

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 approved for use 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 but has been weakened so it can replicate in the body several times and generate an immune response without causing the disease, e.g. rotavirus, chickenpox, measles, mumps and rubella vaccine viruses.

Inactivated or dead vaccines

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

Subunit vaccines

These are made using fragments such as proteins, toxoids or sugars (polysaccharides), derived from the disease-causing organism. 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 80 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.

MF59

No vaccines currently used in New Zealand contain the oil-in-water emulsion MF59. 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.

AS03 and 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 aluminium 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.

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 in urine and faeces after being metabolised (broken down). There is little toxicity in humans and some irritation with very high doses in animals.

Continued...

Excipients continued

Phenol

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

Thiomersal

No vaccines on the New Zealand Immunisation Schedule contain thiomersal, also called thimerosal. Thiomersal is a mercury derived compound that was used as a preservative in vaccines and other health care products internationally for many years. There is no evidence that thiomersal caused any serious or long-term adverse events.

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 monosodium glutamate (salts of amino acids), proteins such as recombinant human albumin (Recombunin[®]) 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 and ionic compounds

Buffers serve to resist changes in pH, such as monopotassium phosphate and sodium borate. Ionic compounds adjust tonicity and maintain osmolarity. The most commonly used ionic compound 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 Written Resources page 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.

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.

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 0800 IMMUNE.

National Immunisation Schedule

Ingredients of vaccines on the current and recent New Zealand National Immunisation Schedules are presented in tables on the following pages. A table showing the vaccine brands on the current Immunisation Schedule can be found on the Written Resources page of 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.

Specific vaccine ingredient tables are presented on the following pages:

Vaccine	Page	Vaccine	Page
Act-HIB	3	IPOL	6
ADT Booster	3	M-M-R II	7
Boostrix	3	Prevenar 13	7
Gardasil	4	Priorix	7
Gardasil 9	4	Rotarix	8
HBvaxPRO	4	RotaTeq	8
Hiberix	5	Synflorix	8
Infanrix-hexa	5	Varilrix	9
Infanrix-IPV	6		

Vaccine ingredients

Act-HIB Vaccine against <i>Haemophilus influenzae</i> type b (Hib) disease Type: Subunit, polysaccharide conjugate vaccine		
Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
<i>Haemophilus influenzae</i> type b (Hib) polysaccharide, conjugated to tetanus toxoid	10 µg 18–30 µg	Antigen Carrier protein
Excipients		
Culture media including bovine derived materials	Residual	Grow <i>Haemophilus influenzae</i> type b (Hib) and <i>Clostridium tetani</i> (tetanus)
Formaldehyde	Residual	Inactivating agent
Sucrose		Stabiliser
Trometamol		Surfactant
Water for injection		Solvent
Sodium chloride 0.4%		Diluent
ADT Booster Vaccine against diphtheria and tetanus diseases Type: Subunit, toxoid vaccine		
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		
Culture media including bovine derived materials	Residual	Grow <i>Clostridium tetani</i> (tetanus) and <i>Corynebacterium diphtheriae</i> (diphtheria)
Formaldehyde	Residual	Inactivating agent
Sodium chloride	4 mg	Adjust tonicity
Sodium hydroxide		Buffer
Water for injection		Solvent
Boostrix Vaccine against diphtheria, tetanus and pertussis diseases Type: Subunit, toxoid and inactivated protein vaccine		
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	0.3 mg 0.2 mg	Adjuvant
Excipients		
Culture media including bovine derived materials	Residual	Grow <i>Clostridium tetani</i> (tetanus), <i>Corynebacterium diphtheriae</i> (diphtheria) and <i>Bordetella pertussis</i> (pertussis)
Formaldehyde, glutaraldehyde	≤100 µg each	Inactivating agent
Sodium chloride	4.5 mg	Adjust tonicity
Glycine		Stabiliser
Polysorbate 80	≤100 µg	Surfactant
Water for injection		Solvent

