Vaccine ingredients

FactSheet For Parents and Caregivers

Immunisation Advisory Centre
ĀRAINGA MATE
THE UNIVERSITY OF AUCKLAND

Vaccine manufacture and composition is complex and tightly regulated to maximise safety. The safety of the individual components, and of the vaccine itself, must be demonstrated before a vaccine can be licensed and used in New Zealand.

All vaccines contain an active component (the antigen) which generates the protective immune response. Vaccines may also contain additional components. A description of these, their function and safety is summarised in this fact sheet.

Types of vaccines and vaccine antigens

Vaccines can be broadly classified as live, inactivated, or subunit. Antigens are, depending on the type of vaccine, killed or weakened forms or fragments of the disease-causing organism. The body responds to the shapes of these antigens, which are very specific. Ingredients vary depending on both the manufacturing process and the nature of the antigen.

Live attenuated vaccines

The virus or bacteria is functional/alive, and can replicate in the body several times, but has been weakened so it cannot cause the disease, e.g., measles, mumps and rubella vaccine viruses.

Inactivated and dead vaccines

These are made from inactivated virus or killed bacteria, e.g., influenza vaccine.

Subunit vaccines

Fragments, such as proteins, toxoids or sugars (polysaccharides), derived from the disease-causing organism are used. Most vaccines on the current New Zealand National Immunisation Schedule are subunit.

Vaccine additives

If required, vaccines may contain the following:

Adjuvant

An adjuvant encourages a stronger immune response to the vaccine antigen.

Excipients

A substance other than the active ingredient included in the manufacturing process or contained in a finished pharmaceutical product. They include:

- Preservatives
- Stabilisers
- Buffers
- Surfactants/emulsifiers
- Solvents
- Residuals
- Diluents

Adjuvants

Aluminium Salts

Aluminium salts have been used as adjuvants for over 70 years. Most commonly these are aluminium hydroxide, aluminium phosphate and potassium aluminium sulphate (alum). Aluminium adjuvants work by helping to retain the antigen at the injection site long enough for an immune response to be generated and by inducing immune system cells and a range of inflammatory factors to the local injection site to enhance the immune response. Most current inactivated and subunit vaccines use aluminium salts which have an impressive safety record. Additionally, the use of aluminium adjuvants in vaccines generally means that less antigen is required.

Some studies have found aluminium containing vaccines to be associated with local reactions and, less often, with the development of subcutaneous nodules at the injection site. This is particularly so if the injection is given too superficially. Other studies have reported fewer reactions with aluminium containing vaccines than those without, and in some cases, fewer vaccine doses were needed.

An individual's exposure to aluminium from vaccines is far less than that received from a normal diet and environmental exposure. Aluminium is the eighth most abundant element on earth and the most common metallic element. It is found in the blood of all animals, including humans, and we are constantly exposed to it. The average daily intake is 10-15mg. Average water has about 0.2mg of aluminium per litre, the hepatitis B vaccine has 0.25mg of aluminium. Aluminium in vaccines is absorbed into the blood and excreted via the kidneys in urine. A recent review of all the available studies of aluminium-containing diphtheria, tetanus and pertussis vaccines (either alone or in combination) did not find any evidence that aluminium salts in vaccines cause serious or long-term adverse events.[1]

MF59

MF59 is an oil-in-water emulsion. It is made using squalene (a hydrocarbon oil) which is common in foods as well as being produced in the body as precursor to cholesterol and steroid hormones. MF59 significantly enhances immune response to a variety of antigens. It is used in some influenza vaccines overseas.

A recent review of safety data from five trials using MF59 adjuvanted v.s. non-adjuvanted influenza vaccines in children and adolescents, aged from 6 months to 18 years, did not identify any safety issues. However, mild to moderate injection site and systemic vaccine reactions were more common after a vaccine containing MF59 vaccine than after a non-adjuvanted vaccine.[2]

AS03 & AS04

No vaccines currently used in New Zealand contain the AS03 and AS04 adjuvants. AS03 is made with squalene, similar to MF59. It has been used in a pandemic influenza vaccine in Europe. AS04 contains aluminum hydroxide and modified molecules from the *Salmonella minnesota* bacterium.

