

Read the Fine Print, Part Two— Nearly 400 Adverse Reactions Listed in Vaccine Package Inserts



By the Children’s Health Defense Team

Package inserts are available online for [all vaccines](#)¹ licensed in the U.S. In addition to containing bits of practical information for the clinicians who administer the vaccines, the inserts provide members of the public with one of their only opportunities to learn about a vaccine’s contraindications, warnings, precautions and—perhaps most importantly—potential adverse reactions.

The inserts communicate the information about adverse reactions in two distinct sections: “Clinical trials experience” (Section 6.1) and “Data from postmarketing experience” from the U.S. or other countries (Section 6.2). In April, 2020, Children’s Health Defense summarized the [postmarketing data](#)² for over three dozen vaccines given routinely to American infants, children and adolescents. That tally showed that vaccines touted for the prevention of 13 illnesses (Table 1) have been linked to at least 217 adverse medical outcomes reported post-licensure,

including serious infections, autoimmune conditions, life-threatening allergies and death.

This combination of clinical trial and postmarketing data presents a dramatic picture, with almost double the total number of undesirable post-vaccination outcomes ...

As noted in April, the postmarketing list is far from exhaustive, because manufacturers have the latitude to decide which outcomes to list in the inserts—using loose criteria determined by severity, frequency of reporting and “strength of evidence for a causal relationship.” In addition, vaccine adverse events are [notoriously](#)

underreported,³ not least because medical schools do not teach doctors to recognize vaccine injuries.⁴ But what would the picture look like if the adverse reactions observed during clinical trials were also added to the list?

Double trouble

Children’s Health Defense can now answer that question. The revised chart (Table 2) includes the adverse reactions reported in the clinical trial sections of 41 vaccine brands covering diphtheria, *Haemophilus influenzae* type b, hepatitis A, hepatitis B, human papillomavirus, influenza, meningococcal infection, pertussis, pneumococcal infection, polio, rotavirus, tetanus and varicella. This combination of clinical trial and postmarketing data presents a dramatic picture, with almost double the total number of undesirable post-vaccination outcomes—**397 different types** of reactions reported pre- and post-licensure.

Although roughly 400 adverse events is a sobering number, again, it is probably an underestimate. This is because most clinical trials follow participants for an absurdly short period of time—three days⁵ here, seven days⁶ there—and do not capture problems that arise beyond that brief window, even though clinicians recognize⁷ (and the scientific literature confirms) that vaccine reactions are not always immediate or acute. Moreover, even for those few days of monitoring, the inserts are often short on details, citing only a smattering of adverse events collected from a predetermined list of “solicited” reactions and only sometimes accepting “unsolicited” feedback. In addition, the fact that vaccine clinical trials typically compare vaccine against vaccine rather than vaccine against inert placebo makes it easy to divert attention from specific adverse reactions by simply citing “similar rates” of adverse reactions in both groups.

... and that vaccines can cause the very illnesses—or adverse consequences of those illnesses—that they are supposed to prevent.

Clinical trial themes

The April discussion of postmarketing adverse events⁸ noted several themes, including the facts

that *all* vaccines are capable of producing adverse reactions (though Gardasil and Gardasil 9⁹ are macabre standouts) and that vaccines can cause the very illnesses—or adverse consequences of those illnesses—that they are supposed to prevent. The clinical trial data reinforce these points and also highlight some new themes:

- ▶ **The adverse reactions reported following clinical trials do not necessarily match up to the adverse reactions reported post-licensure.** This is particularly the case for vaccine-associated deaths; whereas the April postmarketing-only list included just two categories of death associated with six vaccines, the addition of clinical trial data brings the total up to 40 types of death associated with 13 vaccines.
- ▶ **Sizeable proportions of participants in vaccine clinical trials experience unpleasant reactions, including fever, chills, pain, nausea, diarrhea, vomiting, headache, rash, loss of appetite and irritability.** For example, in clinical trials for the five-pronged Pentacel¹⁰ vaccine (diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b and polio)—given as a four-dose series beginning at six weeks of age—almost half of the young children (48%) experienced injection-site “tenderness” after the first dose (defined as “whimpering” or crying when the arm or leg was touched or moved); about the same percentage (46%) experienced “lethargy,” 59% cried “inconsolably” and 77% were “fussy” or “irritable.” In adolescents, the Adacel¹¹ vaccine given as a booster for tetanus-diphtheria-acellular pertussis (Tdap) produced injection-site pain in almost eight in ten teens (78%), and one in five (20%) study participants experienced pain rated as “moderate to severe.” More than two-fifths (44%) suffered from headaches.
- ▶ **Clinical trials also document more serious reactions with the potential to cause longer-term problems.** Adverse reactions of particular concern—especially in the young—include asthma, seizures, heart problems, sleep problems and joint and muscle pain. Nine vaccines list anorexia as a clinical trial reaction. Surprisingly, while numerous package inserts mention serious and potentially lifelong conditions like transverse myelitis¹² (11 vaccines) and Guillain-Barré syndrome¹³ (20 vaccines) in their postmarketing section, only a few list them as a clinical trial outcome despite hundreds of published studies pointing to post-vaccination onset.

▶ **Intentional and unintentional injuries are more prominent in the clinical trial data than in the postmarketing reports, particularly in association with Gardasil and certain meningococcal vaccines (abbreviated as MenACWY).** These events include alcohol intoxication and drug overdose; suicidal thoughts or attempts; head and limb injuries; and falls resulting in injuries. Noting that syncope (fainting) is a common post-vaccination reaction in adolescents and young adults, the CDC states, “In 2005, the Vaccine Adverse Event Reporting System (VAERS) began detecting a trend of increasing syncope reports that coincided with the licensure of 3 vaccines for adolescents:¹⁴ human papillomavirus (HPV), MenACWY, and Tdap. Of particular concern among adolescents has been the risk for serious secondary injuries, including skull fracture and cerebral hemorrhage.” (One of the robustly healthy volunteers in the current clinical trials for the Moderna Covid-19 vaccine¹⁵ illustrated this very point, narrowly escaping injury when his girlfriend caught him in the midst of a fainting episode.)

▶ **Illustrating how vaccines can cause what they are supposed to prevent, the clinical trials for the ProQuad measles-mumps-rubella-varicella vaccine—intended to prevent infections associated with rashes—highlighted an astounding array of rashes.** The ProQuad¹⁶ insert lists seven different types of rash-related adverse reactions: “rash,” “injection-site rash,” “measles-like rash,” “rubella-like rash,” “varicella-like rash,” “vesicular rash” and “viral exanthema” (an eruptive rash associated with viral infections). Across both the clinical trial and postmarketing data, ProQuad injection also appears to precede numerous infections, including “atypical measles” and measles, varicella (chickenpox), bronchitis, cellulitis and other skin infections, herpes simplex (cold sores), herpes zoster (shingles), influenza or “influenza-like illness,” meningitis, pneumonia, respiratory tract infections, sinusitis, sore throats and other viral infections.

Researchers interested in solutions rather than convenient coronavirus cover stories would do well to review the information contained in vaccine package inserts.

Mysteries explained?

