

# VARILRIX

## SCHEDULING STATUS:

**S4**

### 1. NAME OF THE MEDICINE:

VARILRIX Lyophilised virus vaccine. Powder for solution and injection.

### 2. QUALITATIVE AND QUANTITATIVE:

VARILRIX is a lyophilised preparation of the live attenuated OKa strain of the varicella-zoster virus, obtained by propagation of the virus in MRC<sub>5</sub> human diploid cell culture.

Each 0,5 ml of the reconstituted vaccine contains not less than 2000 plaque forming units (PFU) of the live attenuated varicella-zoster (OKa strain) virus.

Contains sugar (anhydrous lactose 32 mg/dose) and sugar alcohol (mannitol 8 mg/dose, sorbitol 6 mg/dose).

For full list of excipients, see 6.1.

### 3. PHARMACEUTICAL FORM:

Powder for solution and injection.

**Vaccine:** Cream to yellowish or pinkish coloured cake or powder of lyophilised vaccine.

**Diluent:** Clear and colourless liquid.

### 4. CLINICAL PARTICULARS:

#### 4.1 Therapeutic Indications:

**Healthy subjects:** VARILRIX is indicated for active immunisation against varicella of healthy infants (from the age of 9 months), children and adolescents.

**High-risk patients and healthy close contacts:** VARILRIX is also indicated for active immunisation against varicella of susceptible high-risk patients and their susceptible healthy close contacts.

**Patients with acute leukaemia:** Patients suffering from leukaemia have been recognised to be at special risk when they develop varicella and should therefore receive the vaccine if they have no history of the disease or are found to be seronegative.

**When immunising patients in the acute phase of leukaemia:** Maintenance chemotherapy should be withheld one week before and one week after immunisation. Patients under radiotherapy should normally not be immunised during the treatment phase.

**Patients under immunosuppressive treatment:** Patients under immunosuppressive treatment (including corticosteroid therapy) for malignant solid tumours or for serious chronic diseases (such as chronic renal failure, auto-immune diseases, collagen diseases, severe bronchial asthma) are predisposed to severe varicella.

Generally, patients are immunised when they are in complete haematological remission from the disease. It is advised that the total lymphocyte count should be at least  $1\ 200/\text{mm}^3$  or no other evidence of lack of cellular immune competence exists.

**Patients with planned organ transplantation:** If organ transplantation (e.g., kidney transplant) is being considered, immunisation should be carried out a few weeks before the administration of the immunosuppressive treatment.

**Patients with chronic diseases:** Other chronic diseases, such as metabolic and endocrine disorders, chronic pulmonary and cardiovascular diseases, mucoviscidosis and neuromuscular abnormalities may also predispose to severe varicella.

**Healthy close contacts:** Susceptible healthy close contacts should be immunised in order to reduce the risk of transmission of the virus to high-risk patients. These include parents and

siblings of high-risk patients and medical, paramedical personnel and other people who are in close contact with varicella patients or high-risk patients.

#### **4.2 Posology and method of administration:**

##### **Posology:**

0,5 ml of reconstituted vaccine contains one immunising dose.

##### **Healthy Subjects:**

- **Children 9 months up to and including 12 years of age:**

Children from the age of 9 months up to and including 12 years of age should receive 2 doses of VARILRIX to ensure optimal protection against varicella.

It is preferable to administer the second dose at least 6 weeks after the first dose but in no circumstances less than 4 weeks.

- **Adolescents and adults from 13 years of age and above:**

From 13 years of age and above: 2 doses. It is preferable to administer the second dose at least 6 weeks after the first dose but in no circumstances less than 4 weeks.

##### **High-risk patients:**

In high-risk patients additional doses of vaccine might be 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:**

VARILRIX is to be injected subcutaneously (SC) or intramuscularly (IM) in the deltoid region or in the anterolateral area of the thigh.

VARILRIX should **not** be administered intradermally.

VARILRIX should be administered subcutaneously in subjects with bleeding disorders (e.g., thrombocytopenia or any coagulation disorder).

**Note:** VARILRIX must under no circumstances be administered intravenously.

**Use and handling:**

The diluent and the reconstituted vaccine 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 diluent or the reconstituted vaccine.

