012  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope   |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| 314011   | 15/02/2013  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope  |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| 314290   | 20/02/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Cold sweat<br>Pallor   |
| 314291   | 20/02/2013  | M   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope  |
| 314430   | 22/02/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Headache   |
| 314432   | 21/02/2013  | M   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope   |

# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine  |   | Reaction                |
|----------|-------------|-----|-----|---|---|-------------------------|
| 314434   | 21/02/2013  | M   | 14  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope              |
| 314758   | 27/02/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Dizziness               |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                         |
| 314759   | 27/02/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Dizziness               |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                         |
| 314760   | 27/02/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope              |
| 314761   | 27/02/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Cold sweat              |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Nausea<br>Hyperhidrosis |
| 314763   | 27/02/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Nausea                  |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Dizziness               |
| 314764   | 27/02/2013  | F   | 11  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope                 |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                         |
| 314765   | 27/02/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Cold sweat              |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Nausea<br>Presyncope    |
| 314782   | 28/02/2013  | M   | 12  | Boostrix (Dtpa Vaccine) -Suspected                      | 0 | Vomiting                |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope                 |

# DAEN Case Line Listing

Cases Count: 227

| Case No.      | Report Date | Sex | Age | Medicine  |   | Reaction          |
|---------------|-------------|-----|-----|---|---|-------------------|
| <b>314846</b> | 01/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Anxiety           |
| Duplicate     |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Chest discomfort  |
| <b>314872</b> | 01/03/2013  | M   | 14  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Dizziness         |
| <b>314874</b> | 01/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope        |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                   |
| <b>314877</b> | 01/03/2013  | M   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Dizziness         |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                   |
| <b>314881</b> | 01/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Dizziness         |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                   |
| <b>314882</b> | 01/03/2013  | M   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Malaise           |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Dizziness         |
| <b>314884</b> | 01/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope        |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                   |
| <b>314909</b> | 01/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope           |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                   |
| <b>315040</b> | 05/03/2013  | M   | 15  | Human Papillomavirus Recombinant Vaccine NOS -Suspected |   | Visual impairment |
| <b>315046</b> | 06/03/2013  | M   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope        |

# DAEN Case Line Listing

Cases Count: 227

| Case No.            | Report Date | Sex | Age | Medicine  |   | Reaction             |
|---------------------|-------------|-----|-----|---|---|----------------------|
| 315047              | 06/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Urinary incontinence |
|                     |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope              |
| 315048              | 06/03/2013  | M   | 14  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope              |
| 315115<br>Duplicate | 07/03/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Skin discolouration  |
|                     |             |     |     | Hepatitis B Vaccine -Other drug                         | 0 |                      |
| 315117<br>Duplicate | 07/03/2013  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Vomiting             |
|                     |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope              |
| 315143              | 07/03/2013  | M   | 12  | Boostrix (Dtpa Vaccine) -Suspected                      | 0 | Syncope              |
|                     |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                      |
| 315155              | 07/03/2013  | M   | 12  | Boostrix (Dtpa Vaccine) -Suspected                      | 0 | Syncope              |
|                     |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                      |
| 315156              | 07/03/2013  | M   | 12  | Boostrix (Dtpa Vaccine) -Suspected                      | 0 | Syncope              |
|                     |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                      |
| 315198              | 08/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Dizziness            |
|                     |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                      |
| 315201              | 08/03/2013  | M   | 12  | H-B-Vax II (Hepatitis B Vaccine) -Suspected             | 0 | Nausea               |
|                     |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope              |





# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine  |   | Reaction                          |
|----------|-------------|-----|-----|---|---|-----------------------------------|
| 315206   | 08/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope                           |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                                   |
| 315209   | 08/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope                           |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                                   |
| 315473   | 13/03/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 1 | Headache<br>Dizziness<br>Vomiting |
| 315544   | 13/03/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope                        |
| 315545   | 13/03/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope                        |
| 315547   | 13/03/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope                        |
| 315548   | 13/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope                        |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                                   |
| 315551   | 13/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope                        |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                                   |
| 315552   | 13/03/2013  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope                        |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                                   |
| 315553   | 13/03/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope                        |

