NEW ZEALAND DATA SHEET

1. PRODUCT NAME

VARIVAX®
Varicella Virus Vaccine Live (Oka/Merck)
0.5 mL single dose vial

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

VARIVAX is live, attenuated virus vaccine (a lyophilised preparation of the Oka/Merck strain of varicella).

Each 0.5 mL dose of VARIVAX contains: a minimum of 1350 PFU (plaque forming units) of Oka/Merck varicella virus when reconstituted as directed and stored at room temperature for 150 minutes.

The product also contains residual components of MRC-5 cells and trace quantities of neomycin and bovine calf serum from MRC-5 culture media. The product contains no preservative.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder and solvent for suspension for injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

VARIVAX is indicated for vaccination against varicella in individuals 12 months of age and older.

4.2 Dose and method of administration

For Subcutaneous Administration
Do not inject intravenously.

Children 12 months to 12 years of age should receive a 0.5 mL dose administered subcutaneously. A second dose of VARIVAX administered at least 3 months later is recommended to ensure optimal protection against varicella (see Section 5 PHARMACOLOGICAL PROPERTIES).

Adolescents and adults 13 years of age and older should receive a 0.5 mL dose administered subcutaneously at elected date and a second 0.5 mL dose 4 to 8 weeks later.

The outer aspect of the upper arm (deltoid region) is the preferred site of injection.

For instructions on reconstitution of VARIVAX before administration, see section 6.6.

4.3 Contraindications

History of hypersensitivity to any component of the vaccine, including gelatin.

History of anaphylactoid reaction to neomycin (each dose of reconstituted vaccine contains trace quantities of neomycin).

Blood dyscrasias, leukaemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.

Immunosuppressive therapy (including high-dose corticosteroids); however, VARIVAX is not contraindicated for use with topical corticosteroids or low-dose corticosteroids, as are commonly used for asthma prophylaxis. Individuals who are on immunosuppressant drugs are more susceptible to infections than healthy individuals. Vaccination with live attenuated varicella vaccine can result in a more extensive vaccine-associated rash or disseminated disease in individuals on immunosuppressant doses of corticosteroids.

Primary and acquired immunodeficiency states, including immunosuppression in association with AIDS or other clinical manifestations of infection with human immunodeficiency virus, except immunosuppression in asymptomatic children with CD4 T-lymphocyte percentages ≥25%.

Family history of congenital or hereditary immunodeficiency, unless the immune competence of the potential vaccine recipient is demonstrated.

Active untreated tuberculosis.

Any active febrile illness with fever >38.5°C (>101.3°F) however, low-grade fever itself is not a contraindication to vaccination.

Pregnancy; the possible effects of the vaccine on foetal development are unknown at this time. However, wild-type varicella is known to sometimes cause foetal harm. If vaccination of post pubertal females is undertaken, pregnancy should be avoided for three months following vaccination (See Fertility, pregnancy and lactation, *Pregnancy*).

4.4 Special warnings and precautions for use

Adequate treatment provisions, including epinephrine injection (1:1000), should be available for immediate use should an anaphylactoid reaction occur.

The duration of protection from varicella infection after vaccination with VARIVAX is unknown.

The safety and efficacy of VARIVAX have not been established in children and young adults who are known to be infected with human immunodeficiency viruses with and without evidence of immunosuppression (see also Contraindications).

Transmission
Post-marketing experience suggests that transmission of varicella vaccine virus (Oka/Merck) resulting in varicella infection including disseminated disease may occur rarely between vaccine recipients (who develop or do not develop a varicella-like rash) and contacts susceptible to varicella including healthy as well as high risk individuals.

Therefore, vaccine recipients should attempt to avoid, whenever possible, close association

with susceptible high risk individuals for up to six weeks. In circumstances where contact with high risk individuals is unavoidable, the potential risk of transmission of vaccine virus should be weighed against the risk of acquiring and transmitting wild-type varicella virus. Susceptible high risk individuals include:

- immunocompromised individuals
- pregnant women without documented history of varicella or laboratory evidence of prior infection
- newborn infants of mothers without documented history of varicella or laboratory evidence of prior infection.

Paediatric Use
No clinical data are available on safety or efficacy of VARIVAX in children less than one year of age. Administration to infants under twelve months of age is not recommended.

4.5 Interaction with other medicines and other forms of interaction

Vaccination should be deferred for at least 5 months following blood or plasma transfusions, or administration of immune globulin or varicella-zoster immune globulin (VZIG).