One of the autoimmune conditions encountered during the clinical trials for meningococcal and rotavirus vaccines (and also reported post-licensure) is a condition called Kawasaki disease¹⁷ (KD). Diagnosed solely on the basis of symptoms (high fever plus symptoms such as rash, redness and lymph node swelling), KD came out of nowhere in the 1960s and 1970s when childhood vaccine programs were starting to gear up. The published literature confirms Bexero meningococcal B¹⁸ and rotavirus¹⁹ vaccination as likely triggers for KD and, in addition, points to numerous other vaccines as possible culprits, including those for hepatitis A,²⁰ hepatitis B,²¹ influenza,²² Pevnar-13²³ and multiple vaccines²⁴ administered in a single health care visit. Canadian researchers have identified KD as a “condition of interest”²⁵ for pediatric vaccine safety surveillance.

Ordinarily fairly obscure, KD made headlines this year when researchers started speculating that it might be one of the apparently myriad faces of SARS-CoV-2. In the UK—the first country in the world to start administering (in 2015) three doses of Bexero to infants—researchers were also the first to suggest²⁶ that KD might be Covid-19-related. This week, a different group of researchers raised the same question about another low-profile autoimmune condition, myasthenia gravis,²⁷ asking whether it, too, could be connected to SARS-CoV-2. Researchers interested in solutions rather than convenient coronavirus cover stories would do well to review the information contained in vaccine package inserts. This information clearly points the way to a different set of questions and answers, pertaining not only to autoimmunity but also to the many other health problems besieging American children.

Table 1. Vaccine package inserts reviewed

TYPE OF VACCINE	BRAND NAME	MANUFACTURER
Vaccines containing diphtheria, tetanus and pertussis components	Adacel (Tdap) ²⁸ Boostrix (Tdap) ²⁹ Daptacel (DTaP) ³⁰ Diphtheria and Tetanus Toxoids Adsorbed (DT) ³¹ Infanrix (DTaP) ³² Kinrix (DTaP-IPV) ³³ Pediatrix (DTaP-HepB-IPV) ³⁴ Pentacel (DTaP-IPV/Hib) ³⁵ Quadracel (DTaP-IPV) ³⁶ Tdvax (Td) ³⁷ Tenivac (Td) ³⁸	Sanofi Pasteur GlaxoSmithKline (GSK) Sanofi Sanofi GSK GSK GSK Sanofi Sanofi MassBiologics Sanofi
Haemophilus influenzae type b (Hib)	ActHIB ³⁹ Hiberix ⁴⁰ PedvaxHIB ⁴¹	Sanofi GSK Merck
Hepatitis A and/or B	Engerix-B (HepB) ⁴² Havrix (HepA) ⁴³ Recombivax HB (HepB) ⁴⁴ Twinrix (HepA/HepB) ⁴⁵ Vaqta (HepA) ⁴⁶	GSK GSK Merck GSK Merck
Human papillomavirus (HPV)	Gardasil ⁴⁷ Gardasil 9 ⁴⁸	Merck Merck
Influenza	Afluria Quadrivalent ⁴⁹ Fluarix ⁵⁰ Flublok Quadrivalent (age 18 and older) ⁵¹ Flucelvax Flulaval Quadrivalent ⁵² FluMist ⁵³ Fluzone Quadrivalent ⁵⁴	Seqirus GSK Protein Sciences Corporation Seqirus GSK AstraZeneca Sanofi
Meningococcal A, C, W and/or Y	Menactra ⁵⁵ Menomune ⁵⁶ Menveo ⁵⁷	Sanofi Sanofi GSK
Meningococcal B	Bexero ⁵⁸ Trumenba ⁵⁹	GSK Pfizer
Measles-mumps-rubella (MMR) and MMR+varicella (MMRV)	MMR-II ⁶⁰ Proquad ⁶¹	Merck Merck
Pneumococcal	Prevnar-13 ⁶² Pneumovax-23 ⁶³	Pfizer Merck
Inactivated polio (IPV)	IPOL ⁶⁴	Sanofi
Rotavirus vaccines	Rotarix ⁶⁵ RotaTeq ⁶⁶	GSK Merck
Varicella	Varivax ⁶⁷	Merck

Table 2. Clinical trial and post-marketing adverse events reported in vaccine package inserts, by body system

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
Allergic (6)	Allergic reactions/hypersensitivity	Varivax	ActHIB, Adacel, Afluria, Bexero, Boostrix, Daptacel, Engerix-B, Fluarix, Flublok, FluMist, Fluzone, Gardasil/Gardasil 9, Hiberix, Infanrix, IPOL, Kinrix, Menveo, Pediarix, Pentacel, Quadracel, Recombivax, Tenivac, Trumenba, Twinrix
	Allergy to vaccine	Gardasil/Gardasil 9	
	Anaphylaxis and anaphylactoid reactions, including shock	Bexero, Fluarix, MMR-II	ActHIB, Adacel, Afluria, Bexero, Boostrix, Daptacel, Engerix-B, Fluarix, Flublok, Flucelvax, Flulaval, FluMist, Fluzone, Gardasil/Gardasil 9, Havrix, Hiberix, Infanrix, IPOL, Kinrix, Menactra, Menveo, MMR-II, Pediarix, Pentacel, Pneumovax-23, Prevnar-13, ProQuad, Quadracel, Recombivax, RotaTaq, Tenivac, Trumenba, Twinrix, Varivax
	Angioedema, angioneurotic edema	Menveo, MMR-II, Recombivax	ActHIB, Adacel, Boostrix, Daptacel, Engerix-B, Fluarix, Flucelvax, Flulaval, FluMist, Fluzone, Havrix, Hiberix, Infanrix, Kinrix, Menactra, Menomune, MMR-II, Pediarix, PedvaxHIB, Pneumovax-23, Prevnar-13, ProQuad, RotaTaq, Tenivac, Twinrix, Varivax
	Serum sickness		Afluria, Engerix-B, Fluarix, Havrix, Pneumovax-23, Recombivax, Twinrix
	Urticaria [hives]	Engerix-B, Havrix, MMR-II, PedVaxHIB, Prevnar-13, Recombivax, Twinrix, Vaqta, Varivax	ActHIB, Adacel, Afluria, Boostrix, DT, Engerix-B, Fluarix, Flucelvax, Flulaval, FluMist, Fluzone, Gardasil/Gardasil 9, Hiberix, Infanrix, IPOL, Kinrix, Menactra, MMR-II, Pediarix, Pentacel, Pneumovax-23, Prevnar-13, Quadracel, Recombivax, RotaTaq, Tenivac, Twinrix
Autoimmune (15)	Autoimmune diseases		Gardasil/Gardasil 9
	Autoimmune thyroiditis	Gardasil/Gardasil 9	
	Celiac disease	Gardasil/Gardasil 9	
	Cutaneous lupus erythematosus	Gardasil/Gardasil 9	
	Diabetes mellitus (insulin-dependent)	Boostrix, Gardasil/Gardasil 9, Pediarix, Pneumovax-23	MMR-II
	Graves'/Basedow's disease	Gardasil/Gardasil 9	