# DAEN Case Line Listing

Cases Count: 227

| Case No.  | Report Date | Sex | Age | Medicine  |   | Reaction             |
|-----------|-------------|-----|-----|---|---|----------------------|
| 315555    | 13/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Cold sweat           |
|           |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope           |
| 315559    | 13/03/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope           |
| 315572    | 13/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope              |
|           |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                      |
| 315573    | 13/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Dizziness            |
|           |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                      |
| 315616    | 14/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope              |
| Duplicate |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                      |
| 315621    | 14/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope              |
|           |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                      |
| 315625    | 14/03/2013  | F   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Nausea               |
|           |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Dizziness<br>Syncope |
| 315629    | 14/03/2013  | M   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Nausea               |
| 315632    | 14/03/2013  | M   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Nausea<br>Pallor     |
| 315633    | 14/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Dizziness            |
|           |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                      |

# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine  |   | Reaction                          |
|----------|-------------|-----|-----|---|---|-----------------------------------|
| 315637   | 14/03/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope                           |
| 315643   | 14/03/2013  | M   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Headache                          |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Asthenia<br>Arthralgia<br>Pyrexia |
| 315658   | 15/03/2013  | M   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope                           |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                                   |
| 315659   | 15/03/2013  | M   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Headache                          |
|          |             |     |     | Varicella Vaccine -Suspected                            | 0 | Vomiting<br>Pyrexia               |
| 315660   | 15/03/2013  | M   | 14  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope                        |
| 315666   | 15/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Headache                          |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope                           |
| 315799   | 18/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope                        |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                                   |
| 315800   | 18/03/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope                        |
| 315801   | 18/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Malaise                           |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope                        |
| 315802   | 18/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope                        |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                                   |

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Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine  |   | Reaction                                   |
|----------|-------------|-----|-----|---|---|--|
| 315803   | 18/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Paraesthesia                               |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Dizziness                                  |
| 315804   | 18/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Dizziness                                  |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| 315806   | 18/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Malaise                                    |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Dizziness                                  |
| 315840   | 19/03/2013  | M   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 2 | Lymphadenopathy<br>Pyrexia<br>Vomiting     |
| 315919   | 20/03/2013  | M   | 13  | H-B-Vax II (Hepatitis B Vaccine) -Suspected             | 0 | Syncope                                    |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| 316065   | 22/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope                                 |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| 316073   | 22/03/2013  | M   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope                                    |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| 316075   | 22/03/2013  | M   | 15  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Vision blurred<br>Corneal reflex decreased |
| 316097   | 22/03/2013  | M   | 14  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope                                    |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |

# DAEN Case Line Listing

Cases Count: 227

| Case No.      | Report Date | Sex | Age | Medicine  |   | Reaction                               |
|---------------|-------------|-----|-----|---|---|--|
| <b>316099</b> | 22/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope                                |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| <b>316100</b> | 22/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope                                |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| <b>316104</b> | 22/03/2013  | M   | 14  | DTPa Vaccine (Dtpa Vaccine) -Suspected                  | 0 | Nausea<br>Syncope<br>Throat irritation |
| Duplicate     |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
|               |             |     |     |   |   |  |
| <b>316140</b> | 25/03/2013  | M   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope                                |
| Duplicate     |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| <b>316142</b> | 25/03/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope                                |
| Duplicate     |             |     |     |   |   |  |
| <b>316148</b> | 25/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope                                |
|               |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |
| <b>316160</b> | 25/03/2013  | M   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope                                |
| <b>316203</b> | 25/03/2013  | M   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope                                |
| <b>316228</b> | 26/03/2013  | M   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Syncope                                |
|               |             |     |     | Varicella Vaccine -Suspected                            | 0 |  |
| <b>316378</b> | 27/03/2013  | M   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope                                |
| Duplicate     |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |  |

# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine  |   | Reaction                |
|----------|-------------|-----|-----|---|---|-------------------------|
| 316390   | 27/03/2013  | M   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope              |
| 316393   | 27/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope              |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                         |
| 316395   | 27/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope              |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                         |
| 316399   | 27/03/2013  | M   | 13  | Hepatitis B Vaccine -Suspected                          | 0 | Vomiting                |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                         |
| 316412   | 27/03/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Dizziness               |
| 316413   | 27/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Syncope                 |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                         |
| 316414   | 27/03/2013  | M   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Dizziness               |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                         |
| 316415   | 27/03/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Dizziness<br>Hypoacusis |
| 316416   | 27/03/2013  | F   | 12  | Hepatitis B Vaccine -Suspected                          | 0 | Presyncope              |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 |                         |
| 316417   | 27/03/2013  | M   | 14  | Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0 | Presyncope              |