Following administration of VARIVAX, any immune globulin including VZIG should not be given for 2 months thereafter unless its use outweighs the benefits of vaccination.

Vaccine recipients should avoid use of salicylates for 6 weeks after vaccination with VARIVAX as Reye syndrome has been reported following the use of salicylates during wild-type varicella infection.

Results from clinical studies indicate that VARIVAX can be administered concomitantly with M-M-R® II (Measles, Mumps and Rubella Virus Vaccine Live), diphtheria and tetanus toxoids and pertussis vaccine adsorbed and *Haemophilus influenzae* type b conjugate combined vaccine, or *Haemophilus influenzae* type b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) combined vaccine. If VARIVAX is not given concomitantly with M-M-R II, a 1-month interval between the 2 live virus vaccines should be observed.

Limited data from an experimental product containing varicella vaccine suggest that VARIVAX can be administered concomitantly with DTaP (diphtheria, tetanus, acellular pertussis) and PedvaxHIB* [*Haemophilus b* Conjugate Vaccine (Meningococcal Protein Conjugate)] using separate sites and syringes and with OPV (oral poliovirus vaccine).

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate and well-controlled studies in pregnant women. It is not known whether VARIVAX can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, VARIVAX should not be administered to pregnant females, furthermore, pregnancy should be avoided for three months following vaccination (see Contraindications).

Nursing Mothers
It is not known whether varicella vaccine virus is secreted in human milk. Therefore, because some viruses are secreted in human milk, caution should be exercised if VARIVAX is administered to a nursing woman.

* Not currently registered in New Zealand

Fertility
VARIVAX has not been evaluated for its potential to impair fertility.

4.7 Effects on ability to drive and use machines

There are no data to suggest that VARIVAX affects the ability to drive or operate machinery.

4.8 Undesirable effects

Clinical Studies
In clinical trials, varicella vaccine (Oka/Merck) was administered to over 17,000 healthy children, adolescents and adults. Varicella vaccine (Oka/Merck) was generally well tolerated.

In a double-blind placebo-controlled study among 956 healthy children and adolescents, 914 of whom were serologically confirmed to be susceptible to varicella, the only adverse reactions that occurred at a significantly ($p<0.05$) greater rate in vaccine recipients than in placebo recipients were pain and redness at the injection site and varicella-like rash.

Children 1 to 12 Years of Age
One-Dose Regimen in Children
In clinical trials involving healthy children monitored for up to 42 days after a single dose of varicella vaccine (Oka/Merck), the frequency of fever, injection-site complaints, or rashes were reported as follows:

Table 1
Fever, Local Reactions or Rashes (%) in Children 1 to 12 Years of Age
0 to 42 Days After Receipt of a Single Dose of Varicella Vaccine (Oka/Merck)

Reaction	N	% Experiencing Reaction	Peak Occurrence in Postvaccination Days
Fever ≥102°F (39°C) Oral	8824	14.7%	0-42
Injection-site complaints (pain/soreness, swelling and/or erythema, rash, pruritus, haematoma, induration, stiffness)	8913	19.3%	0-2
Varicella-like rash (injection site) Median number of lesions	8913	3.4% 2	8-19
Varicella-like rash (generalised) Median number of lesions	8913	3.8% 5	5-26

In addition, the most frequently (≥1%) reported adverse experiences, without regard to causality, are listed in decreasing order of frequency: upper respiratory illness, cough, irritability, fatigue, disturbed sleep, diarrhoea, loss of appetite, vomiting, otitis, headache, malaise, abdominal pain, other rash, nausea, chills, lymphadenopathy, myalgia, lower respiratory illness, allergic reactions (including allergic rash, hives), stiff neck, arthralgia, itching.

Pneumonitis has been reported rarely (<1%) in children vaccinated with varicella vaccine (Oka/Merck); a causal relationship has not been established.

Febrile seizures have occurred rarely (<0.1%) in children vaccinated with varicella vaccine (Oka/Merck); a causal relationship has not been established.

Clinical safety of refrigerator-stable varicella vaccine (Oka/Merck) (n=635) was compared with that of the licensed frozen formulation of varicella vaccine (Oka/Merck) (n=323) for 42 days postvaccination in children 12 to 23 months of age. The safety profiles were comparable for the two different formulations. Pain/tenderness/soreness and erythema were the most commonly reported local reactions. The most common systemic adverse events (reported by ≥10% of subjects, irrespective of causality) were reported in decreasing order of frequency as follows: fever ≥102.0°F (38.9°C) oral; upper respiratory infection; otitis media; cough; rhinorrhea and irritability. Six subjects reported serious adverse events.