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Guillain-Barré syndrome (GBS)	IPOL, MMR-II, PedVaxHIB	Adacel, Afluria, Engerix-B, Fluarix, Flulaval, FluMist, Fluzone, Gardasil/Gardasil 9, Havrix, Menactra, Menomune, MMR-II, PedvaxHIB, Pneumovax-23, ProQuad, Recombivax, Tenivac, Vaqta, Varivax
	Kawasaki disease	Menveo, Rotarix, RotaTaq	Rotarix, RotaTaq
	Lupus-like syndrome		Recombivax
	Multiple sclerosis (or exacerbation)	Gardasil/Gardasil 9	Engerix-B, Havrix, Recombivax, Twinrix
	Pancreatitis	MMR-II, Pneumovax-23	Gardasil/Gardasil 9, MMR-II
	Rheumatoid arthritis/ juvenile rheumatoid arthritis	Gardasil/Gardasil 9	
	Scleroderma	Gardasil/Gardasil 9	
	Systemic lupus erythematosus	Gardasil/Gardasil 9	Recombivax
	Thrombocytopenia/ idiopathic thrombocytopenic purpura (ITP) [<i>low platelets</i>]	Daptacel, Gardasil/Gardasil 9, MMR-II, PedVaxHIB	Afluria, Engerix-B, Fluzone, Gardasil/Gardasil 9, Havrix, Infanrix, Kinrix, MMR-II, Pneumovax-23, ProQuad, Recombivax, Rotarix, Twinrix, Vaqta, Varivax
Blood/lymphatic system (11)	Anemia (aplastic or hemolytic)		Gardasil/Gardasil 9, Pneumovax-23, ProQuad, Varivax
	Epistaxis [<i>nosebleed</i>]		FluMist, ProQuad
	Extravasation [<i>blood vessel leakage</i>]		ProQuad
	Hematochezia [<i>bloody stools</i>]	RotaTaq	ProQuad, Rotarix, RotaTaq
	Hemorrhage	Gardasil/Gardasil 9	
	Increased erythrocyte sedimentation rate		Recombivax
	Leukocytosis [<i>increased white blood cells</i>]	MMR-II	MMR-II, Pneumovax-23
	Lymphadenitis/swollen lymph nodes	Adacel	Boostrix, Pneumovax-23, ProQuad
	Lymphadenopathy, including regional	Engerix-B, Havrix, MMR-II, Recombivax, Varivax	Boostrix, Daptacel, DT, Fluarix, Flulaval, Fluzone, Gardasil/Gardasil 9, Infanrix, IPOL, Kinrix, Menactra, Menveo, MMR-II, PedvaxHIB, Pneumovax-23, Prevnar-13, ProQuad, Tenivac
	Neutropenia, chronic	Pediarix	
	Thrombocytopenia/ idiopathic thrombocytopenic purpura (ITP) [<i>low platelets</i>]*	Daptacel, Gardasil/Gardasil 9, MMR-II, PedVaxHIB	Afluria, Engerix-B, Fluzone, Gardasil/Gardasil 9, Havrix, Infanrix, Kinrix, MMR-II, Pneumovax-23, ProQuad, Recombivax, Rotarix, Twinrix, Vaqta, Varivax

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
Cardiac (10)	Angina pectoris	Pneumovax-23, Tenivac	
	Cyanosis* [<i>bluish, low oxygen</i>]		Daptacel, Hiberix, Infanrix, Pediarix, Pentacel, Prevnar-13, Quadracel
	Heart failure	Pneumovax-23	
	Hypotension	Engerix-B, Recombivax	Adacel, Menactra
	Myocardial infarction	Pneumovax-23	
	Myocarditis [<i>heart muscle inflammation</i>]	Gardasil/Gardasil 9	Adacel, Boostrix
	Palpitations		Engerix-B, Twinrix
	Pericarditis [<i>pericardial inflammation</i>]		FluMist
	Pleuropericarditis	Flublok (> age 50)	
	Tachycardia [<i>abnormally high heart rate</i>]		Engerix-B, Fluarix, Recombivax, Twinrix
Congenital (1)	Congenital anomaly		Havrix
Death, by cause (40)	Unspecified	Flublok, IPOL, Prevnar-13, Tenivac	Gardasil/Gardasil 9
	Acute lymphocytic leukemia	Gardasil/Gardasil 9	
	Acute renal failure	Gardasil/Gardasil 9	
	Arrhythmia	Gardasil/Gardasil 9	
	Asphyxia	Pentacel	
	Aspiration	Daptacel	
	Autoimmune disease	Gardasil/Gardasil 9	
	Breast cancer	Gardasil/Gardasil 9	
	Cardiopulmonary arrest	Tenivac	
	Cardiovascular	Prevnar-13, Pneumovax-23	
	Cerebral hemorrhage	Gardasil/Gardasil 9	
	Cerebrovascular accident	Gardasil/Gardasil 9	
	Congenital immunodeficiency and sepsis	Pediarix	
	Convulsive disorder	Pediarix	
	Drug overdose	Gardasil/Gardasil 9	
	Fetal		MMR-II
	Gunshot wound	Gardasil/Gardasil 9	
	Head trauma	Pentacel	
	Homicide	Gardasil/Gardasil 9	
	Hyperthyroidism	Gardasil/Gardasil 9	
Hypovolemic septic shock	Gardasil/Gardasil 9		

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Infectious disease	Gardasil/Gardasil 9	
	Intussusception	RotaTeq	Rotarix, RotaTeq
	Motor vehicle accident	Gardasil/Gardasil 9	
	Myocardial infarction	Tenivac	
	Nasopharyngeal cancer	Gardasil/Gardasil 9	
	Neoplasm	Gardasil/Gardasil 9, Prevnar-13	
	Neuroblastoma	Pediarix, Pentacel	
	Pancreatic cancer	Gardasil/Gardasil 9	
	Peritonitis	Prevnar-13	
	Pneumonia	Rotarix	
	Pulmonary embolism	Gardasil/Gardasil 9	
	Pulmonary infection	Prevnar-13	
	Pulmonary tuberculosis	Gardasil/Gardasil 9	
	Sepsis, septic shock	Gardasil/Gardasil 9, Menveo, Prevnar-13	
	Stomach adenocarcinoma	Gardasil/Gardasil 9	
	Sudden infant death syndrome (SIDS)	Menveo, Pediarix, Pentacel, Prevnar-13, RotaTeq	Infanrix
	Suicide	Gardasil/Gardasil 9	
	Traumatic brain injury/cardiac arrest	Gardasil/Gardasil 9	
	Unexplained sudden death	Gardasil/Gardasil 9	
Ear/labyrinth (8)	Earache	Recombivax	
	Ear pain		Engerix-B, Infanrix, Menveo, ProQuad, Twinrix
	Hearing impaired		Menveo
	Nerve deafness	MMR-II	MMR-II, ProQuad
	Otitis media/ear infection	Afluria, Fluarix, PedVaxHIB, RotaTeq, Vaqta, Varivax	MMR-II
	Tinnitus		Engerix-B, Recombivax, Twinrix
	Vertigo	Havrix, Recombivax, Twinrix	Engerix-B, Fluarix, Menveo
	Vestibular/balance disorder		Menveo
Endocrine (6)	Cushing's syndrome	Menveo	
	Goiter	Gardasil/Gardasil 9	
	Hyperthyroidism	Gardasil/Gardasil 9	
	Hypothyroidism	Gardasil/Gardasil 9	
	Thyroiditis	Gardasil/Gardasil 9	
	Toxic nodular goiter	Gardasil/Gardasil 9	