Theoretical concerns have been raised that these new adjuvants may cause overproduction of inflammatory factors leading to autoimmune disease. However, a large analysis of 68,000 people, some who had received AS04 adjuvanted vaccines and others who had not (controls), concluded that both vaccine recipients and controls had a low rate of autoimmune disorders.[3]

Excipients

Preservatives

Preservatives stop unwanted microbial contamination of vaccines. They have been used in vaccines for many years. Very few serious adverse events have been associated with the use of these preservatives.

2-phenoxyethanol

The most commonly used preservative in vaccines is 2-phenoxyethanol. It is also used in cosmetics, eye and ear drops and baby care products where it is absorbed through skin. 2-phenoxyethanol is excreted by being exhaled and, after being metabolised (broken down), and in urine and faeces. There is little toxicity in humans and some irritation with very high doses in animals.

Phenol

Phenol is an aromatic alcohol infrequently used as a preservative in vaccines.

Thiomersal

Thiomersal, also called thimerosal, is a mercury derived compound that has been used as a preservative in vaccines and other health care products internationally for many years. There are no thiomersal containing vaccines on the New Zealand Immunisation Schedule. There is no evidence that thiomersal causes any serious or long-term adverse events. Schedule vaccines in use are either single dose vaccine vials or alternative preservatives have been used. More information on thiomersal can be found on the Immunisation Advisory Centre website.

Stabilisers

Stabilisers inhibit chemical reactions and prevent components separating or sticking to the vial during transport and storage. Examples of stabilisers include sugars such as lactose and sucrose, amino acids such as glycine and monosodiumglutamate (salts of amino acids), proteins such as recombinant human albumin (Recombumin®) derived from baker's yeast or fetal bovine (cow) serum and gelatin, partially hydrolysed collagen usually of porcine (pig) but can be of bovine origin.

Buffers

Buffers serve to resist changes in pH, adjust tonicity and maintain osmolarity. The most commonly used buffer is sodium chloride (table salt).

Surfactants

Surfactants are a type of emulsifier. They assist particles remain suspended in liquid, preventing settling and clumping, by lowering the surface tension of the liquid. An example is polysorbate 80 (Tween 80®), made from sorbitol (sugar alcohol) and oleic acid (omega-9 fatty acid), which is also used in foods such as ice cream. Surfactants are also used in shampoos, toothpastes, inks and fabric softeners.

Solvents

A solvent is a substance that dissolves another substance, creating a solution. The most common solvent used in everyday living, and vaccine manufacture, is water.

Residuals

Residuals are the remaining minute quantities of substances that have been used during the manufacturing or production process of individual vaccines. Residuals depend on the process used, which may have involved cell culture mediums, egg proteins, yeast, antibiotics such as neomycin or streptomycin or inactivating agents such as formaldehyde. These substances are only present as traces and often measured as parts per million and parts per billion in the final vaccine formulation.

Diluents

A diluent is a liquid used to dilute a vaccine to the proper concentration immediately prior to administration. This is usually sterile water.

Animal derived products

Some people have concerns about animal derived products such as gelatin in vaccines. This may be for faith-based reasons or concerns about the safety of animal derived products. More information on animal derived products in vaccines can be found on the Immunisation Advisory Centre web site.

Allergies to vaccine ingredients

Very rarely, vaccines provoke a serious allergic reaction called anaphylaxis. The risk of this occurring is between less than once to up to three times out of every million doses of a vaccine. The components more likely to cause such a reaction are gelatin, egg proteins and antibiotics, although theoretically an allergic reaction can be triggered by almost anything.

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There are very few occasions when vaccines should not be given. However, a person's allergy history should always be assessed prior to immunisation. A vaccine should not be given when there is a history of anaphylaxis to an ingredient in the vaccine or to a previous dose of the same vaccine. A vaccine can be given when past reactions were not anaphylaxis, for example, reactions which have only involved the skin.

A person with a history of anaphylaxis after exposure to egg can usually be given MMR vaccine safely as the vaccine does not contain enough of the egg protein to cause a problem. The hydrolysed gelatin in the MMR vaccine has been recognised as a cause of anaphylaxis.[4]

Antibiotics in vaccines are only present in minute traces, usually an insufficient amount to cause a problem. An allergy to sulfonamide, beta-lactam or cephalosporin antibiotics is not a contraindication for vaccines containing traces of neomycin, streptomycin, polymyxin B or gentamicin, the antibiotics typically found in vaccines.