VARILRIX must be reconstituted by adding the contents of the supplied container of diluent to the vial containing the powder. The mixture should be well shaken until the powder is completely dissolved in the diluent. Due to minor variations of its pH, the colour of the reconstituted vaccine may vary from clear peach to pink coloured solution.

***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 immediately.

Withdraw the entire contents of the vial.

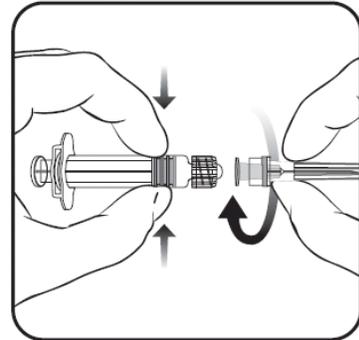
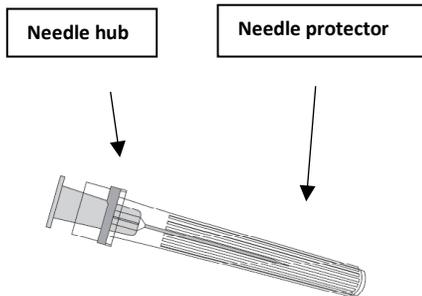
A new needle should be used to administer the vaccine. The administration needle should be for subcutaneous or intramuscular injection.

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

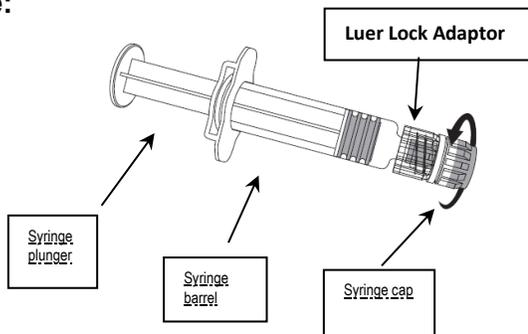
VARILRIX must be reconstituted by adding the entire content of the pre-filled syringe of diluent to the vial containing the powder.

To attach the 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.

**Needle:**



**Syringe:**



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 the 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 immediately.

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 the injection needle by repeating step 2 above. The administration needle should be for subcutaneous or intramuscular injection.

#### **4.3 Contraindications:**

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

- subjects with primary or acquired immunodeficiency states, with a total lymphocyte count less than 1 200 per mm<sup>3</sup>
- subjects presenting other evidence of lack of cellular immune competence (e.g., subjects with leukaemia's, lymphomas, blood dyscrasias, clinically manifest HIV infection)
- subjects receiving immunosuppressive therapy, including high dose corticosteroids (see section 4.4).

VARILRIX is contraindicated in subjects with known hypersensitivity to neomycin, or to any component of the vaccine. A history of contact dermatitis to neomycin is not contraindicated.

VARILRIX is contraindicated in pregnant women. Pregnancy should be avoided for one month after immunisation (see section 4.6).

In high-risk patients, VARILRIX should not be administered at the same time as other live attenuated vaccines. Inactivated vaccines may be administered in any temporal relationship to VARILRIX, given that no specific contra-indication has been established.

#### **4.4 Special warnings and precautions for use:**

The administration of VARILRIX should be postponed in patients suffering from acute severe febrile illness. In healthy subjects, the presence of minor infection, however, is not a contraindication for immunisation.

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 place to avoid injury from faints.

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.

Limited protection against varicella may be obtained by vaccination up to 72 hours after exposure to natural disease.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

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.

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.

It is advised that contact of vaccinees with persons who may be immunocompromised due to HIV infection or other immunodeficiency should be avoided for at least 14 days post immunisation.

There is limited data on the use of VARILRIX in immunocompromised subjects, therefore vaccination should be considered with caution and only when, in the opinion of the physician, the benefits outweigh the risks.

Immunocompromised subjects who have no contraindication for this vaccination (see section 4.3) may not respond as well as immunocompetent subjects, therefore some of these subjects

may acquire varicella despite appropriate vaccine administration. Immunocompromised subjects should be monitored carefully for signs of varicella.

Very few reports exist on disseminated varicella with internal organ involvement following vaccination with Oka varicella vaccine strain mainly in immunocompromised subjects.

In high-risk patients VARILRIX should not be administered at the same time as other live attenuated vaccines.

VARILRIX must not be administered intravascularly or intradermally.