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
Eye (17)	Conjunctivitis	Vaqta	
	Eye complaints	Varivax	
	Eye irritation/itching	Vaqta	
	Eye pain		Fluarix, Flulaval
	Eye redness		Fluarix
	Eye swelling		Bexero, Fluarix
	Eyelid ptosis [drooping]		Menveo
	Eyelid swelling		Fluarix, ProQuad
	Keratitis [corneal inflammation]		Engerix-B
	Ocular hyperemia [eye inflammation]		Fluzone
	Ocular palsies [nerve damage]	MMR-II	MMR-II, ProQuad
	Optic neuritis/neuropathy, papillitis [optic nerve inflammation]	Gardasil/Gardasil 9, MMR-II	Engerix-B, Fluzone, MMR-II, ProQuad, Recombivax, Twinrix
	Photophobia [light intolerance]	Havrix	Flulaval
	Retinitis, necrotizing [inflammation]	MMR-II	MMR-II, ProQuad, Varivax
	Retrobulbar neuritis [nerve damage]		MMR-II, ProQuad
	Uveitis [eye inflammation]	Gardasil/Gardasil 9	Recombivax
Visual disturbances		Engerix-B, Recombivax, Twinrix	
Gastrointestinal (21)	Abdominal pain, discomfort	Boostrix, Engerix-B, Fluarix, Flulaval, FluMist, Gardasil/Gardasil 9, Havrix, Menomune, Recombivax, Twinrix, Vaqta, Varivax	Fluarix, ProQuad
	Candidiasis		ProQuad
	Colonic polyp	Tenivac	
	Constipation	Engerix-B, Infanrix, Vaqta, Varivax	Recombivax
	Crohn's disease	Gardasil/Gardasil 9	
	Diarrhea	Adacel, Afluria, Boostrix, Engerix-B, Fluarix, Flulaval, Gardasil/Gardasil 9, Havrix, Hiberix, Menactra, Menomune, Menveo, MMR-II, PedVaxHIB, Prevna-13, ProQuad, Recombivax, Rotarix, RotaTeq, Trumenba, Twinrix, Vaqta, Varivax	Daptacel, FluMist, Menomune, MMR-II, Pediarix, Pentacel

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Dysgeusia [<i>altered sense of taste</i>]	Havrix	
	Dyspepsia [<i>indigestion</i>]	Pneumovax-23, Recombivax	Engerix-B, Twinrix
	Dysphagia [<i>swallowing difficulties</i>]		Flulaval
	Gastroenteritis	Flulaval, Gardasil/Gardasil 9, Kinrix, Menveo, Pediarix, Pentacel, Prevnar-13, Rotarix, RotaTeq, Vaqta	Rotarix, RotaTeq
	Gastrointestinal infection	FluMist	
	Inflammatory bowel disease	Gardasil/Gardasil 9	
	Inguinal hernia	Menactra	
	Intussusception, including recurrent	Rotarix, RotaTeq	Rotarix, RotaTeq
	Mouth ulcers		ProQuad
	Nausea	Adacel, Afluria, Bexero, Boostrix, Engerix-B, Fluarix, Flublok, Flulaval, Gardasil/Gardasil 9, Havrix, Menveo, MMR-II, Recombivax, Twinrix, Vaqta, Varivax	Daptacel, DT, Fluarix, FluMist, Gardasil/Gardasil 9, Menomune, MMR-II, Pneumovax-23, Tdva
	Swelling of mouth, throat or tongue		Fluarix
	Teething	Afluria, Vaqta, Varivax	
	Ulcerative colitis	Gardasil/Gardasil 9, Pneumovax-23	
	Vitello-intestinal duct remnant	Menveo	
	Vomiting	ActHIB, Adacel, Afluria, Boostrix, Daptacel, Engerix-B, Fluarix, Flulaval, Fluzone, Gardasil/Gardasil 9, Havrix, Hiberix, IPOL, Menactra, Menomune, Menveo, MMR-II, PedVaxHIB, Prevnar-13, ProQuad, Recombivax, Rotarix, RotaTeq, Trumenba, Twinrix, Vaqta, Varivax	Flulaval, FluMist, Fluzone, Gardasil/Gardasil 9, Menomune, MMR-II, Pediarix, Pentacel, Pneumovax-23, Tenivac
General and injection site (35)	Abnormal gait		Flulaval
	Apathy		ProQuad

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Asthenia [<i>fatigue, weakness</i>]	Hiberix, Pneumovax-23, Vaqta	Fluarix, Flulaval, Fluzone, Gardasil/Gardasil 9, Infanrix, Menomune, Pediarix, Tenivac
	Body aches	Adacel, Recombivax	Fluarix
	Chest pain	Pneumovax-23, Tenivac	Fluarix, Flulaval, Fluzone
	Chills/shivering	Adacel, Afluria, Engerix-B, Fluarix, Flublok, Flucelvax, Flulaval, FluMist, Menactra, , Menveo, Prevnar-13, Recombivax, Trumenba, Vaqta, Varivax	Fluarix, Gardasil/Gardasil 9, Havrix, Menomune, Twinrix
	Decreased limb mobility		Pneumovax-23
	Dehydration	Kinrix, Menveo, Pentacel, Rotarix, Vaqta	
	Drowsiness/sleepiness	ActHIB, Daptacel, Fluarix, Flulaval, Fluzone, Havrix, Hiberix, Infanrix, IPOL, Kinrix, Menactra, Menomune, Menveo, Pediarix, PedvaxHIB	
	Ecchymosis [<i>bruising</i>]	Engerix-B, Fluarix, Flucelvax, Pneumovax-23, ProQuad, Recombivax, Twinrix, Vaqta	Engerix-B, Recombivax, Twinrix
	Edema	Vaqta	Adacel
	Fatigue	Afluria, Bexero, Boostrix, Engerix-B, Fluarix, Flublok, Flucelvax, Flulaval, Havrix, Menactra, Menomune, Menveo, MMR-II, Prevnar-13, Recombivax, Trumenba, Twinrix, Varivax	Gardasil/Gardasil 9, Menomune, Menveo
	Feeling hot		Fluarix
	Fever/pyrexia	ActHIB, Adacel, Afluria, Bexero, Boostrix, Daptacel, DT, Engerix-B, Fluarix, Flublok, Flucelvax, Flulaval, FluMist, Fluzone, Gardasil/Gardasil 9, Havrix, Hiberix, Infanrix, IPOL, Kinrix, Menactra, Menomune, Menveo, MMR-II, Pediarix, PedVaxHIB, Pentacel, Prevnar-13, ProQuad, Quadracel, Recombivax, Rotarix, RotaTeq, Tenivac, Trumenba, Twinrix, Vaqta, Varivax	Menomune, Menveo, MMR-II, Pneumovax-23, Tdvax
	Hematoma	Gardasil/Gardasil 9, Havrix, Varivax	

