AUSTRALIAN PRODUCT INFORMATION

VARILRIX HUMAN SERUM ALBUMIN-FREE (varicella) vaccine, (live, attenuated), powder and diluent for solution for injection.

1 NAME OF THE MEDICINE

Live varicella vaccine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

VARILRIX is a lyophilised preparation of the live attenuated Oka strain of varicella-zoster virus, obtained by propagation of the virus in MRC_5 human diploid cell culture.

Each 0.5 mL dose of the reconstituted vaccine contains not less than $10^{3.3}$ plaque-forming units (PFU) of the varicella-zoster virus.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

VARILRIX meets the World Health Organisation requirements for biological substances and for varicella vaccines.

List of excipients with known effect

VARILRIX also contains the excipient ingredient phenylalanine and residual amounts of neomycin sulphate, which is carried over from the manufacturing process.

For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS.

3 PHARMACEUTICAL FORM

Powder and diluent for solution for injection.

VARILRIX is presented as a slightly cream to yellowish or pinkish coloured powder for reconstitution with clear and colourless sterile diluent.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

VARILRIX is indicated for active immunisation against varicella of healthy children and adults from 9 months of age.

Groups who would particularly benefit from vaccination include:

- Non-immune adults, especially those in at-risk occupations such as health care workers, teachers and workers in children's day-care centres
- Non-immune parents of young children
- Non-immune household contacts, both adults and children, of immunocompromised patients with no history of the disease

4.2 DOSE AND METHOD OF ADMINISTRATION

VARILRIX should be administered as a single dose by subcutaneous injection only. The upper arm (deltoid region) is the preferred site of injection.

UNDER NO CIRCUMSTANCES SHOULD VARILRIX BE ADMINISTERED INTRAVENOUSLY. VARILRIX should not be administered intradermally.

Dosage (dose and interval)

Infants and Children (aged 9 months up to and including 12 years of age)

Children from the age of 9 months up to 12 years of age, two doses of VARILRIX administered at least 6 weeks apart is recommended for the benefit of enhanced immune response against varicella virus.

Adolescents and Adults (13 years of age and over)

Two 0.5 mL doses of reconstituted VARILRIX, administered at least 6 weeks apart, are required.

Interchangeability

- A single dose of VARILRIX may be administered to those who have already received a single dose of another varicella-containing vaccine.
- A single dose of VARILRIX may be administered followed by a single dose of another varicella-containing vaccine.

Method of administration

Due to minor variations of its pH, the colour of the reconstituted vaccine may vary from a clear peach to a pink coloured solution. Vaccines should be inspected visually for any foreign particulate matter and/or variation of physical aspect prior to reconstitution or administration. In the event of either being observed, do not use the vaccine.

After reconstitution, it is recommended that the vaccine be injected as soon as possible. However, it has been demonstrated that the vaccine may be kept for up to 90 minutes at room temperature (25˚C) or up to 8 hours in the refrigerator (2˚C to 8˚C). If not used within these timeframes, the reconstituted vaccine must be discarded. For use in a single individual, on one occasion only. VARILRIX contains no antimicrobial agent. Use once only and discard any residue.

Alcohol and other disinfecting agents must be allowed to evaporate from the skin before the injection of the vaccine as they may inactivate the virus.

Further guidance regarding the use of vaccines is found in the Australian Immunisation Handbook.

Reconstitution

Instructions for reconstitution of the vaccine with diluent presented in ampoules

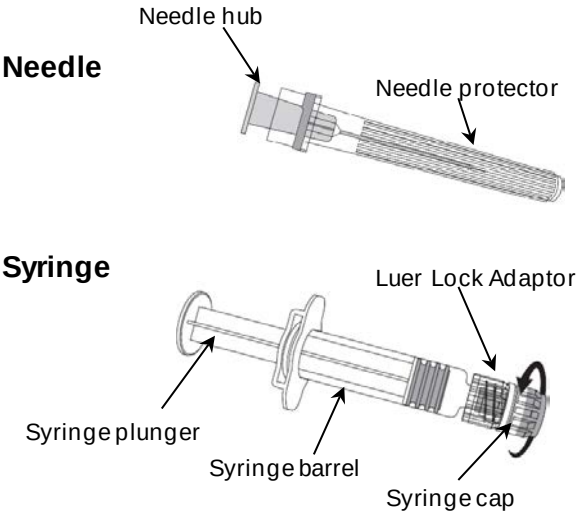
VARILRIX must be reconstituted by adding the entire contents of the supplied ampoule of diluent to the vial containing the powder. The mixture should be well shaken until the powder is completely dissolved in the diluent.