Further advice about allergies and vaccine contraindications should be sought from a medical practitioner with expertise in vaccines or by calling one of our Immunisation Advisors for free on 0800 IMMUNE.

Vaccine ingredients

Ingredients of vaccines on the New Zealand National Immunisation Schedule are presented in tables on the following pages. Details of the current Immunisation Schedule can be found on the Immunisation Advisory Centre website. National Immunisation Schedule vaccines are fully funded for certain age groups of children and some adults, for information about who is eligible for specific vaccines ask your doctor, nurse or 0800 IMMUNE.

List of quantity abbreviations			
ng	Nanogram	CCID50	50% cell culture infectious dose
µg	Microgram	ppm	Part per million
µL	Microlitre	<	Less than
mg	Milligram	≤	Less than or equal to
DU	D-antigen unit		
IU	International unit		
Lf U	Lime flocculation unit		

Vaccines are prescription medicines. Talk to your doctor or nurse about the benefits and any risks.

References

1. Jefferson T, Rudin M, Di Pietrantonj C. Adverse events after immunisation with aluminium-containing DTP vaccines: Systematic review of the evidence. Lancet Infect Dis. 2004;4(2):84-90.

2. Black S, Della Cioppa G, Malfroot A, Nacci P, Nicolay U, Pellegrini M, et al. Safety of MF59-adjuvanted versus non-adjuvanted influenza vaccines in children and adolescents: An integrated analysis. 2010;28(45):7331-6.

3. Harandi AM, Davies G, Olesen OF. Vaccine Adjuvants: Scientific Challenges and Strategic Initiatives. Expert Rev Vaccines. 2009;8(3):293-8.

4. Strebel P, Papania M, Gustavo H, Halsey N. Measles vaccine. In: Plotkin S, Orenstein W, Offit P, editors. Vaccines. 5th ed. Philadelphia: Elsevier Inc; 2008.

Information on individual vaccine ingredients was sourced from:

- The relevant vaccine data sheet published by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority. Available from: http://www.medsafe.govt.nz/.
- The relevant vaccine data sheet published by the U.S. Food and Drug Administration. Available from: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm.
- The relevant vaccine data sheet published by the European Medicines Agency. Available from: http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/epar_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001d124.
- Vaccine excipient & media summary, by vaccine. In: Atkinson W, Wolfe S, Hamborsky J, Centers for Disease Control and Prevention, editors. Epidemiology and prevention of vaccine-preventable diseases. 12th ed. Washington DC: Public Health Foundation; 2011.
- Vaccine excipient & media summary, by excipient. In: Atkinson W, Wolfe S, Hamborsky J, Centers for Disease Control and Prevention, editors. Epidemiology and prevention of vaccine-preventable diseases. 12th ed. Washington DC: Public Health Foundation; 2011.

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Infanrix®-*hexa*
Vaccine against diphtheria, tetanus, pertussis, polio, hepatitis B, *Haemophilus influenzae* type b (Hib) diseases
Vaccine type: Subunit

Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Diphtheria toxoid, adsorbed	Not less than 30 IU (25 Lf U)	Antigen
Tetanus toxoid, adsorbed	Not less than 40 IU (10 Lf U)	Antigen
Pertussis toxoid, adsorbed	25 µg	Antigen
Filamentous haemagglutinin, adsorbed	25 µg	Antigen
Pertactin, (69 kiloDalton outer membrane protein)	8 µg	Antigen
r-Hepatitis B surface antigen, adsorbed (HBsAg)	10 µg	Antigen
Inactivated Polio Virus Type 1	40 DU	Antigen
Inactivated Polio Virus Type 2	8 DU	Antigen
Inactivated Polio Virus Type 3	32 DU	Antigen
Haemophilus influenzae type b capsular polysaccharide, conjugated to tetanus toxoid	10 µg 20–40 µg	Antigen Carrier protein
Adjuvants		
Aluminium as:		
Aluminium hydroxide and Aluminium phosphate	0.5 mg 0.32 mg	Adjuvant Adjuvant
Excipients		
Culture media	Residual	Grow *Clostridium tetani* (tetanus), *Corynebacterium diphtheriae* (diphtheria), *Bordetella pertussis* (pertussis); stabilise polio viruses
Glutaraldahyde	Residual	Inactivate pertussis toxins
Formaldehyde	≤ 100 µg	Antimicrobial; stabiliser; inactivate tetanus, diphtheria toxins and polio viruses
Amino acids, bovine derived materials, glutamate, phosphate, sucrose, vitamins	Residual	Components of culture medium
Recombinant human albumin	Residual	Stabiliser in culture media
Glycine	Residual	Protein stabiliser
2-phenoxyethanol		Preservative
Neomycin, polymyxin		Antibacterial
Polysorbate 80, polysorbate 20	Residual	Surfactant
Potassium chloride	Residual	Buffer; component of growth media
Disodium phosphate, monopotassium phosphate	Residual	Buffer
Sodium chloride	4.5 mg	Buffer
Water for injections		Solvent
Lactose		Stabiliser in Hib freeze-drying filling