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Hypertremia [<i>excess sodium</i>]	Kinrix	
	Increased arm circumference	Adacel, Boostrix, Daptacel, Infanrix, Kinrix, Pentacel, Quadracel	
	Increased thigh circumference	Infanrix	
	Injected limb—extensive swelling	Boostrix, Daptacel, Infanrix, Quadracel	ActHIB, Bexero, Hiberix, Menactra, Menveo
	Injection-site abscess		Adacel, Daptacel, Fluarix, Flulaval, PedvaxHIB, Pentacel, Quadracel
	Injection-site bruising	Afluria, Gardasil/Gardasil 9, ProQuad, Vaqta	Adacel, Flulaval
	Injection-site cellulitis		Afluria, Daptacel, Fluarix, Flulaval, Menveo, Pediarix, Quadracel, Tenivac
	Injection-site pain and other reactions (induration, warmth)	ActHIB, Adacel, Afluria, Bexero, Boostrix, Daptacel, DT, Engerix-B, Fluarix, Flublok, Flucelvax, Flulaval, Fluzone, Gardasil/Gardasil 9, Havrix, Hiberix, Infanrix, IPOL, Kinrix, Menactra, Menomune, Menveo, Pediarix, PedvaxHIB, Pentacel, Pneumovax-23, Prevnar-13, ProQuad, Quadracel, Recombivax, Tenivac, Trumenba, Twinrix, Vaqta, Varivax	Adacel, Afluria, Bexero, Boostrix, Daptacel, DT, Engerix-B, Fluarix, Flucelvax, Flulaval, Havrix, Hiberix, Infanrix, IPOL, Kinrix, Menactra, Menomune, Menveo, MMR-II, Pediarix, Pentacel, Pneumovax-23, Prevnar-13, ProQuad, Quadracel, Tdvax, Tenivac, Twinrix
	Injection-site rash	ProQuad, Vaqta, Varivax	Daptacel, Flulaval, IPOL, Prevnar-13
	Interference with normal activity of arm	Daptacel, DT, Prevnar-13	
	Itching	Afluria, Varivax	
	Lightheadedness	Recombivax	
	Listlessness		Quadracel
	Malaise	Adacel, Afluria, Engerix-B, Fluarix, Flucelvax, Fluzone, Gardasil/Gardasil 9, Havrix, Menactra, Menomune, Menveo, MMR-II, Quadracel, Recombivax, Tenivac, Varivax	Gardasil/Gardasil 9, Menomune, Menveo, MMR-II, Pneumovax-23, Tdvax, Twinrix
	Medical attention sought	Pediarix	
	Pain in extremity	Fluarix	
	Peripheral edema		ActHIB, MMR-II, Pneumovax-23, ProQuad, Tdvax, Tenivac, Varivax
	Severe pain	Bexero	

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Swelling	Afluria, Adacel, Boostrix, Daptacel, DT, Engerix-B, Fluarix, Flublok, Flucelvax, Fluzone, Infanrix, IPOL, Kinrix, Menactra, Menomune, Pediarix, PedVaxHIB, Pentacel, Pneumovax-23, Prevnar-13, ProQuad, Quadracel, Recombivax, Tenivac, Trumenba, Twinrix, Vaqta, Varivax	Menveo, MMR-II, ProQuad
	Tiredness	Adacel, FluMist, IPOL	
Hepatobiliary/liver (3)	Elevation of liver enzymes		Recombivax
	Hepatitis	Menveo	Havrix, Twinrix
	Jaundice		Havrix, Twinrix
Infections and infestations (51)	Appendicitis	Gardasil/Gardasil 9, Menveo	
	Atypical measles	MMR-II	MMR-II, ProQuad
	Bronchiolitis	Daptacel, Pediarix, Pentacel, Prevnar-13, RotaTeq	
	Bronchitis	Flulaval	Infanrix, ProQuad
	Cellulitis	Daptacel, Infanrix, Tenivac, Vaqta	Daptacel, Gardasil/Gardasil 9, Infanrix, Pneumovax-23, ProQuad, Tdvax, Varivax
	Cellulitis-like reaction	Afluria	
	Chlamydia	Gardasil/Gardasil 9	
	Cholecystitis	Tenivac	
	Croup	Afluria, Fluzone, Vaqta	
	Early-onset Hib disease	PedVaxHIB	PedvaxHIB
	Glomerulonephritis	Gardasil/Gardasil 9	
	Herpes simplex/cold sore	Varivax	ProQuad
	Herpes zoster [shingles]	ProQuad, Menactra	Engerix-B, ProQuad, Recombivax, Twinrix, Varivax
	Infection		ProQuad
	Influenza, influenza-like illness	Engerix-B, Fluarix, Gardasil/Gardasil 9, Recombivax, Twinrix	Afluria, Flulaval, Havrix, ProQuad
	Invasive Hib disease		Pentacel
	Laryngitis	Menveo	Flulaval
	Laryngotracheo-bronchitis	Vaqta	
	Localized infection	Tenivac	

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Measles		ProQuad
	Measles-like rash	MMR-II, ProQuad, Vaqta	MMR-II
	Meningitis (<i>aseptic, eosinophilic</i>)	Daptacel	Engerix-B, FluMist, MMR-II, Pentacel, ProQuad, Twinrix, Varivax
	Nasal congestion	Afluria, Fluarix, Gardasil/Gardasil 9, Vaqta	
	Pelvic inflammatory disease	Gardasil/Gardasil 9, Menveo	
	Pharyngitis/nasopharyngitis	Afluria, Bexero, Fluarix, Flulaval, Gardasil/Gardasil 9, Havrix, Pneumovax-23, ProQuad, Recombivax, RotaTeq, Vaqta	Fluarix, Varivax
	Pharyngitis streptococcal	Vaqta	
	Pharyngolaryngeal pain	Fluarix	
	Pneumonia, pneumonitis, lobar pneumonia, bilateral pneumonia	Daptacel, Gardasil/Gardasil 9, Hiberix, Menomune, Menveo, MMR-II, Pentacel, Prevnar-13, RotaTeq, Varivax	MMR-II, ProQuad, Varivax
	Pulmonary congestion		ProQuad
	Pulmonary embolism	Gardasil/Gardasil 9	Gardasil/Gardasil 9
	Nephritis/pyelonephritis [<i>kidney infection</i>]	Gardasil/Gardasil 9	
	Pertussis	Daptacel	
	Respiratory congestion	Fluarix, Vaqta	
	Respiratory tract infection (upper or lower)	Afluria, Engerix-B, Fluarix, Flulaval, FluMist, Gardasil/Gardasil 9, Havrix, PedVaxHIB, Pneumovax-23, ProQuad, Recombivax, Twinrix, Vaqta, Varivax	Infanrix, Pediarix, ProQuad
	Rhinitis	Fluarix, Flucelvax, MMR-II, Recombivax, Vaqta	Fluarix, Flulaval, Havrix, MMR-II, Pentacel, ProQuad
	Roseola	Vaqta	
	Rubella-like rash	ProQuad, Vaqta	
	Secondary bacterial infection (skin, tissue)		Varivax
	Sepsis	Daptacel, Pediarix	
	Sinusitis	FluMist	ProQuad
	Skin infection		ProQuad
	Sore throat	FluMist, MMR-II	MMR-II, ProQuad