Appropriate medical treatment should always be readily available including adrenaline in case of rare anaphylactic reactions following administration of the vaccine. For this reason, the vaccinee should remain under medical supervision for 30 minutes after immunisation.

It must be expected that the reactogenicity following co-administration of VARILRIX and more reactogenic vaccines will be determined by the reactions of the latter.

#### **Excipient Warnings:**

VARILRIX contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not be given VARILRIX (see section 6.1).

VARILRIX contains traces of neomycin. VARILRIX should not be used in patients with a known hypersensitivity to this antibiotic.

#### **4.5 Interactions with other medicines and other forms of interaction:**

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.

In subjects who have received immune globulin or a blood transfusion, immunisation should be delayed for at least three months because of likelihood of vaccine failure 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.

**Healthy subjects:**

VARILRIX can be administered at the same time as any other vaccines. Different injectable vaccines should always be administered at different injection sites.

Should a measles containing vaccine not be given at the same time as VARILRIX, it is recommended that an interval of at least one month should be respected, since it is recognised that measles vaccination may lead to short lived suppression of the cell-mediated immune response.

**High-risk patients:**

VARILRIX should not be administered at the same time as other live attenuated vaccines. Inactivated vaccines may be administered in any temporal relationship to VARILRIX, given that no specific contraindication has been established. However, different injectable vaccines should always be administered at different injection sites (see section 4.3).

**4.6 Fertility, pregnancy and lactation:**

**Pregnancy:**

VARILRIX is contraindicated during pregnancy. Pregnant women must not be vaccinated with VARILRIX. Pregnancy should be avoided for one month after immunisation (see section 4.3).

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.

**Breastfeeding:**

Administration of VARILRIX is not advised during breastfeeding.

**Fertility:**

No data available.

**4.7 Effects on ability to drive and use machines:**

It would not be expected that vaccination would affect the ability to drive or operate machinery.

**4.8 Undesirable effects:**

**Clinical trial data:**

**Healthy subjects:**

More than 7900 individuals have participated in clinical trials evaluating the reactogenicity profile of the vaccine administered subcutaneously either alone or concomitantly with other vaccines.

The safety profile presented below is based on a total of 5 369 doses of VARILRIX administered alone to children, adolescents and adults.

Frequencies are reported as follows:

Very common:  $\geq 1/10$

Common:  $\geq 1/100$  to  $< 1/10$

Uncommon:  $\geq 1/1\ 000$  to  $< 1/100$

Rare:  $\geq 1/10\ 000$  to  $< 1/1\ 000$

Very rare:  $< 1/10\ 000$ , including isolated reports.

<b>System organ class</b>	<b>Frequency</b>	<b>Adverse reactions</b>
<b><i>Infections and infestations</i></b>	Uncommon	upper respiratory tract infection, pharyngitis
<b><i>Blood and lymphatic system disorders</i></b>	Uncommon	lymphadenopathy
<b><i>Psychiatric disorders</i></b>	Uncommon	irritability

<b><i>Nervous system disorders</i></b>	Uncommon	headache, somnolence
<b><i>Eye disorders</i></b>	Rare	conjunctivitis
<b><i>Respiratory, thoracic and mediastinal disorders</i></b>	Uncommon	cough, rhinitis
<b><i>Gastrointestinal disorders</i></b>	Uncommon	nausea, vomiting
	Rare	abdominal pain, diarrhoea
<b><i>Skin and subcutaneous tissue disorders</i></b>	Common	rash
	Uncommon	varicella-like rash, pruritus
	Rare	urticaria
<b><i>Musculoskeletal and connective tissue disorders</i></b>	Uncommon	arthralgia, myalgia
<b><i>General disorders and administration site conditions</i></b>	Very common	pain, redness
	Common	swelling at the injection site*, fever (oral/axillary temperature $\geq 37,5$ C or rectal temperature $\geq 38,0$ C)*
	Uncommon	fever (oral/axillary temperature $> 39,0^{\circ}\text{C}$ or rectal temperature $> 39,5^{\circ}\text{C}$ ), fatigue, malaise

\* Swelling at the injection site and fever were reported very commonly in studies conducted in adolescents and adults. Swelling was also reported very commonly after the second dose in children under 13 years of age.

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

No differences were seen in the reactogenicity profile between initially seropositive and initially seronegative subjects.