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Synflorix®

Vaccine against pneumococcal disease

Vaccine type: Subunit conjugate (10 valent)

Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Pneumococcal polysaccharide serotypes 1, 5, 6B, 7F, 9V, 14, 23F [†]	1 µg each	Antigens
Pneumococcal polysaccharide serotype 4 [†]	3 µg	Antigen
Pneumococcal polysaccharide serotype 18C [††]	3 µg	Antigen
Pneumococcal polysaccharide serotype 19F [†††]	3 µg	Antigen
Conjugated to:		
[†]Protein D (derived from non-typeable *Haemophilus influenzae*)	9–16 µg	Carrier protein
[††]Tetanus toxoid	5–10 µg	Carrier protein
[†††]Diphtheria toxoid	3–6 µg	Carrier protein
Adjuvants		
Aluminium as aluminium phosphate	0.5 mg	Adjuvant
Excipients		
Sodium chloride	4.3 mg	Buffer
Water for injection		Solvent

RotaTeq®

Vaccine against rotavirus disease

Vaccine type: Live attenuated (oral)

Ingredients	Quantity/dose (2mL)	Function
Active substances		
Live reassortant rotaviruses G1, G3	2.2 x 106 infectious units each	Antigens
Live reassortant rotavirus G2	2.8 x 106 infectious units	Antigen
Live reassortant rotavirus G4	2.0 x 106 infectious units	Antigen
Live reassortant rotavirus P1A[8]	2.3 x 106 infectious units	Antigen
Adjuvants		
Nil		
Excipients		
Culture media	Residual	Grow rotaviruses
Inorganic salts, amino acids and vitamins	Residual	Components of culture medium
Fetal bovine serum	Trace	Component of culture medium; stabiliser
Sodium citrate	Residual	Buffer
Sodium phosphate monobasic monohydrate	Residual	Buffer
Sodium hydroxide	Residual	Buffer
Polysorbate 80	Residual	Surfactant
Sucrose		Stabiliser
Purified water		Solvent
DNA from porcine circoviruses 1 and 2	Fragments	From porcine-derived material used in vaccine manufacture

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Act-HIB™

Vaccine against *Haemophilus influenzae* type b (Hib) disease

Vaccine type: Subunit conjugate

Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Haemophilus influenzae type b (Hib) polysaccharide, conjugated to tetanus toxoid	10 µg 18–30 µg	Antigen Carrier protein
Adjuvants		
Nil		
Excipients		
Culture media	Residual	Grow *Haemophilus influenzae* type b (Hib) and *Clostridium tetani* (tetanus)
Ammonium sulfate	Residual	Protein fractionation
Formaldehyde	< 0.5 µg	Antimicrobial; stabiliser; toxin inactivation
Trometamol	0.6 mg	Buffer
Sucrose	42.5 mg	Stabiliser
Sodium chloride 0.4%		Diluent