Two-Dose Regimen in Children

In a clinical trial involving healthy children who received two doses of varicella vaccine (Oka/Merck) 3 months apart and were monitored for up to 42 days after any dose, the frequency of fever, injection-site complaints, rashes, and systemic clinical complaints are reported in Table 2. The 2-dose regimen of varicella vaccine was generally well tolerated, with a safety profile generally comparable to that of the 1-dose regimen.

Table 2
Fever, Local Reactions or Rashes (%) in Children 1 to 12 Years of Age 0 to 42 Days After Receipt of Varicella Vaccine (Oka/Merck)

Reaction	N	Post dose 1 (n=1102)	N	Post dose 2 (n=1022)
Fever ≥ 38.9°C	1077	14.3%	975	10.5%
Injection site complaints (soreness, erythema, swelling, varicella like rash, pruritus, ecchymosis, hematoma, induration, pyrexia)	1081	25.7%	981	25.8%
Varicella like rash, injection site	1081	3.7%	981	1.6%
Varicella like rash, generalised	1081	3.4%	981	1.2%
Systemic clinical complaints	1081	85.8%	981	66.3%

n = Number of subjects who received the indicated injection
N = number of subjects with follow-up data for the indicated category following both Dose 1 and Dose 2

Adolescents and Adults 13 Years of Age and Older

In clinical trials involving healthy adolescents and adults, the majority of whom received two doses of varicella vaccine (Oka/Merck) and were monitored for up to 42 days after any dose, the frequency of fever, injection-site complaints, or rashes were reported as follows:

Table 3 Fever, Local Reactions, or Rashes (%) in Adolescents and Adults 0 to 42 Days After Receipt of Varicella Vaccine (Oka/Merck)						
Reaction	**N**	**Post Dose 1**	**Peak Occurrence in Postvaccination Days**	**N**	**Post Dose 2**	**Peak Occurrence in Post-vaccination Days**
Fever ≥100°F (37.8°C) Oral	1584	10.2%	14-27	956	9.5%	0-42
Injection-site complaints (soreness, erythema, swelling, rash, pruritus, pyrexia, haematoma, induration, numbness)	1606	24.4%	0-2	955	32.5%	0-2
Varicella-like rash (injection site) Median number of lesions	1606	3.1% 2	6-20	955	1.0% 2	0-6
Varicella-like rash (generalised) Median number of lesions	1606	5.5% 5	7-21	955	0.9% 5.5	0-23

In addition, the most frequently (≥1%) reported adverse experiences, without regard to causality, are listed in decreasing order of frequency: upper respiratory illness, headache, fatigue, cough, myalgia, disturbed sleep, nausea, malaise, irritability, diarrhoea, stiff neck, lymphadenopathy, chills, abdominal pain, loss of appetite, arthralgia, otitis, itching, vomiting, other rashes, lower respiratory illness, allergic reactions (including allergic rash, hives), and dizziness.

Post-Marketed Clinical Studies
In a post-marketing study conducted to evaluate short-term safety (follow-up of 30 or 60 days) in approximately 86,000 children, 12 months to 12 years of age, and in approximately 3600 adolescents and adults, 13 years of age and older, varicella vaccine (Oka/Merck) was generally well tolerated. No serious vaccine-related adverse events were reported.

As with any vaccine, there is the possibility that broad use of the vaccine could reveal adverse reactions not observed in clinical trials.

Post-Marketed Experience
The following additional adverse effects have been reported regardless of causality since the vaccine has been marketed:

Body As A Whole: Anaphylaxis (including anaphylactic shock) and related phenomena such as angioneurotic oedema, facial oedema, and peripheral oedema; anaphylaxis in individuals with or without an allergic history.

Eye Disorders: Necrotizing retinitis (reported only in immunocompromised individuals).

Gastrointestinal Disorders: Nausea, vomiting

Haemic and Lymphatic System: Aplastic anaemia, thrombocytopaenia (including idiopathic thrombocytopaenic purpura [ITP]), lymphadenopathy.