After reconstitution, the vaccine should be used promptly.

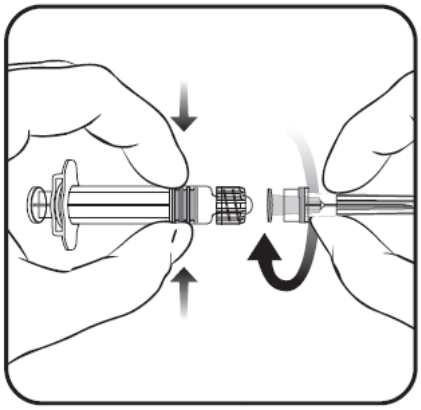
Withdraw the entire contents of the vial. Inject the entire contents of the syringe, using a new needle for administration.

Instructions for reconstitution of the vaccine with diluent presented in pre-filled syringe

VARILRIX must be reconstituted by adding the entire contents of the pre-filled syringe of diluent to the vial containing the powder. To attach a needle to the syringe, carefully read the instructions given with pictures 1 and 2. However, the syringe provided with VARILRIX might be slightly different than the syringe illustrated.



Picture 1



Picture 2

Always hold the syringe by the barrel, not by the syringe plunger or the Luer Lock Adaptor (LLA), and maintain the needle in the axis of the syringe (as illustrated in picture 2). Failure to do this may cause the LLA to become distorted and leak.

During assembly of the syringe, if the LLA comes off, a new vaccine dose (new syringe and vial) should be used.

1. Unscrew the syringe cap by twisting it anticlockwise (as illustrated in picture 1).

2. Attach a needle to the syringe by gently connecting the needle hub into the LLA and rotate a quarter turn clockwise until you feel it lock (as illustrated in picture 2).

3. Remove the needle protector, which may be stiff.

4. Add the diluent to the powder. The mixture should be well shaken until the powder is completely dissolved in the diluent.

After reconstitution, the vaccine should be used promptly.

5. Withdraw the entire contents of the vial.

6. A new needle should be used to administer the vaccine. Unscrew the needle from the syringe and attach an injection needle by repeating step 2 above.

Inject the entire contents of the syringe.

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

4.3 CONTRAINDICATIONS

VARILRIX is contraindicated in children and adults with known hypersensitivity to neomycin or to any other component of the vaccine. A history of contact dermatitis to neomycin is not a contraindication.

VARILRIX is contraindicated in children and adults having shown signs of hypersensitivity after previous administration of varicella vaccine.

VARILRIX is contraindicated in pregnant women. Pregnancy should be avoided for one month after vaccination (see Section 4.6 FERTILITY, PREGNANCY AND LACTATION, Use in pregnancy).

VARILRIX is contraindicated in patients with severe humoral or cellular immunodeficiency such as:

- patients with primary and acquired immunodeficiency states with a total lymophocyte count less than 1,200 per mm^3.
- patients presenting other evidence of lack of cellular immune competence (e.g. children and adults with leukaemias, lymphomas, blood dyscrasias, clinically manifest HIV infection).
- patients receiving immunosuppressive therapy including high doses of corticosteroids (further guidance is found in the Australian Immunisation Handbook).

See Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE.

As with other vaccines, the administration of VARILRIX should be postponed in children and adults suffering from acute severe febrile illness. In healthy children and adults, the presence of a minor infection, however, is not a contraindication to immunisation.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

VARILRIX must not be administered intravascularly or intradermally

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in a place to avoid injury from faints.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of rare anaphylactic reactions following the administration of a vaccine.

Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine since they can inactivate the attenuated viruses in the vaccine.

Transmission of the Oka vaccine virus has been shown to occur at a very low rate in seronegative contacts of vaccinees with rash. Transmission of the Oka vaccine from a vaccinee who does not develop a rash to seronegative contacts cannot be excluded.

The mild nature of the rash which developed in the healthy contacts indicates that the virus remains attenuated after passage through human hosts. Vaccine recipients should attempt to avoid contact with susceptible high risk individuals for up to 6 weeks, where possible.

As for any vaccine, vaccination with VARILRIX may not result in protection from subsequent infection with varicella virus in 100% of susceptible persons given the vaccine (see Section 5.1 PHARMACODYNAMIC PROPERTIES, Clinical trials).