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Sneezing	FluMist	
	Staph infection	Menveo	
	Tonsillitis		Fluarix
	Tracheitis	PedVaxHIB	
	Transmission of vaccine virus strains		RotaTeq
	Varicella	Flulaval, Menveo	
	Varicella (vaccine strain)		ProQuad, Varivax
	Varicella-like rash	ProQuad, Vaqta, Varivax	ProQuad
	Viral infection	ProQuad, Vaqta	Pentacel
Injury (intentional and unintentional) (10)	Accidental drug ingestion	Hiberix	
	Alcohol intoxication	Pneumovax-23	
	Fall	Menactra	Menveo
	Falling with injury		Gardasil/Gardasil 9
	Head injury		Menveo
	Intentional multiple-drug overdose	Menveo	
	Limb injury	Menveo	
	Road accident	Menveo	
	Suicidal depression	Menveo	
Suicide attempt	Menveo		
Investigations (6)	Abnormal liver function tests		Engerix-B, Twinrix
	Alanine aminotransferase increased		Menveo
	Body temperature increased		Menveo
	Creatine phosphokinase increased	Havrix	
	Diagnostic studies	Pediarix	
	Increased serum C-reactive protein		Pneumovax-23
Metabolic (3)	Change in eating habits	Menveo	
	Loss of appetite, decreased appetite	Afluria, DT, Fluarix, Flulaval, FluMist, Fluzone, Havrix, Hiberix, Infanrix, Kinrix, Menactra, Pediarix, Prevnar-13, Recombivax, Rotarix, Varivax	Pentacel

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Mitochondrial encephalomyopathy, Leigh syndrome exacerbation [<i>neurometabolic</i>]		FluMist
Musculoskeletal and connective tissue (24)	Ankylosing spondylitis [<i>rare arthritis</i>]	Gardasil/Gardasil 9	
	Arm pain	Engerix-B, Vaqta	
	Arthralgia [<i>joint pain</i>]	Adacel, Bexero, Engerix-B, Fluarix, Flublok, Flucelvax, Flulaval, Gardasil/Gardasil 9, Havrix, MMR-II, Menactra, Menomune, Menveo, Prevnar-13, Recombivax, Tenivac, Trumenba, Twinrix, Varivax	Boostrix, Engerix-B, Gardasil/Gardasil 9, IPOL, Menomune, Menveo, MMR-II, Pneumovax-23, ProQuad, Recombivax, Tdvax, Twinrix
	Arthritis	Gardasil/Gardasil 9, MMR-II	Engerix-B, Flulaval, MMR-II, Pneumovax-23, ProQuad, Recombivax, Twinrix
	Arthropathy	Gardasil/Gardasil 9	
	Back pain	Engerix-B, Fluarix, Gardasil/Gardasil 9, Pneumovax-23, Recombivax, Twinrix, Vaqta	Boostrix
	Bone pain		Menveo
	Cramps	Engerix-B, Recombivax	
	Hip and wrist fracture	Tenivac	
	Hypotonia [<i>low muscle tone</i>]	Pentacel	Daptacel, Hiberix, Infanrix, Pediarix, Prevnar-13, Quadracel
	Invertebral disc protrusion	Menactra	
	Muscle spasm		Adacel
	Muscle weakness/weakness	Adacel, Engerix-B, Recombivax, Tenivac, Twinrix	Engerix-B, Flulaval, Recombivax, Twinrix
	Musculoskeletal pain	Fluarix	ProQuad
	Musculoskeletal stiffness		Havrix
	Myalgia [<i>muscle pain</i>]	Adacel, Afluria, Bexero, Daptacel, Engerix-B, Fluarix, Flublok, Flucelvax, Flulaval, FluMist, Fluzone, Gardasil/Gardasil 9, Havrix, Menactra, Menveo, MMR-II, Pneumovax-23, Quadracel, Recombivax, Trumenba, Twinrix, Vaqta, Varivax	Boostrix, Gardasil/Gardasil 9, IPOL, Menactra, Menomune, MMR-II, ProQuad, Tdvax, Tenivac

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Myositis [<i>muscle inflammation</i>]		Adacel
	Neck pain	Engerix-B, Fluarix, Pneumovax-23, Recombivax	
	Pain in extremities		Fluarix, Fluzone, Pediarix, Recombivax, Tdvax, Tenivac
	Psoriatic arthropathy	Gardasil/Gardasil 9	
	Reactive arthritis	Gardasil/Gardasil 9	
	Shoulder pain	Engerix-B, Recombivax	
	Stiff neck	Recombivax, Varivax	
	Stiffness	Pneumovax-23, Vaqta, Varivax	
Nervous system (45)	Acute disseminated encephalomyelitis (ADEM)	Menveo, MMR-II	Gardasil/Gardasil 9, Menactra, MMR-II, ProQuad
	Ataxia [<i>nervous system dysfunction</i>]	MMR-II	MMR-II, ProQuad, Varivax
	Bulging fontanelle		Pediarix
	Cerebellar ataxia		Vaqta
	Convulsions/seizures	ActHIB, Daptacel, Havrix, Hiberix, Infanrix, Menactra, Menomune, Menveo, Pediarix, PedVaxHIB, Pentacel, Prevnar-13, RotaTeq	ActHIB, Adacel, Afluria, Boostrix, Daptacel, DT, Fluarix, Flulaval, Fluzone, Gardasil/Gardasil 9, Havrix, Hiberix, IPOL, Kinrix, Menactra, MMR-II, Quadracel, Recombivax, Tdvax, Twinrix, Varivax
	Depressed level of consciousness		Boostrix, Pediarix, Pentacel
	Dizziness	Engerix-B, Gardasil/Gardasil 9, MMR-II, Recombivax, Twinrix	Fluarix, Flulaval, Fluzone, Gardasil/Gardasil 9, Havrix, Menactra, Menomune, Menveo, MMR-II, ProQuad, Tdvax, Tenivac, Varivax
	Encephalitis, vaccine-induced encephalitis [<i>brain inflammation</i>]	MMR-II	Boostrix, Engerix-B, FluMist, MMR-II, Pediarix, Recombivax, Twinrix, Vaqta, Varivax
	Encephalomyelitis [<i>brain and spinal cord</i>]		Afluria, Fluarix, Fluzone
	Encephalopathy [<i>brain disease</i>]	MMR-II, Pentacel	Afluria, Engerix-B, Flulaval, Havrix, Infanrix, MMR-II, ProQuad, Twinrix
	Facial palsy, Bell's palsy		Adacel, Boostrix, Engerix-B, Fluarix, FluMist, Fluzone, Menactra, Menveo, ProQuad, Recombivax, Twinrix, Varivax
	Facial (or cranial) nerve paralysis	Adacel	Flulaval