# DAEN Case Line Listing

Cases Count: 227

| Case No.      | Report Date | Sex | Age | Medicine  |        | Reaction  |
|---------------|-------------|-----|-----|---|--------|---|
| 316418        | 27/03/2013  | M   | 14  | Human Papillomavirus Recombinant Vaccine NOS -Suspected                                   | 0      | Dizziness   |
| 316600        | 02/04/2013  | M   | 14  | Human Papillomavirus Recombinant Vaccine NOS -Suspected                                   | 0      | Presyncope  |
| 316606        | 02/04/2013  | M   | 14  | Human Papillomavirus Recombinant Vaccine NOS -Suspected                                   | 0      | Presyncope  |
| 316609        | 02/04/2013  | F   | 12  | Hepatitis B Vaccine -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0<br>0 | Presyncope  |
| 316627        | 02/04/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected                                   | 0      | Rash generalised  |
| 316802        | 03/04/2013  | M   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected                                   | 0      | Dizziness   |
| 316807        | 03/04/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected                                   | 0      | Malaise<br>Injection site mass<br>Pyrexia<br>Presyncope<br>Decreased appetite |
| 317287        | 08/04/2013  | M   | 12  | Hepatitis B Vaccine -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0<br>0 | Syncope   |
| 317366        | 09/04/2013  | M   | 12  | Hepatitis B Vaccine -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected | 0<br>0 | Rash erythematous   |
| <b>317460</b> | 10/04/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected                                   | 12     | Syncope   |
| Duplicate     |             |     |     |   |        |   |

# DAEN Case Line Listing

Cases Count: 227

| Case No.                   | Report Date | Sex | Age | Medicine  |        | Reaction  |
|----------------------------|-------------|-----|-----|---|--------|---|
| <b>317787</b><br>Duplicate | 15/04/2013  | M   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected   | 0      | Nausea  |
| <b>331733</b>              | 27/11/2013  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected   | 0      | Tremor  |
| <b>355187</b>              | 27/02/2015  | M   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected   | 3      | Mobility decreased<br>Headache<br>Malaise<br>Fatigue    |
| <b>355813</b>              | 11/03/2015  | M   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected   | 0      | Vaccination error                                       |
| <b>355952</b>              | 12/03/2015  | M   | 12  | Boostrix (Dtpa Vaccine) -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected     | 0<br>0 | Wheezing  |
| <b>356902</b>              | 30/03/2015  | M   | 12  | Boostrix (Dtpa Vaccine) -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected     | 0<br>0 | Headache<br>Nausea<br>Vomiting                          |
| <b>356903</b>              | 30/03/2015  | M   | 13  | Boostrix (Dtpa Vaccine) -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected     | 0<br>0 | Dizziness<br>Vomiting                                   |
| <b>359899</b>              | 22/05/2015  | M   | 13  | DTPa Vaccine (Dtpa Vaccine) -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected |        | Muscular weakness<br>Paraesthesia<br>Headache<br>Tremor |
| <b>369034</b>              | 15/10/2015  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected   | 0      | Nausea<br>Vomiting                                      |
| <b>376943</b>              | 05/03/2016  | F   | 33  | Hepatitis B Vaccine -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected         |        | Lymphadenopathy<br>Nasopharyngitis                      |





# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine   |        | Reaction   |
|----------|-------------|-----|-----|--|--------|--|
| 377675   | 18/03/2016  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected  | 1      | Malaise<br>Asthenia<br>Paraesthesia<br>Headache<br>Pollakiuria<br>Nausea<br>Dizziness                                    |
| 385329   | 29/03/2016  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected  | 0      | Rash<br>Peripheral swelling  |
| 393183   | 10/08/2016  | F   | 12  | Boostrix (Dtpa Vaccine) -Suspected   | -63    | Influenza like illness   |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected  | -63    |  |
| 399033   | 16/11/2016  | U   | ??  | Gardasil (Human Papillomavirus Recombinant Vaccine Quadrivalent) -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected |        | Headache<br>Interchange of vaccine products<br>Tachycardia<br>Anaphylactic reaction<br>Cough<br>Pruritus<br>Hypertension |
| 399036   | 16/11/2016  | U   | ??  | Gardasil (Human Papillomavirus Recombinant Vaccine Quadrivalent) -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected |        | Headache<br>Interchange of vaccine products<br>Tachycardia<br>Anaphylactic reaction<br>Cough<br>Pruritus<br>Hypertension |
| 405805   | 24/03/2017  | F   | 12  | Diphtheria-Tetanus-Pertussis Vaccine NOS -Suspected<br>Human Papillomavirus Recombinant Vaccine NOS -Suspected                         | 0<br>0 | Syncope  |

# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine   |   | Reaction   |
|----------|-------------|-----|-----|--|---|--|
| 406001   | 28/03/2017  | F   | 12  | DTPa Vaccine (Dtpa Vaccine) -Suspected                         | 0 | Concomitant disease aggravated   |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected        | 0 |  |
| 406150   | 30/03/2017  | M   | 11  | Boostrix (Dtpa Vaccine) -Suspected                             | 5 | Dyspnoea   |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected        | 5 |  |
| 411710   | 13/06/2017  | F   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected        | 0 | Nausea<br>Myalgia  |
|          |             |     |     | Varicella Vaccine -Suspected                                   | 0 |  |
| 415447   | 04/08/2017  | M   | 12  | Human Papillomavirus Recombinant Nonavalent vaccine -Suspected | 0 | Syncope<br>Pallor  |
| 415536   | 07/08/2017  | F   | ??  | Human Papillomavirus Recombinant Vaccine NOS -Suspected        |   | Respiratory disorder<br>Scoliosis<br>Pain<br>Headache<br>Paraesthesia<br>Depression<br>Insomnia<br>Panic attack<br>Hypersomnia<br>Cyanosis<br>Fatigue<br>Palpitations<br>Syncope<br>Pallor |
| 420666   | 26/10/2017  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected        | 2 | Injection site reaction  |
|          |             |     |     | Varicella Vaccine -Suspected                                   | 2 |  |
| 421583   | 08/11/2017  | M   | 13  | Human Papillomavirus Recombinant Vaccine NOS -Suspected        | 0 | Headache<br>Pyrexia  |



# DAEN Case Line Listing

Cases Count: 227

| Case No. | Report Date | Sex | Age | Medicine   |    | Reaction  |
|----------|-------------|-----|-----|--|----|---|
| 423156   | 01/12/2017  | F   | 11  | Human Papillomavirus Recombinant Vaccine NOS -Suspected  | 0  | Nausea  |
|          |             |     |     | Varicella Vaccine -Suspected   | 0  | Hyperhidrosis<br>Pallor   |
| 423700   | 09/12/2017  | F   | 15  | Human Papillomavirus Recombinant Nonavalent vaccine -Suspected                                       | 31 | Gastrooesophageal reflux disease<br>Impaired gastric emptying<br>Vomiting |
| 428413   | 01/03/2018  | F   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected  | 0  | Headache  |
| 429008   | 12/03/2018  | F   | 11  | DTPa Vaccine (Dtpa Vaccine) -Suspected   |    | Nervous system disorder   |
|          |             |     |     | Human Papillomavirus Recombinant Vaccine NOS -Suspected  |    | Febrile infection-related epilepsy syndrome<br>Seizure                    |
| 430089   | 27/03/2018  | M   | 12  | Boostrix (Dtpa Vaccine) -Suspected   | 1  | Nausea  |
|          |             |     |     | Human Papillomavirus Vaccine Bivalent (Human Papillomavirus Recombinant Vaccine Bivalent) -Suspected | 1  | Vomiting  |
| 431021   | 11/04/2018  | M   | 12  | Human Papillomavirus Recombinant Vaccine NOS -Suspected  |    | Nausea  |
| 432957   | 10/05/2018  | M   | 12  | Human Papillomavirus Recombinant Nonavalent vaccine -Suspected                                       | 1  | Pain<br>Pyrexia   |

Selection Parameters : Date Range: 01/01/1960 To 31/12/2059 Medicine Status: General marketing Medicine Names: Human Papillomavirus Recombinant Nonavalent vaccine, Human Papillomavirus Recombinant Vaccine NOS, Human Papillomavirus Vaccine Bivalent