As for other varicella vaccines, cases of varicella disease have been shown to occur in persons who have previously received VARILRIX. These breakthrough cases are usually mild, with a fewer number of lesions and less fever as compared to cases in unvaccinated individuals.

The duration of protection from varicella infection with VARILRIX is unknown. The need for and timing of booster doses is uncertain at present. In a highly vaccinated population, immunity of some individuals may wane due to lack of exposure to natural varicella as a result of shifting epidemiology.

It is not known whether VARILRIX given immediately after exposure to wild varicella virus will prevent illness. Results of a small household contact study using another live varicella virus vaccine containing the same varicella strain as VARILRIX suggested that some protection was provided by that vaccine when vaccination occurred within 72 hours of exposure.

There are inadequate data to assess the incidence and severity of herpes zoster (shingles) after vaccination with VARILRIX.

There is limited data on the use of VARILRIX in immunocompromised patients, therefore vaccination should be considered with caution and only when, in the opinion of the physician, the benefits outweigh the risks, further guidance is found in the Australian Immunisation Handbook.

Immunocompromised patients who have no contraindication for this vaccination (see Section 4.3 CONTRAINDICATIONS) may not respond as well as immunocompetent children and adults, therefore some of these patients may acquire varicella despite appropriate vaccine administration. Immunocompromised patients should be monitored carefully for signs of varicella.

Very few reports exist on disseminated varicella with internal organ involvement following vaccination with the Oka varicella vaccine strain and these are mainly in immunocompromised patients.

Use in the elderly

No data available.

Paediatric use

See Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

VARILRIX should not be mixed in the same syringe with other vaccines. Different injection sites should always be used.

There was no reduction in safety and immunogenicity when VARILRIX was given concomitantly, at a separate site, using a separate syringe, with a Measles-Mumps-Rubella vaccine and with a Diphtheria-Tetanus-Acellular pertussis vaccine. There are no data on concomitant administration with other live or inactivated vaccines or on administration of vaccines after VARILRIX has been given. If it is necessary to administer more than 1 live virus vaccine at the same time, these may be given at the same visit at different sites. If not given on the same day, the live viral vaccinations should be separated by an interval of at least 4 weeks.

If tuberculin testing has to be done it should be carried out before or simultaneously with vaccination since it has been reported that live viral vaccines may cause a temporary depression of tuberculin skin sensitivity. As this anergy may last up to a maximum of 6 weeks, tuberculin testing should not be performed within that period after vaccination to avoid false negative results.

VARILRIX may be administered at the same time as a measles-containing vaccine. If this is not possible, an interval of at least one month should elapse before the measles-containing vaccine is given. Measles vaccination may lead to short lived suppression of the cell mediated immune response.

In children and adults who have received immune globulin or a blood transfusion, immunisation should be delayed for at least three months because of the likelihood of vaccine failure due to passively acquired varicella antibodies.

Salicylates should be avoided for 6 weeks after varicella vaccination as Reye's syndrome has been reported following the use of salicylates during natural varicella infection.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy

(Pregnancy Category B2)

Pregnant women must not be vaccinated with VARILRIX. Pregnancy should be avoided for one month after vaccination. Women who intend to become pregnant should be advised to delay pregnancy.

Adequate human data on the use of VARILRIX during pregnancy are not available and animal studies on reproductive toxicity have not been conducted.

Use in lactation

The effect on breast fed infants of the administration of VARILRIX to their mothers has not been evaluated in clinical studies.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Clinical Trial Data

More than 5500 subjects aged 9 months and over have been vaccinated with VARILRIX in ongoing and completed trials. Pain at the injection site was usually described as mild, and swelling and redness >2cm in diameter were infrequently observed.

No serious adverse events were considered to be unequivocally related to vaccination.

In the four week follow-up of a double-blind, placebo-controlled efficacy study in children aged 12-30 months (n=513), there was no significant difference in the nature or incidence of symptoms in subjects who received the vaccine compared to placebo.

In the adolescent/adult studies there was no increase in reactogenicity following the second dose. The incidence of symptoms after vaccination of seropositive individuals was not different from that of seronegative subjects.