Infections and Infestations: Varicella (vaccine strain)

Nervous/Psychiatric: Encephalitis†; cerebrovascular accident; transverse myelitis; Guillain-Barré syndrome; Bell's palsy; ataxia; febrile and non-febrile seizures; aseptic meningitis; meningitis†; dizziness; paresthesia; irritability; syncope.

Respiratory: Pharyngitis; pneumonia/pneumonitis; upper respiratory tract infection.

Skin: Stevens-Johnson syndrome; erythema multiforme; Henoch-Schönlein purpura; secondary bacterial infections of skin and soft tissue, including cellulitis; herpes zoster†.

†Cases caused by wild-type varicella or vaccine strain varicella have been reported in immunocompromised or immunocompetent individuals.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

There are no data with regard to overdose.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Viral Vaccines; ATC code: J07BK01

Summary of clinical trial data

Ten-year Efficacy in Children
In a clinical trial, a total of 2216 children 12 months to 12 years of age with a negative history of varicella were randomized to receive either 1 dose of varicella vaccine (Oka/Merck) (n=1114) or 2 doses of varicella vaccine (Oka/Merck) (n=1102) given 3 months apart. Subjects were actively followed for varicella, any varicella-like illness, or herpes zoster and any exposures to varicella or herpes zoster on an annual basis for 10 years after vaccination. Persistence of varicella-zoster vaccine (VZV) antibody was measured annually for 9 years. Most cases of varicella reported in recipients of 1 dose or 2 doses of vaccine were mild. The estimated vaccine efficacy for the 10-year observation period was 94% for 1 dose and 98% for 2 doses ($p<0.001$). This translates to a 3.4-fold lower risk of developing varicella >42 days postvaccination during the 10-year observation period in children who received 2 doses than in those who received 1 dose (2.2% vs. 7.5%, respectively).

There are an insufficient number of breakthrough varicella cases in vaccinated children to assess the rate of protection of varicella vaccine (Oka/Merck) against the serious complications of varicella (e.g., encephalitis, hepatitis, pneumonia).

Immunogenicity of Varicella Vaccine (Oka/Merck)

Clinical trials with several formulations of the vaccine containing attenuated virus ranging from 1000 to 50,000 PFU per dose have demonstrated that varicella vaccine (Oka/Merck) induces detectable humoral immune responses in a high proportion of individuals and is generally well tolerated in healthy individuals ranging from 12 months to 55 years of age.

The following section presents immunogenicity data on a 1-dose regimen and a 2-dose regimen in children, and a 2-dose regimen in adolescents and adults.

One-Dose Regimen in Children
Seroconversion as defined by the acquisition of any detectable varicella antibodies (based on assay cut off that generally corresponds to 0.6 units in the gpELISA, a highly sensitive assay which is not commercially available) was observed in 98% of vaccinees at approximately 4 to 6 weeks postvaccination in 9610 susceptible children 12 months to 12 years of age who received doses ranging from 1000 to 50,000 PFU. Rates of breakthrough disease were significantly lower among children with varicella antibody titres ≥5 gpELISA units compared to children with titres <5 gpELISA units. Titres ≥5 gpELISA units were induced in approximately 83% of children vaccinated with a single dose of vaccine at 1000 to 50,000 PFU per dose. The immune response rate to varicella vaccine (Oka/Merck) (as determined by the percentage of subjects with varicella antibody titres ≥5 gpELISA units at 6 weeks post-vaccination, an approximate correlation of protection) in subjects participating in follow-up studies ranged from 72 to 98%.

Immunogenicity of refrigerator-stable varicella vaccine (Oka/Merck) (formulations containing attenuated virus ranging from 6650 to 28,400 PFU per dose), was compared with that of the licensed frozen formulation (9189 PFU per dose) in a double-blind, randomized, multicenter study in children 12 to 23 months of age, all of whom received M-M-R II concomitantly. The per-protocol analysis included all subjects with prevaccination varicella antibody titers <1.25 gpELISA units; the antibody responses were comparable across the 3 treatment groups, with the percentage of subjects with varicella antibody titers ≥5 gpELISA units at 6 weeks postvaccination ranging from 93 to 95%.

Two Dose Regimen in Children
In a multicenter study, healthy children 12 months to 12 years of age received either 1 dose of varicella vaccine (Oka/Merck) or 2 doses administered 3 months apart. The immunogenicity results are shown in the following table.