In a clinical trial, 328 children aged 11 to 21 months received GSK's combined measles, mumps, rubella and varicella vaccine (containing the same varicella strain as VARILRIX) either by subcutaneous or intramuscular route. A comparable safety profile was observed for both administration routes.

**High-risk patients:** There are only very limited data from clinical trials available in patients at high risk of severe varicella. However, vaccine-associated reactions (principally papulo-vesicular eruptions and fever) are usually mild. As in healthy subjects, redness, swelling and pain at the site of injection are mild and transient.

**Post-marketing data:**

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

**Infections and infestations:** herpes zoster

**Blood and lymphatic disorders:** thrombocytopenia

**Immune system disorders:** hypersensitivity, anaphylactic reactions

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

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

**Skin and subcutaneous tissue disorders:** erythema multiforme.

**Reporting of suspected adverse events:**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions**

**Reporting Form**”, found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>.

**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. See section 4.8. Treatment is symptomatic and supportive.

## 5. PHARMACOLOGICAL PROPERTIES:

### 5.1 Pharmacodynamic properties:

A 30.2 Biologicals, Antigens

VARILRIX produces an attenuated clinically inapparent varicella infection in susceptible subjects. The presence of antibodies is accepted to be an indication of protection.

The efficacy of GlaxoSmithKline (GSK)'s Oka varicella vaccines in preventing confirmed varicella disease (by Polymerase Chain Reaction (PCR) or exposure to varicella case) has been evaluated in a large active controlled multicountry clinical trial in which children aged 12-22 months received one dose of VARILRIX or two doses of combined measles, mumps, rubella and varicella (Oka) vaccine. Vaccine efficacy against confirmed varicella of any severity and against moderate or severe confirmed varicella was demonstrated after a primary follow-up period of 2 years (median duration 3,2 years). Persistent efficacy was observed in the same study during the long-term follow-up period of 6 years (median duration 6,4 years) and 10 years (median duration 9,8 years). The data are presented in the Table below.

<b>Group</b>	<b>Timing</b>	<b>Efficacy against confirmed varicella of any severity</b>	<b>Efficacy against moderate or severe confirmed varicella</b>
<b>VARILRIX (1 dose)</b>	Year 2	65,4 % (97,5 % CI: 57,2;72,1)	90,7 % (97,5 % CI: 85,9;93,9)

<b>N = 2 487</b>	Year 6 <sup>(1)</sup>	67,0 % (95 % CI: 61,8;71,4)	90,3 % (95 % CI: 86,9;92,8)
	Year 10 <sup>(1)</sup>	67,2 % (95% CI: 62,3;71,5)	89,5 % (95% CI: 86,1;92.1)
<b>Combined measles, mumps, rubella and varicella (Oka) vaccine (2 doses) N = 2 489</b>	Year 2	94,9 % (97,5 % CI: 92,4;96,6)	99,5 % (97,5 % CI: 97,5;99,9)
	Year 6 <sup>(1)</sup>	95,0 % (95 % CI: 93,6;96,2)	99,0 % (95 % CI: 97,7;99,6)
	Year 10 <sup>(1)</sup>	95,4 % (95 % CI: 94,0;96,4)	99,1 % (95 % CI: 97,9;99,6)

N = number of subjects enrolled and vaccinated

(1) descriptive analysis

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 hospitalisations and ambulatory visits among children were respectively 81 % and 87 % overall.

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

#### **Immune response after intramuscular administration:**

The immunogenicity of VARILRIX administered intramuscularly is based on a comparative study where 283 healthy children aged 11 to 21 months received GSK's combined measles, mumps, rubella and varicella vaccine (containing the same varicella strain as VARILRIX) either by subcutaneous or intramuscular route. Comparable immunogenicity was demonstrated for both administration routes.

## **5.2 Pharmacokinetic properties:**

Evaluation of pharmacokinetic properties is not required for vaccines.

## **6. PHARMACEUTICAL PARTICULARS:**

### **6.1 List of Excipients:**

Powder: amino acids, lactose, mannitol and sorbitol.

Diluent: water for injection.

Residues: neomycin sulphate.

### **6.2. Incompatibilities:**

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

### **6.3 Shelf life:**

24 months

### **6.4 Special precautions for storage:**

Store in refrigerator between +2 °C and +8 °C. Protect from light.

Discard any unused portion.

Keep all medicines out of reach of children.