Vaccine ingredients

Gardasil Vaccine against human papillomavirus disease (4-valent) Type: Subunit, recombinant protein vaccine		
Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
r-HPV 6 & 18 L1 proteins	20 µg	Antigen
r-HPV 11 & 16 L1 proteins	40 µg	Antigen
Adjuvants		
Aluminium as amorphous aluminium hydroxyphosphate sulphate	225 µg	Adjuvant
Excipients		
Culture media including yeast protein	Residual	Grow human papillomaviruses and yeast
Sodium chloride	9.56 mg	Adjust tonicity
Sodium borate	35 µg	Buffer
L-histidine	0.78 mg	Stabiliser
Polysorbate 80	50 µg	Surfactant
Water for injection		Solvent

Gardasil 9 Vaccine against human papillomavirus disease (9-valent) Type: Subunit, recombinant protein vaccine		
Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
r-HPV 31, 33, 45, 52 & 58	20 µg	Antigen
r-HPV 6 L1 protein	30 µg	Antigen
r-HPV 11 & 18 L1 proteins	40 µg	Antigen
r-HPV 16 L1 protein	60 µg	Antigen
Adjuvants		
Aluminium as amorphous aluminium hydroxyphosphate sulphate	500 µg	Adjuvant
Excipients		
Culture media including yeast protein	Residual	Grow human papillomaviruses and yeast
Sodium chloride	9.56 mg	Adjust tonicity
Sodium borate	35 µg	Buffer
L-histidine	0.78 mg	Stabiliser
Polysorbate 80	50 µg	Surfactant
Water for injection		Solvent

HBvaxPRO Vaccine against hepatitis B disease Type: Subunit, recombinant protein vaccine		
Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Hepatitis B surface antigen	5 µg	Antigen
Adjuvants		
Aluminium as amorphous aluminium hydroxyphosphate sulphate	0.25 mg	Adjuvant
Excipients		
Culture media including yeast protein	Residual	Grow hepatitis B viruses and yeast
Formaldehyde	Residual	Purify yeast protein
Sodium chloride	4.5 mg	Adjust tonicity
Sodium borate	35 µg	Buffer
Water for injection		Solvent

Hiberix Vaccine against <i>Haemophilus influenzae</i> type b (Hib) disease Type: Subunit, polysaccharide conjugate vaccine		
Ingredients	Quantity/dose (0.5ml)	Function
Active substances		
<i>Haemophilus influenzae</i> type b (Hib) polysaccharide, conjugated to tetanus toxoid	10 µg Approximately 25 µg	Antigen Carrier protein
Excipients		
Culture media including bovine derived material	Residual	Grow <i>Haemophilus influenzae</i> type b (Hib) and <i>Clostridium tetani</i> (tetanus)
Formaldehyde	≤ 0.5 µg	Inactivating agent
Lactose	12.6 mg	Stabiliser
Sodium chloride 0.9%		Diluent

Infanrix-hexa Vaccine against diphtheria, tetanus, pertussis, polio, hepatitis B, <i>Haemophilus influenzae</i> type b (Hib) diseases Type: Subunit, toxoid, inactivated protein, inactivated virus, recombinant protein and polysaccharide conjugate vaccine		
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
<i>Haemophilus influenzae</i> 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
Excipients		
Culture media including medium 199, bovine derived material	Residual	Grow <i>Clostridium tetani</i> (tetanus), <i>Corynebacterium diphtheriae</i> (diphtheria), <i>Bordetella pertussis</i> (pertussis); stabilise polio viruses
Formaldehyde	Residual	Inactivating agent
Potassium chloride, sodium chloride, disodium phosphate		Adjust tonicity
Monopotassium phosphate	Residual	Buffer
Glycine, lactose		Stabiliser
Polysorbate 20, polysorbate 80		Surfactant
Neomycin, polymyxin B	Residual	Antibacterial
Water for injection		Solvent