Table 1: Percentage of Vaccinees reporting solicited symptoms with respect to placebo recipients

	Children		**Adolescents**		**Adults**	
	VARILRIX (N = 340)	placebo (N = 172)	VARILRIX (N = 333)	placebo (N = 112)	VARILRIX (N = 108)	placebo (N = 58)
Local reactions	8.2%	7.6%	2.4%	0%	25.9%	13.8%
Fever* (temperature ≥ 38°C) ***(> 39.5°C)***	51.8% *(5.9%)*	51.2% *(5.2%)*	1.8% *(0%)*	2.7% *(0%)*	26.9% *(0%)*	24.1% *(0%)*
Rash (any) ***(varicella-like vesicular rash)***	37.4% *(6.2%)*	36.6% *(5.2%)*	0.6% *(0.3%)*	1.8% *(0%)*	6.7% *(1.0%)*	7.9% *(1.6%)*

Total post-vaccination period for evaluation of adverse events: 42 days for children (28 days for local reactions and fever), 98 days for adolescents and 126 days for adults.

*Not solicited in all trials.

AE reporting rate was highly variable, depending on study methodology

In non-placebo controlled trials, the incidence of local and general adverse events varied widely, which may in part reflect the differing methodologies used for collection of the safety data.

The adverse events listed below are by body system and are categorised by frequency according to the following definitions: very common events reported at a frequency of greater or equal to 1/10 patients; common events are reported at a frequency of less than 1/10 but greater or equal to 1/100 patients; uncommon events reported at a frequency of less than 1/100 but greater or equal to 1/1000; rare events reported at a frequency of less than 1/1000 but greater or equal to 1/10000; very rare events reported at a frequency of less than 1/10000 patients. Causality has not necessarily been established.

Events reported in children

Local reactions
Very common: Pain at the injection site; redness, swelling
Common: swelling (>2cm), redness (>2cm), injection site reaction
Uncommon: contact dermatitis

A trend for higher incidence of pain, redness and swelling after the second dose was observed as compared to the first dose.

Body as a whole
Common: Fever, rash, injury, viral infection
Uncommon: Varicella-like rash, fever >39°C, fatigue, pain, infection, bacterial infection, fungal infection
Uncommon: malaise

Blood and lymphatic system disorders
Uncommon: lymphadenopathy

Skin and appendages
Common: Pruritis, *Uncommon*: Eczema, purpura, sweat gland disorder, dry skin
Rare: urticaria

Gastrointestinal
Common: Diarrhoea, abdominal pain, vomiting, toothache
Uncommon: Nausea, dyspepsia

Musculo-skeletal
Uncommon: Arthralgia, myalgia

Central Nervous System
Common: Headache, nervousness
Uncommon: somnolence, irritability

Respiratory
Common: URTI, coughing, pharyngitis, rhinitis
Uncommon: asthma, sinusitis, respiratory disorder

Special Senses
Common: conjunctivitis, otitis media
Uncommon: earache

Events reported in adults (after dose 1 and/or dose 2)

Local reactions
Very common: Pain at the injection site, injection site reaction, redness, injection site inflammation
Common: injection site mass

Body as a whole
Very Common: Fever
Common: fatigue, chest pain, injury, malaise; infection viral; swelling at the injection site
Uncommon: Varicella-like rash

Skin and appendages
Common: Dermatitis, pruritis, rash
Rare: urticaria

Gastrointestinal
Common: Diarrhoea, abdominal pain, vomiting, nausea, gastroenteritis

Central Nervous System
Very common: headache
Common: dizziness, migraine, somnolence
Uncommon: irritability

Respiratory
Very common: URTI, pharyngitis
Common: asthma, bronchitis, coughing, sinusitis, rhinitis, sputum increased

Haematologic/lymphatic
Common: Lymphadenopathy, lymphadenopathy cervical

Musculo-skeletal
Common: Arthralgia, back pain, myalgia

Special Senses
Rare: conjunctivitis

Post-marketing Data

More than 15 million doses of VARILRIX have been distributed since first approval in October 1994.

During post-marketing surveillance, the following additional reactions have been reported after varicella vaccination:

Varicella-like rashes occurring >2 weeks after vaccination have been reported *very rarely*. The median number of vesicles reported was 50, and fever was reported as present in approximately one-third of all cases of breakthrough disease.