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Facial paresis <i>[impaired facial movement]</i>		Fluarix, Menveo
	Febrile convulsions/ seizures	Afluria, Daptacel, Fluzone, Infanrix, Hiberix, Menveo, MMR-II, Pediarix, Pentacel, Prevnar-13, ProQuad, RotaTeq, Vaqta, Varivax	Afluria, Daptacel, Fluzone, IPOL, MMR-II, PedvaxHIB, Pneumovax-23, ProQuad, Quadracel, Recombivax
	Headache	Adacel, Afluria, Bexero, Boostrix, Engerix-B, Fluarix, Flublok, Flucelvax, Flulaval, FluMist, Fluzone, Gardasil/Gardasil 9, Havrix, Menactra, Menomune, Menveo, Pneumovax-23, Prevnar-13, ProQuad, Quadracel, Recombivax, Tenivac, Trumenba, Twinrix, Vaqta, Varivax	DT, Gardasil/Gardasil 9, Infanrix, IPOL, Menomune, Menveo, MMR-II, ProQuad, Tdvax, Twinrix
	Hypoesthesia <i>[decreased tactile sensitivity]</i>		Adacel, Engerix-B, Fluarix, Flulaval, Havrix, Recombivax, Twinrix
	Hypokinesia <i>[loss of muscle movement]</i>		Flulaval
	Hypotonic-hyporesponsive episode (HHE)	Daptacel, Infanrix, Prevnar-13	Daptacel, Hiberix, Kinrix, Pediarix, Pentacel, Quadracel
	Hypertonia	Havrix	
	Infantile spasms	Daptacel, Pediarix	
	Lethargy	ActHIB, Daptacel, FluMist, Pentacel	Pediarix
	Limb paralysis		Flulaval
	Measles inclusion body encephalitis (MIBE)	MMR-II	MMR-II, ProQuad
	Migraine	Adacel, Fluarix, Twinrix	Engerix-B, Recombivax
	Motor neuron disease		Gardasil/Gardasil 9
	Myelitis <i>[spinal cord disease]</i>		Adacel, Fluarix, Fluzone, Havrix, Recombivax, Twinrix
	Nerve compression	Adacel	
	Neuralgia <i>[nerve pain]</i>		Afluria
	Neuritis (including brachial, polyneuritis)	MMR-II	Adacel, Afluria, Engerix-B, Fluarix, Fluzone, MMR-II, Twinrix

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Neuropathy, polyneuropathy	MMR-II	Afluria, Engerix-B, Fluarix, Havrix, MMR-II, ProQuad, Recombivax, Twinrix
	Numbness	Varivax	
	Paralysis		Engerix-B, Gardasil/Gardasil 9, Twinrix
	Paresis [<i>partial paralysis</i>]		Engerix-B, Twinrix
	Paresthesia [<i>abnormal skin sensations</i>]	MMR-II, Recombivax, Twinrix	Adacel, Afluria, Boostrix, Engerix-B, Fluarix, Flucelvax, Flulaval, Fluzone, Havrix, IPOL, Menactra, Menomune, MMR-II, Pneumovax-23, ProQuad, Tenivac, Varivax
	Partial seizures, seizures	Menveo	Daptacel, Engerix-B, ProQuad
	Presyncope [<i>feeling faint</i>]		Flucelvax
	Radiculopathy [<i>“pinched nerve” in spine</i>]	Pneumovax-23	Pneumovax-23, Recombivax
	Somnolence	Engerix-B, ProQuad, Twinrix	Daptacel, DT, Flulaval, Havrix, Hiberix, IPOL, Pediarix, Pentacel, Quadracel, Recombivax
	Subacute sclerosing panencephalitis (SSPE)	MMR-II	MMR-II, ProQuad
	Syncope, vasovagal syncope [<i>fainting</i>]	Flublok, MMR-II, Twinrix	Adacel, Bexero, Boostrix, Daptacel, DT, Engerix-B, Fluarix, Flucelvax, Flulaval, Fluzone, Gardasil/Gardasil 9, Havrix, Hiberix, Infanrix, Kinrix, Menactra, Menomune, Menveo, MMR-II, Pediarix, ProQuad, Recombivax, Tenivac, Trumenba
	Tingling	Engerix-B	
	Tonic convulsions	Menveo	Menveo
	Transverse myelitis	MMR-II	Afluria, Engerix-B, Fluzone, Gardasil/Gardasil 9, Menactra, MMR-II, ProQuad, Recombivax, Twinrix, Varivax
	Tremors	Pneumovax-23	Flulaval, ProQuad
	Unresponsiveness	Daptacel	
Psychiatric (15)	Agitation	Engerix-B, Twinrix	IPOL, ProQuad, Recombivax
	Anorexia	ActHIB, Daptacel, Havrix, Engerix-B, IPOL, Menactra, Menomune, Twinrix, Vaqta	

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Crying (abnormal, unusual, persistent or inconsolable)	ActHIB, Daptacel, DT, Flulaval, Fluzone, Hiberix, Infanrix, IPOL, Menactra, Menveo, PedVaxHIB, Pentacel, Prevnar-13, Vaqta	Pediarix
	Decreased sleep	Prevnar-13	
	Depression	Pneumovax-23	
	Disturbed sleep	Recombivax, Varivax	
	Fretfulness	Daptacel	
	Fussiness	ActHIB, Daptacel, Hiberix, Infanrix, IPOL, Pediarix, Pentacel	
	Hypersomnia		ProQuad
	Increased sleep	Prevnar-13	
	Insomnia	Engerix-B, Gardasil/Gardasil 9, Havrix, Recombivax, Twinrix, Vaqta	Flulaval, Pediarix
	Irritability	ActHIB, Afluria, Engerix-B, Fluarix, Flulaval, FluMist, Fluzone, Havrix, Hiberix, Infanrix, IPOL, Menactra, Menomune, Menveo, Pediarix, PedVaxHIB, Pentacel, Prevnar-13, ProQuad, Recombivax, Rotarix, RotaTeq, Twinrix, Vaqta, Varivax	MMR-II, Recombivax
	Nervousness	Varivax	Pediarix, ProQuad
	Restlessness	Hiberix	Pediarix
	Screaming		Daptacel, Pediarix, Pentacel, Quadracel
Reproductive (2)	Dysmenorrhea	Fluarix	
	Menstruation disorders	Vaqta	
Respiratory, thoracic and mediastinal (19)	Apnea	ActHIB, Daptacel	Engerix-B, Hiberix, Infanrix, Kinrix, Pediarix, Pentacel, Prevnar-13
	Asthma, asthma-like symptoms	Daptacel, FluMist, Gardasil/Gardasil 9, Pediarix, Pentacel, Tenivac, Vaqta	Engerix-B, Fluarix, Twinrix
	Asthmatic crisis	Gardasil/Gardasil 9	
	Bronchial constriction	Vaqta	
	Bronchial hyperreactivity	Havrix	
	Bronchospasm, bronchial spasm	Daptacel, Gardasil/Gardasil 9, MMR-II, Prevnar-13, RotaTeq	Engerix-B, Fluarix, Flulaval, Gardasil/Gardasil 9, MMR-II, ProQuad, Recombivax, Tenivac, Twinrix