Infanrix-IPV

Vaccine against diphtheria, tetanus, pertussis and polio diseases

Type: Subunit, toxoid, inactivated protein and inactivated virus vaccine

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	Less than 0.625 mg by assay	Adjuvant
Excipients		
Culture media including medium 199, bovine derived material	Residual	Grow <i>Clostridium tetani</i> (tetanus), <i>Corynebacterium diphtheriae</i> (diphtheria), <i>Bordetella pertussis</i> (pertussis); stabilise polio viruses
Formaldehyde	Residual	Inactivating agent
Potassium chloride, disodium phosphate Sodium chloride	Residual	Adjust tonicity
Monopotassium phosphate	Residual	Buffer
Glycine	Residual	Stabiliser
Polysorbate 80	Residual	Surfactant
Neomycin, polymyxin B	Residual	Antibacterial
Water for injection		Solvent

IPOL

Vaccine against polio disease

Type: Inactivated virus vaccine

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
Excipients		
Culture media including medium 199 hanks, bovine derived material	Residual	Grow polio viruses
Formaldehyde	2–20 µg	Inactivating agent
Sodium chloride	Residual	Adjust tonicity
Hydrochloric acid or sodium hydroxide		Buffer
Polysorbate 80	Residual	Surfactant
Neomycin, polymyxin B, streptomycin	Residual	Antibacterial
2-phenoxyethanol	2–3 µL	Preservative
Water for injection		Solvent

Vaccine ingredients

M-M-R II		Type: Live attenuated virus vaccine
Vaccine against measles, mumps and rubella diseases		
Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Attenuated Enders' attenuated Edmonston measles virus	Not less than 1,000 CCID ₅₀	Antigen
Attenuated Jeryl Lynn (B Level) mumps virus	Not less than 12,500 CCID ₅₀	Antigen
Attenuated Wistar RA 27/3 rubella virus	Not less than 1,000 CCID ₅₀	Antigen
Excipients		
Culture media including medium 199, minimum essential medium, bovine derived material	Residual	Grow measles, mumps and rubella viruses
'Other ingredients' not specified	Residual	Components of growth media; buffer
Sodium chloride	Residual	Adjust tonicity
Sodium phosphate		Buffer
Hydrolised gelatin, recombinant human albumin, sorbitol, sucrose	14.5 mg, ≤ 0.3 mg, 14.5 mg, 1.9 mg	Stabiliser
Neomycin	Residual	Antibacterial
Water for injection		Diluent
Prevenar 13		Type: Subunit, polysaccharide conjugate vaccine
Vaccine against pneumococcal disease (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	2.2 µg	Antigen
Pneumococcal polysaccharide serotype 6B	4.4 µg	Antigen
All conjugated to diphtheria CRM197	34 µg	Carrier protein
Adjuvants		
Aluminium as aluminium phosphate	0.565 mg	Adjuvant
Excipients		
Culture media	Residual	Grow <i>Streptococcus pneumoniae</i> (pneumococcal) and <i>Corynebacterium diphtheria</i> (diphtheria)
Sodium chloride	Residual	Adjust tonicity
Succinic acid	295 µg	Buffer
Polysorbate 80	100 µg	Surfactant
Water for injection		Solvent
Priorix		Type: Live attenuated virus vaccine
Vaccine against measles, mumps and rubella diseases		
Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Attenuated Schwartz measles virus	Not less than 10 ^{3.0} CCID ₅₀	Antigen
Attenuated RIT 4385 (derived from Jeryl Lynn) mumps virus	Not less than 10 ^{3.7} CCID ₅₀	Antigen
Attenuated Wistar RA 27/3 rubella virus	Not less than 10 ^{3.0} CCID ₅₀	Antigen
Excipients		
Culture media including amino acids, bovine derived material	Residual	Grow measles, mumps and rubella viruses
Hydrolised gelatin, lactose, mannitol, sorbitol		Stabiliser
Neomycin	Residual	Antibacterial
Water for injection		Diluent

Vaccine ingredients

Rotarix Vaccine against rotavirus disease		Type: Live attenuated virus vaccine
Ingredients	Quantity/dose (1.5mL)	Function
Active substances		
Attenuated RIX 4414 strain of human rotavirus of the G1P[8] type	10 ^{6.0} CCID ₅₀	Antigen
Excipients		
Culture media including dulbecco's modified eagle medium, bovine and porcine derived material	Residual	Grow rotaviruses
DNA from porcine circoviruses 1	Fragments	From porcine-derived material used during manufacture
Disodium adipate		Buffer
Sucrose		Stabiliser
Water for injection		Solvent