Infections and infestations
Very Rare: varicella
Rare: herpes zoster

Blood and lymphatic system disorders
Rare: thrombocytopenia

Immune system disorders
Rare: hypersensitivity, anaphylactic reactions

Nervous system disorders
Rare: encephalitis, cerebrovascular accident, cerebellitis, cerebellitis like symptoms (including transient gait disturbance and transient ataxia), convulsions

Vascular disorders
Rare: vasculitis (including Henoch Schonlein purpura and Kawasaki syndrome)

Skin and subcutaneous tissue disorders
Rare: erythema multiforme

The following additional side effects have been reported regardless of causality since the vaccine has been marketed:

Skin
Stevens-Johnson syndrome

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Cases of accidental administration of more than the recommended dose of VARILRIX have been reported. Amongst these cases, the following adverse events were reported: lethargy and convulsions. In the other cases reported as overdose there were no associated adverse events.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

VARILRIX produces an attenuated clinically inapparent varicella infection in susceptible subjects, with the subsequent production of varicella-specific antibodies

Clinical trials

Efficacy studies

The efficacy of GlaxoSmithKline (GSK)'s Oka/RIT varicella vaccines in preventing confirmed varicella disease (varicella cases were confirmed by, polymerase chain reaction {PCR} or exposure to a varicella case) has been evaluated in a large active controlled clinical trial in which children aged 12-22 months received one dose of VARILRIX (N = 2263) or two doses of PRIORIX-TETRA (N = 2279). The co-primary objective of this trial with respect to VARILRIX was to demonstrate vaccine efficacy of ≥60% in comparison to PRIORIX. The efficacy of VARILRIX (one dose) versus PRIORIX in respect of preventing confirmed varicella cases was 65.4% (97.5% CI: 57.2-72.1%), the lower limit of the 2-sided 97.5% CI however did not exceed the pre-defined criterion of 60%. The observed vaccine efficacy against confirmed varicella of any severity and against moderate or severe confirmed varicella after one dose of VARILRIX and after 2 doses of PRIORIX-TETRA (mean follow-up period 35 months) are presented in Table 2.

Table 2: Efficacy results after one dose of VARILRIX compared to 2 doses of PRIORIX TETRA

Group	N	n	Vaccine Efficacy 97.5%CI
Efficacy against confirmed Varicella of any Severity			
VARILRIX	2263	243	65.4% 57.2 – 72.1
PRIORIX-TETRA	2279	37	94.9% 92.4 – 96.6
Efficacy against confirmed Moderate or Severe Varicella			
VARILRIX	2263	37	90.7% 85.9 – 93.9
PRIORIX-TETRA	2279	2	99.5% 97.5 – 99.9

N= Number of subjects included in each group

n = Number of subjects reporting at least one event(s) in each group

In another randomised placebo-controlled trial conducted in children (n=327) 12 - 30 months of age one dose of VARILRIX vaccine was administered and followed up for an average of 29.3 months. The protective efficacy against common clinical cases of varicella was 100% and against clinical varicella of any severity was calculated as 88% (95% CI 72-96). The median number of vesicles in breakthrough cases in children was 2 (placebo group median = 30).

In a randomised placebo-controlled trial conducted in adults (n=233) two doses of VARILRIX vaccine were administered at an interval of 2 months and then followed up for an average of 18 months. Efficacy against clinical varicella of any severity was conservatively estimated at 75.9% (95% CI 43.8-89.7); errors in the methodology used in this trial imply that efficacy cannot be accurately determined. Of the 11 vaccinees with breakthrough disease, only 2 had >200 vesicles, compared with 57% of the unvaccinated subjects.

In both trials, subjects who responded to vaccination and who later developed breakthrough varicella had fewer lesions than unvaccinated individuals, demonstrating attenuation of varicella infection for those subjects who were not protected completely.

In a 3 year follow-up study, lower incidences of varicella breakthrough cases were reported in the group receiving two-doses of PRIORIX-TETRA (1 case, 0.44%) than in the group receiving only one dose of VARILRIX (4 cases, 5.06%), however the number of breakthrough cases were too small to make any conclusion about comparative vaccine efficacy. No cases of measles, mumps or rubella breakthrough disease were reported in any group during this 3 years follow-up.

Effectiveness studies

Effectiveness data suggest a higher level of protection and a decrease in breakthrough varicella following two doses of vaccine than following one dose.

The effectiveness of one dose of VARILRIX was estimated in different settings (outbreaks, case-control and database studies) and ranged from 20%-92% against any varicella disease and from 86%-100% against moderate or severe disease.

The impact of one dose of VARILRIX in reducing varicella hospitalizations and ambulatory visits among children in a study performed in Uruguay were respectively 81% and 87% overall.