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Cough	Afluria, Fluarix, Flucelvax, Flulaval, Fluzone, Gardasil/Gardasil 9, FluMist, MMR-II, ProQuad, Recombivax, Rotarix, Vaqta, Varivax	Fluarix, Fluzone, Infanrix, MMR-II, Pediarix, Pentacel
	Cyanosis* [<i>bluish discoloration, low oxygen</i>]		Daptacel, Hiberix, Infanrix, Pediarix, Pentacel, Prevnar-13, Quadracel
	Difficulty breathing		Menactra
	Dyspnea [<i>shortness of breath</i>]	Prevnar-13	Fluarix, Flulaval, Fluzone, Havrix, Menomune, Pediarix, Quadracel, Twinrix
	Dysphonia [<i>vocal abnormalities</i>]		Flulaval
	Hypoxia	Daptacel, FluMist	
	Oropharyngeal pain	Afluria, Flucelvax, Flulaval, Gardasil/Gardasil 9	Fluzone, Menveo
	Respiratory distress	Havrix	Fluarix
	Rhinorrhea [<i>runny nose</i>]	Afluria, Fluarix, Flulaval, FluMist, Fluzone, HepB, MMR-II, ProQuad, Rotarix, Vaqta, Varivax	Fluzone
	Stridor [<i>high-pitched wheezing</i>]		Fluarix
	Throat tightness		Flulaval, Fluzone
	Upper airway swelling		Menactra
	Wheezing	FluMist, Menveo, Vaqta	Fluzone, Menactra, ProQuad
Skin/ subcutaneous tissue (33)	Acute hemorrhagic edema of infancy	MMR-II	MMR-II, ProQuad
	Alopecia [<i>hair loss</i>]	Gardasil/Gardasil 9	Engerix-B, Recombivax, Twinrix
	Contact rash	Varivax	
	Dermatitis	Vaqta, Varivax	
	Diaper rash	Varivax	
	Dry skin	Varivax	
	Eczema	Varivax	Engerix-B, Recombivax, Twinrix
	Erythema [<i>skin redness</i>]	ActHIB, Adacel, Afluria, Bexero, Engerix-B, Flucelvax, Fluzone, IPOL, Menactra, Menveo, PedVaxHIB, Pneumovax-23, Prevnar-13, ProQuad, Quadracel, Recombivax, Twinrix, Vaqta, Varivax	Fluarix, Infanrix, Menactra, Menveo, MMR-II, Pediarix, Pentacel, Tdvax

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Erythema multiforme [<i>skin disorder</i>]	Flucelvax, MMR-II, Prevnar-13	Engerix-B, Fluarix, Havrix, MMR-II, Pneumovax-23, ProQuad, Prevnar-13, Recombivax, Twinrix, Varivax
	Erythema nodosum [<i>nodules or lumps</i>]	Gardasil/Gardasil 9	Engerix-B, Recombivax, Twinrix
	Exanthem/viral exanthema [<i>widespread rash</i>]	ProQuad, Vaqta	Boostrix
	Facial swelling/edema	Prevnar-13	Daptacel, Fluarix, MMR-II, ProQuad, Varivax
	Heat rash	Varivax	
	Hyperhidrosis [<i>abnormal sweating</i>]		Flulaval, Havrix, Twinrix
	Impetigo		ProQuad, Varivax
	Lichen planus [<i>inflammatory skin rash</i>]		Engerix-B, Twinrix
	Panniculitis [<i>disease of fatty layer of skin</i>]	MMR-II	MMR-II, ProQuad
	Parotitis [<i>salivary gland inflammation</i>]	MMR-II	MMR-II, ProQuad
	Pigmentation disorder	Gardasil/Gardasil 9	
	Pruritus [<i>itchy skin</i>]	Afluria, Engerix-B, Fluarix, Havrix, MMR-II, Pneumovax-23, ProQuad, Recombivax, Twinrix, Vaqta, Varivax	ActHIB, Adacel, Afluria, Boostrix, Daptacel, Fluarix, Flucelvax, Flulaval, Fluzone, Infanrix, Kinrix, Menactra, Menomune, Menveo, MMR-II, Prevnar-13, ProQuad, Tdvax, Tenivac
	Psoriasis	Gardasil/Gardasil 9	
	Purpura [<i>red/purple spots</i>]	MMR-II	Engerix-B, MMR-II, ProQuad
	Pustular psoriasis	Gardasil/Gardasil 9	
	Rash	Adacel, Afluria, Engerix-B, Flublok, Flulaval, Havrix, Menactra, Menomune, Menveo, MMR-II, PedVaxHIB, Prevnar-13, ProQuad, Recombivax, Twinrix, Vaqta, Varivax	ActHIB, Adacel, Afluria, Bexero, Boostrix, Daptacel, DT, Fluarix, Flucelvax, Flulaval, FluMist, Fluzone, Hiberix, Infanrix, IPOL, Menomune, MMR-II, Pediarix, Pentacel, Pneumovax-23, Prevnar-13, Quadracel, Tdvax, Tenivac
	Rash morbilliform	Vaqta	
	Rash vesicular	ProQuad, Vaqta	
	Skin discoloration		Pentacel
	Skin exfoliation		Menveo
	Skin induration		MMR-II, ProQuad

BODY SYSTEM	MEDICAL DISORDER	REPORTED IN CLINICAL TRIALS	REPORTED POST-MARKETING
	Stevens-Johnson syndrome [<i>severe skin reaction</i>]	Gardasil/Gardasil 9, MMR-II	Engerix-B, Fluarix, Fluzone, MMR-II, ProQuad, Recombivax, Varivax
	Sweating	Engerix-B, Fluarix, Flucelvax, Pneumovax-23, Recombivax, Twinrix	
	Vesiculation		MMR-II
	Vitiligo	Gardasil/Gardasil 9	
Vascular (10)	Cerebrovascular accident	Kinrix, Pneumovax-23, Tenivac	ProQuad, Varivax
	Deep venous thrombosis		Gardasil/Gardasil 9
	Flushing	Engerix-B, Recombivax, Twinrix	Flulaval, Fluzone
	Henoch-Schönlein purpura [<i>blood vessel inflammation</i>]	MMR-II	Boostrix, Fluarix, MMR-II, ProQuad, Varivax
	Pallor		DT, Flulaval, Hiberix, Pediarix, Pentacel, Prevnar-13, Quadracel
	Petechiae [<i>bleeding capillaries</i>]	Engerix-B, Twinrix	Pediarix, Recombivax
	Polyarteritis nodosa [<i>damaged arteries</i>]		Recombivax
	Raynaud's phenomenon	Gardasil/Gardasil 9	
	Renal vasculitis		Afluria
	Vasculitis	MMR-II	Afluria, Engerix-B, Fluarix, Fluzone, Havrix, MMR-II, Recombivax, Twinrix
Urogenital (6)	Dysuria [<i>difficult urination</i>]	Recombivax	
	Epididymitis [<i>testicular inflammation</i>]	MMR-II	MMR-II, ProQuad
	Orchitis [<i>inflammation of the testes</i>]	MMR-II	MMR-II, ProQuad
	Proteinuria	Gardasil/Gardasil 9	
	Urinary retention	Pneumovax-23	
	Urinary tract infection	Gardasil/Gardasil 9, RotaTeq	

Endnotes

- 1 <https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states>
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- 3 <https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>
- 4 <https://childrenshealthdefense.org/news/vaccine-injuries-ratio-one-for-every-39-vaccines-administered/>
- 5 <https://www.fda.gov/media/74385/download>
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- 8 <https://childrenshealthdefense.org/news/read-the-fine-print-vaccine-package-inserts-reveal-hundreds-of-medical-conditions-linked-to-vaccines/>
- 9 <https://childrenshealthdefense.org/news/25-reasons-to-avoid-the-gardasil-vaccine/>
- 10 <https://www.fda.gov/media/74385/download>
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- 13 <https://pubmed.ncbi.nlm.nih.gov/?term=guillain+barre+vaccine>
- 14 <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html>
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