M-M-R® II

Vaccine against measles, mumps and rubella diseases

Vaccine type: Live attenuated

Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Attenuated measles virus	Not less than 1,000 CCID50	Antigen
Attenuated mumps virus	Not less than 12,500 CCID50	Antigen
Attenuated rubella virus	Not less than 1,000 CCID50	Antigen
Adjuvants		
Nil		
Excipients		
Amino acids, glutamate, neomycin, phosphate, sucrose, and vitamins	Residual	Components of culture media
Fetal bovine serum	< 1 ppm	Component of culture media
Recombinant human albumin	≤ 0.3 mg	Stabiliser in culture media
Sorbitol	14.5 mg	Stabiliser
Sodium phosphate		Component of growth media
Sucrose	1.9 mg	Stabiliser
Sodium chloride		Buffer
Gelatin (hydrolysed)	14.5 mg	Stabiliser
Other ingredients		Buffers; components of growth media
Neomycin	Approximately 25 µg	Antibacterial
Water for injection		Diluent

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Infanrix®-IPV
Vaccine against diphtheria, tetanus, pertussis and polio diseases
Vaccine type: Subunit

Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Diphtheria toxoid, adsorbed	Not less than 30 IU (25 Lf U)	Antigen
Tetanus toxoid, adsorbed	Not less than 40 IU (10 Lf U)	Antigen
Pertussis toxoid, adsorbed	25 µg	Antigen
Filamentous haemagglutinin, adsorbed	25 µg	Antigen
Pertactin, (69 kiloDalton outer membrane protein)	8 µg	Antigen
Inactivated Polio Virus Type 1	40 DU	Antigen
Inactivated Polio Virus Type 2	8 DU	Antigen
Inactivated Polio Virus Type 3	32 DU	Antigen
Adjuvants		
Aluminium hydroxide	< 0.625 mg by assay	Adjuvant
Excipients		
Culture medium	Residual	Grow *Clostridium tetani* (tetanus), *Corynebacterium diphtheriae* (diphtheria), *Bordetella pertussis* (pertussis); stabilise polio viruses
Glutaraldahyde	Residual	Inactivate pertussis toxins
Formaldehyde	≤ 100 µg	Antimicrobial; stabiliser; inactivate tetanus, diphtheria toxins; inactivate polio viruses
Amino acids, bovine derived materials, glutamate, phosphate, sucrose, vitamins	Residual	Components of culture medium
Recombinant human albumin	Residual	Stabiliser in culture media
Glycine	Residual	Protein stabiliser
2-phenoxyethanol	Residual	Preservative
Neomycin, polymyxin	Trace	Antibacterial
Potassium chloride	Residual	Buffer; component of growth media
Disodium phosphate, monopotassium phosphate	Residual	Buffer
Sodium chloride	4.5 mg	Buffer
Water for injection		Solvent

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Boostrix®
Booster vaccine against diphtheria, tetanus and pertussis diseases

Vaccine type: Subunit

Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Diphtheria toxoid, adsorbed	Not less than 2.5 Lf U	Antigen
Tetanus toxoid, adsorbed	Not less than 5 Lf U	Antigen
Pertussis toxoid, adsorbed	8 µg	Antigen
Filamentous haemagglutinin, adsorbed	8 µg	Antigen
Pertactin (69 kiloDalton outer membrane protein)	2.5 µg	Antigen
Adjuvants		
Aluminium as aluminium hydroxide and aluminium phosphate	< 0.39 mg by assay	Adjuvant
Excipients		
Culture media including bovine derived materials	Residual	Grow C*lostridium tetani* (tetanus), *Corynebacterium diphtheriae* (diphtheria) and *Bordetella pertussis* (pertussis)
Glutaraldehyde	≤ 100 µg	Inactivate pertussis toxins
Formaldehyde	≤ 100 µg	Antimicrobial; inactivate tetanus, diphtheria pertussis toxins; stabiliser
Polysorbate 80		Surfactant
Sodium chloride 0.9%	4.5 mg	Buffer

Gardasil®
Vaccine against human papillomavirus disease

Vaccine type: Subunit

Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
r-HPV 6 & 18 L1 proteins	20 µg	Antigens
r-HPV 11 & 16 L1 proteins	40 µg	Antigens
Adjuvants		
Aluminium as amorphous aluminium hydroxyphosphate sulphate	225 µg	Adjuvant
Excipients		
Amino acids, carbohydrates, mineral salts, vitamins	Residual	Components of culture medium
Yeast protein	< 7 µg	Culture medium residual
Sodium chloride	9.56 mg	Buffer
L-histidine	0.78 mg	Stabiliser
Polysorbate 80	50 µg	Surfactant
Sodium borate	35 µg	Buffer
Water for injection		Solvent