Table 4
Summary of VZV Antibody Responses at 6 Weeks Postdose 1 and 6 Weeks Postdose 2 in Initially Seronegative Children 12 Months to 12 Years of Age (Vaccinations 3 Months Apart)

	Varicella Vacccine (Oka/Merck)1-Dose Regimen (N = 1114)	**Varicella Vaccine (Oka/merck)2-Dose Regimen (3 Months Apart)** (N = 1102)	
	6 Weeks Postvaccination (n=892)	6 Weeks Postdose 1 (n=851)	6 Weeks Postdose 2 (n=769)
Seroconversion Rate	98.9%	99.5%	99.9%

Percent with VZV Antibody Titre ≥5 gpELISA units/mL	84.9%	87.3%	99.5%
Geometric mean titres in gpELISA units/mL (95% CI)	12.0 (11.2, 12.8)	12.8 (11.9, 13.7)	141.5 (132.3, 151.3)

N= Number of subjects vaccinated.
n= Number of subjects included in immunogenicity analysis.

The results from this study and other studies in which a second dose of varicella vaccine (Oka/Merck) was administered 3 to 6 years after the initial dose demonstrate significant boosting of the VZV antibody response with a second dose. VZV antibody levels after 2 doses given 3 to 6 years apart are comparable to those obtained when the 2 doses are given 3 months apart.

Two-Dose Regimen in Adolescents and Adults
In a multicentre study involving susceptible adolescents and adults 13 years of age and older, two doses of varicella vaccine (Oka/Merck) administered four to eight weeks apart induced a seroconversion rate (gpELISA ≥0.6 units) of approximately 75% in 539 individuals four weeks after the first dose and of 99% in 479 individuals four weeks after the second dose. The average antibody response in vaccinees who received the second dose eight weeks after the first dose was higher than that in those who received the second dose four weeks after the first dose. In another multicentre study involving adolescents and adults, two doses of varicella vaccine (Oka/Merck) administered eight weeks apart induced a seroconversion rate (gpELISA ≥0.6 units) of 94% in 142 individuals six weeks after the first dose and 99% in 122 individuals six weeks after the second dose.

Varicella vaccine (Oka/Merck) induces both humoral and cell-mediated immune responses in vaccinees. The relative contributions of humoral immunity and cell-mediated immunity to protection from varicella are unknown.

Persistence of Immune Response

The following section presents immune persistence data on a 1-dose regimen and a 2-dose regimen in children, and a 2-dose regimen in adolescents and adults.

One Dose Regimen in Children
In those clinical studies involving healthy children who have been followed long-term post single-dose vaccination, detectable varicella antibodies (gpELISA ≥0.6 units) were present in 99.1% (3092/3120) at 1 year, 99.4% (1382/1391) at 2 years, 98.7% (1032/1046) at 3 years, 99.3% (997/1004) at 4 years, 99.2% (727/733) at 5 years, and 100% (432/432) at 6 years post-vaccination.

Two Dose Regimen in Children
Over 9 years of follow-up, the GMTs (geometric mean titre) and percent of subjects with VZV antibody titres ≥5 gpELISA units/mL in the 2-dose recipients were higher than those in the 1-dose recipients for the first year of follow-up and comparable during the entire follow-up period. The cumulative rate of VZV antibody persistence with both regimens remained very high at year 9 (99.0% for the 1-dose group and 98.8% for the 2-dose group).

Two Dose Regimen in Adolescents and Adults
In clinical studies involving healthy adolescents and adults who received 2 doses of vaccine, detectable varicella antibodies (gpELISA ≥0.6 units) were present in 97.9% (568/580) at 1 year, 97.1% (34/35) at 2 years, 100% (144/144) at 3 years, 97.0% (98/101) at 4 years, 97.5% (78/80) at 5 years, and 100% (45/45) at 6 years post-vaccination.

A boost in antibody levels has been observed in vaccinees following exposure to wild-type varicella which could account for the apparent long-term persistence of antibody levels after vaccination in these studies. The duration of protection from varicella obtained using varicella vaccine (Oka/Merck) in the absence of wild-type boosting is unknown. Varicella vaccine (Oka/Merck) also induces cell-mediated immune responses in vaccinees. The relative contributions of humoral immunity and cell-mediated immunity to protection from varicella are unknown.