RotaTeq Vaccine against rotavirus disease		Type: Live attenuated virus vaccine
Ingredients	Quantity/dose (2mL)	Function
Active substances		
Live reassortant rotaviruses G1, G3	2.2 x 10 ⁶ infectious units each	Antigen
Live reassortant rotavirus G2	2.8 x 10 ⁶ infectious units	Antigen
Live reassortant rotavirus G4	2.0 x 10 ⁶ infectious units	Antigen
Live reassortant rotavirus P1A[8]	2.3 x 10 ⁶ infectious units	Antigen
Excipients		
Culture media including bovine and porcine derived material	Residual	Grow rotaviruses
DNA from porcine circoviruses 1 and 2	Fragments	From porcine-derived material used during manufacture
Sodium citrate, sodium hydroxide, sodium phosphate monobasic monohydrate		Buffer
Sucrose		Stabiliser
Polysorbate 80		Surfactant

Synflorix Vaccine against pneumococcal disease (10-valent)		Type: Subunit, polysaccharide conjugate vaccine
Ingredients	Quantity/dose (0.5mL)	Function
Active substances		
Pneumococcal polysaccharide serotypes 1, 5, 6B, 7F, 9V, 14, 23F [†]	1 µg each	Antigen
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 <i>Haemophilus influenzae</i>)	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		
Culture media	Residual	Grow <i>streptococcus pneumoniae</i> (pneumococcal), <i>Corynebacterium diphtheria</i> (diphtheria), <i>Haemophilus influenzae</i> and <i>Clostridium tetani</i> (tetanus)
Sodium chloride	4.3 mg	Adjust tonicity
Water for injection		Solvent

Varilrix (human albumin-free) Vaccine against varicella (chickenpox) disease		Type: Live attenuated virus vaccine
Ingredients	Quantity/dose (0.5ml)	Function
Active substances		
Attenuated Oka strain varicella-zoster virus	10 ^{3.3} PFU	Antigen
Excipients		
Culture media including amino acids , fetal bovine serum	Residual	Grow varicella-zoster virus
Lactose, mannitol, sorbitol		Stabiliser
Neomycin	Residual	Antibacterial
Water for injection		Diluent

References

- Black S, Della Cioppa G, Malroot 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.
- Finn TM, Egan W. Vaccine additives and manufacturing residuals in the United States: licensed vaccines. In: Plotkin S, Orenstein W, Offit P, editors. Vaccines. 6th ed. London: W.B. Saunders; 2013. p. 71-9.
- Garçon N, Hem S, Friede M. Evolution of adjuvants across the centuries. In: Plotkin S, Orenstein W, Offit P, editors. Vaccines. 6th ed. London: W.B. Saunders; 2013. p. 58-70.
- Gomez PL, Robinson JM, Rogalewicz JA. Vaccine manufacturing. In: Plotkin S, Orenstein W, Offit P, editors. Vaccines. 6th ed. London: W.B. Saunders; 2013. p. 44-57.
- Harandi AM, Davies G, Olesen OF. Vaccine adjuvants: Scientific challenges and strategic initiatives. Expert Rev Vaccines. 2009;8(3):293-8.
- 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.
- Medsafe, the New Zealand Medicines and Medical Devices Safety Authority. Vaccine data sheets available from: <http://www.medsafe.govt.nz>.
- Mitkus RJ, King DB, Hess MA, Forshee RA, Walderhaug MO. Updated aluminum pharmacokinetics following infant exposures through diet and vaccination. Vaccine 2011; 29:9538-9554.
- Therapeutic Goods Administration. Vaccine product information sheets available from: <https://www.ebs.tga.gov.au>.
- U.S. Food and Drug Administration. Vaccine data sheets available from: <https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>.