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Prevenar 13®
Vaccine against pneumococcal disease
Vaccine type: Subunit conjugate (13 valent)

Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Pneumococcal polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C,19A, 19F, 23F	2 µg	Antigens
Pneumococcal polysaccharide serotype 6B	4.4 µg	Antigen
All conjugated to diphtheria CRM197		Carrier protein
Adjuvants		
Aluminium as aluminium phosphate	0.57 mg	Adjuvant
Excipients		
Culture media		Grow *Streptococcus pneumoniae* (pneumococcal) and *Corynebacterium diphtheria* (diphtheria)
Polysorbate 80		Surfactant
Succinic acid		Buffer
Sodium chloride		Buffer
Water for injection		Solvent

Pneumovax® 23
Vaccine against pneumococcal disease
Vaccine type: Subunit polysaccharide (23 valent), not for use under 2 years of age

Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Pneumococcal polysaccharide serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C,19A, 19F, 20, 22F, 23F, 33F	25 µg each	Antigens
Adjuvants		
Nil		
Excipients		
Phenol	0.25%	Preservative
Sodium chloride		Buffer
Water for injection		Solvent

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Menactra®
Vaccine against meningococcal disease
Vaccine type: Subunit conjugate (4 valent)

Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Neisseria meningitidis serogroups A, C, Y and W-135	4 µg	Antigens
Conjugated to diphtheria toxoid	48 µg	Carrier protein
Adjuvants		
Nil		
Excipients		
Culture media	Residual	Grow *Neisseria meningitidis*
Growth medium	Residual	Grow *Corynebacterium diphtheriae*
Exposure to bovine derived materials		Component of culture medium
Formaldehyde	< 2.66 µg (< 0.000532%)	Inactivate/detoxify diphtheria toxoid
Sodium phosphate – dibasic anhydrous	0.348 mg	Buffer
Sodium phosphate – monobasic	0.352 mg	Buffer
Sodium chloride	4.35 mg	Buffer
Water for injection		Solvent

ADT™ Booster
Vaccine against diphtheria and tetanus diseases
Vaccine type: Subunit

Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Diphtheria toxoid	Not less than 2 IU	Antigen
Tetanus toxoid	Not less than 20 IU	Antigen
Adjuvants		
Aluminium as aluminium hydroxide (hydrated)	0.5 mg	Adjuvant
Excipients		
Sodium chloride	4 mg	Buffer
Sodium hydroxide q.s. to pH 7		Buffer
Formaldehyde	Residual	Antimicrobial; stabiliser; toxin inactivation
Water for injection		Solvent
Exposure to bovine derived materials		Component of culture medium

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IPOL
Vaccine against polio disease
Vaccine type: Subunit, inactivated

Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Inactivated Polio virus type 1 (Mahoney)	40 DU	Antigen
Inactivated Polio virus type 2 (MEF-1)	8 DU	Antigen
Inactivated Polio virus type 3 (Saukett)	32 DU	Antigen
Adjuvants		
Nil		
Excipients		
Amino acids (including phenylalanine), mineral salts, vitamins and other components (including glucose)	Residual	Components of culture medium
Calf serum protein	< 1 ppm	Component of culture medium
Polysorbate 80		Surfactant
Hydrochloric acid or sodium hydroxide		Buffer
Sodium chloride		Buffer
2-phenoxyethanol	2–3 µL	Preservative
Formaldehyde	2–20 µg	Antimicrobial; stabiliser; inactivate polio viruses
Neomycin	< 5 ng	Antibacterial
Streptomycin	< 200 ng	Antibacterial
Polymyxin B	< 25 ng	Antibacterial
Water for injection		Solvent

HBvaxPRO®
Vaccine against hepatitis B disease
Vaccine type: Subunit

Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Hepatitis B surface antigen	5 µg	Antigen
Adjuvants		
Aluminium as amorphpus aluminium hydroxyphosphate sulphate	0.25 mg	Adjuvant
Excipients		
Phosphate		Buffer
Formaldehyde	Residual	Antimicrobial; stabiliser; toxin inactivation
Sodium borate	35 µg	Buffer
Sodium chloride	4.5 mg	Buffer
Yeast protein	< 1% of protein content	Culture medium residual
Water for injection		Solvent