Immunogenicity Studies

One-dose regimen in children

In subjects aged 9 months to 36 months (n=1573), the overall seroconversion rate following administration of VARILRIX was greater than 98.0% when measured 6 weeks post vaccination. Seroconversion was defined as postvaccination titres ≥ 4 dil^{-1} in a subject with prevaccination titres <4 dil^{-1}, and was determined using a commercial indirect immunofluoresence assay (IFA).

Two-dose regimen in children

In children aged 9 months to 6 years who received two doses of VARILRIX the seroconversion rate, when measured by IFA 6 weeks after vaccination, was 100% after a second vaccine dose. A marked increase of antibody titres was observed following the administration of a second dose (5 to 26-fold GMT increase).

In children aged 11 months to 21 months who received two doses of VARILRIX, the seroconversion rate, when measured by ELISA (seroconversion was defined as post-vaccination titres > 50mIU/mL) 6 weeks after vaccination, was 89.6% after one vaccine dose and 100% after the second vaccine dose.

The following Table 3 presents the range of results seen in 13 clinical trials evaluating the immunogenicity of VARILRIX in infants, adolescents and adults measured by IFA. GMTS are variable across studies, a recognised characteristic of live viral vaccines.

Table 3: Immunogenicity of VARILRIX measured by IFA

AGE RANGE	N	Seroconversion rate %	GMT
9-36 mths			
- Dose 1	1467	92.9 - 100	31 - 104
-			
≥ 12 years			
- Dose 1	350	82.3 - 94.1	20 - 40
- Dose 2	271	100	167 - 236

The seroconversion rate in children aged 12-22 months in the large efficacy trial as measured by ELISA (50 mIU/mL) 6 weeks after one dose of VARILRIX and 6 weeks after two doses of Oka/RIT containing vaccines were 79.2% and 99.6%, respectively.

An increase in the antibody levels of vaccinees who remained seropositive was seen in studies which assessed persistence of antibody response. This suggests boosting due to

exposure to varicella virus in the community. The antibodies have been shown to persist for at least 3 years after vaccination.

Three years after vaccination with two doses of PRIORIX-TETRA, 98.5%, 97.4%, 100% and 99.4% of all vaccinees were still seropositive for respectively anti-measles, anti-mumps, anti-rubella and anti-varicella antibodies.

There is no clinical data available with regards to the persistence and effectiveness of two doses of VARILRIX.

Studies comparing the current formulation of VARILRIX (human albumin-free) with the previous formulation containing human albumin, demonstrated similar immune responses with both formulations. The current formulation of VARILRIX (albumin-free) also demonstrated a similar reactogenicity and safety profile.

5.2 PHARMACOKINETIC PROPERTIES

Not relevant to vaccines.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

The vaccine also contains amino acids, lactose, mannitol and sorbitol. VARILRIX does not contain a preservative. Neomycin sulphate is present as a residual from the manufacturing process.

6.2 INCOMPATIBILITIES

VARILRIX should not be mixed in the same syringe with other vaccines.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

The lyophilised vaccine should be stored in a refrigerator between 2°C and 8°C. The diluent can be stored in the refrigerator or at ambient temperatures. The lyophilised vaccine is not affected by freezing.

When supplies of VARILRIX are distributed from a central cold store, it is necessary to arrange transport under refrigerated conditions.

6.5 NATURE AND CONTENTS OF CONTAINER

VARILRIX is presented as a slightly cream to yellowish or pinkish coloured powder in a glass vial. The sterile diluent is clear and colourless and presented in ampoules and prefilled syringes.

VARILRIX is supplied as:

- a box containing 10 single dose vials of lyophilised vaccine (needles not supplied);
- a box containing a single dose vial of lyophilised vaccine with a diluent syringe included (available in packs of 1 or 10; needles may or may not be included)
- a box containing a single dose vial of lyophilised vaccine with diluent ampoule included (available in packs of 1 or 10; needles not supplied)

Not all pack sizes and container types may be distributed in Australia.

The ampoules, vials and prefilled syringes are made of neutral glass type I, which conforms to European Pharmacopoeia Requirements.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Not relevant to vaccines.

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 4 – Prescription Only Medicine

8 SPONSOR

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street,
Abbotsford, Victoria, 3067, Australia

9 DATE OF FIRST APPROVAL

16 April 2015

10 DATE OF REVISION

1 March 2022

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
2	Revised to include excipients of known effect
6.1	Revised excipient ingredient name

Version 6.0