Vaccination with VARIVAX may not result in protection of all healthy, susceptible children, adolescents, and adults.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Animal Toxicology
Carcinogenesis and Mutagenesis
VARIVAX has not been evaluated for its carcinogenic or mutagenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

sucrose
hydrolysed gelatin
urea
sodium chloride
monosodium L-glutamate
sodium phosphate dibasic
potassium phosphate monobasic
potassium chloride

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

6.3 Shelf life

Before reconstitution, VARIVAX has a shelf-life of 24 months when refrigerated at 2°C to 8°C or colder (36°F to 46°F or colder).

Stability
VARIVAX has a minimum potency level of approximately 1350 PFU 150 minutes after reconstitution at room temperature (20°C to 25°C, 68°F to 77°F).

6.4 Special precautions for storage

Vaccine Vial
During shipment, to ensure that there is no loss of potency, the vaccine must be maintained at a temperature of 2°C to 8°C or colder (36°F to 46°F or colder), but not exceed temperatures lower than -50°C (-58°F). Use of dry ice may subject VARIVAX to temperatures colder than -50°C (-58°F).

Before reconstitution, protect from light.

Discard if reconstituted vaccine is not used within 150 minutes (2½ hours).

Prefilled syringe of diluent:
The prefilled syringe of diluent should be stored at room temperature (20 to 25°C, 68 to 77°F), or in the refrigerator.

Vial of diluent
The vial of diluent should be stored separately at room temperature (20°C to 25°C, 68°F to 77°F) or in the refrigerator if it is supplied in a separate carton to the vaccine.

Combination pack with vaccine vial and diluent
For combination packs with vaccine vial and diluent packaged together, store in the refrigerator at 2°C to 8°C (36°F to 46°F). **DO NOT STORE THE COMBINATION PACK IN THE FREEZER.**

6.5 Nature and contents of container

VARIVAX is supplied as:

- a single dose carton containing a vial of vaccine and a vial of diluent
- a carton containing 10 single dose vials of vaccine and a carton containing 10 vials of diluent
- a single dose carton containing a vial of vaccine and a pre-filled diluent syringe
- a carton containing 10 single dose vials of vaccine and 10 pre-filled diluent syringes

6.6 Special precautions for disposal and other handling

To reconstitute the vaccine, use only the diluent supplied with the vaccine (sterile water for injection BP) since it is free of preservatives or other anti-viral substances which might inactivate the vaccine virus. It may be supplied in the same carton in which case it should be refrigerated. If the diluent is supplied separately it may be stored at room temperature (20°C to 25°C, 68°F to 77°F), or in the refrigerator.

Prefilled syringe of diluent:
To reconstitute the vaccine, inject all of the diluent (0.7 mL) in the prefilled syringe into the vial of lyophilized vaccine and gently agitate to mix thoroughly. Withdraw the entire contents into the syringe and inject the total volume (about 0.5 mL) of reconstituted vaccine subcutaneously, preferably into the outer aspect of the upper arm (deltoid region) or the anterolateral thigh. **It is recommended that the vaccine be administered immediately after reconstitution, to minimise loss of potency. Discard if reconstituted vaccine is not used within 150 minutes.**

Do not freeze reconstituted vaccine.

Parenteral medicine products should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit. VARIVAX when reconstituted is a clear, colourless to pale yellow liquid.

Vial of diluent:
To reconstitute the vaccine, first withdraw 0.7 mL of diluent into the syringe to be used for reconstitution. Inject all of the diluent in the syringe into the vial of lyophilised vaccine and gently agitate to mix thoroughly. Withdraw the entire contents into a syringe and inject the total volume (about 0.5 mL) of reconstituted vaccine subcutaneously, preferably into the outer aspect of the upper arm (deltoid region) or the anterolateral thigh. **It is recommended that the vaccine be administered immediately after reconstitution, to minimise loss of potency. Discard if reconstituted vaccine is not used within 150 minutes.**

Do not freeze reconstituted vaccine.

Caution: A sterile syringe free of preservatives, antiseptics, and detergents should be used for each injection and/or reconstitution of VARIVAX because these substances may inactivate the vaccine virus.

It is important to use a separate sterile syringe and needle for each patient to prevent transmission of infectious agents from one individual to another.

Parenteral medicine products should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit. VARIVAX when reconstituted is a clear, colourless to pale yellow liquid.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99 851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

9. DATE OF FIRST APPROVAL

03 June 1999

10. DATE OF REVISION OF THE TEXT

17 May 2023

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.8	Addition of syncope as an adverse event

S-WPC-V210-I-ref-032023

RCN: 000025626-NZ