### **6.5 Nature and contents of container:**

The vaccine is presented in a 3 ml clear glass vial with a rubber stopper.

The diluent is presented in a clear glass ampoule or a pre-filled syringe with 2 needles.

### **6.6 Special precautions for disposal and other handling:**

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

**Appearance of Reconstituted vaccine:** Clear peach to pink coloured solution, free from visible particles.

**7. HOLDER OF CERTIFICATE OF REGISTRATION:**

GlaxoSmithKline South Africa (Pty) Ltd  
39 Hawkins Avenue  
Epping Industria 1, 7460

**8. REGISTRATION NUMBER:**

32/30.1/0468

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:**

Date of registration: 11 January 2000

**10. DATE OF REVISION OF TEXT:**

21 June 2021

GDS-15

Namibia: Reg No 04/30.1/0879 NS1

Manufacturing details

Lyophilised powder in vials:

Corixa Corporation dba GlaxoSmithKline Vaccines

325 North Bridge Street  
Marietta, Pennsylvania 17547  
USA

Lyophilised powder in vials:  
GlaxoSmithKline Biologicals SA  
Rue de l'Institut, 89  
1330 Rixensart  
Belgium

Water for injections in syringes:  
GlaxoSmithKline Biologicals SA  
Rue de l'Institut, 89  
1330 Rixensart  
Belgium

Water for injection in ampoules:  
Delpharm Tours  
Rue Paul Langevin  
BP 90241 37172 Chambray-lès-Tours  
France

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## Patient Information Leaflet

**SCHEDULING STATUS:** S4

### **VARILRIX Lyophilised virus vaccine. Powder for solution and injection**

Varicella vaccine

Contains sugar (anhydrous lactose 32 mg/dose) and sugar alcohol (mannitol 8 mg/dose, sorbitol 6 mg/dose).

### **Read all of this leaflet carefully before you are given VARILRIX:**

VARILRIX is not for self-medication and must be administered by a healthcare professional.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- VARILRIX has been prescribed for you personally and you should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

This leaflet has been written assuming the person receiving the vaccine is reading it, but it can be given to adults and children so you may be reading it for your child.

### **What is in this leaflet:**

1. What VARILRIX is and what it is used for
2. What you need to know before you use VARILRIX
3. How to use VARILRIX
4. Possible side effects
5. How to store VARILRIX
6. Contents of the pack and other information

## **1. What VARILRIX is and what it is used for:**

VARILRIX is a vaccine for use from 9 months of age to protect against illness caused by the varicella (chickenpox) virus. When a person is vaccinated with VARILRIX, the immune system (the body's natural defence system) will make antibodies to protect the person from being infected by varicella (chickenpox) virus.

## **2. What you need to know before you use VARILRIX:**

### **VARILRIX should not be administered to you, if you:**

- have any severe illness that weakens the immune system (such as blood disorders, cancer or infections)
- have recently received or are still taking treatment that weakens the immune system (including high dose corticosteroids)
- have previously had an allergic reaction to VARILRIX, neomycin (an antibiotic) or any component contained in this vaccine. However, if you have a skin rash (dermatitis) after treatment with neomycin, you can still be vaccinated with VARILRIX.
- you have a bleeding problem or bruise easily.

VARILRIX must not be given during pregnancy. Pregnancy should be avoided for one month following vaccination.

Check with your doctor if you think any of these apply to you.

### **Warnings and precautions:**

#### **Take special care with VARILRIX:**

Tell your doctor or healthcare provider before being given VARILRIX if:

- you have a severe infection with a high temperature. It might be necessary to postpone the vaccination until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first
- you have a history or family history of allergies
- you have a weakened immune system. You should be closely monitored as the responses to the vaccine may not be sufficient to ensure a protection against the illness
- you are due to have a skin test for possible tuberculosis. If this test is done within 6 weeks after receiving VARILRIX, the result may not be reliable.

Fainting can occur following, or even before, any needle injection, therefore, tell the doctor or nurse if you fainted with a previous injection.

VARILRIX cannot completely protect you against catching chicken pox. However, people who have been vaccinated and catch chicken pox usually have a very mild disease, compared with people who have not been vaccinated.

In rare cases the weakened virus can be passed on from a vaccinated person to others. This has only occurred when the person vaccinated had some spots or blisters. Healthy people who become infected in this way only develop a mild rash, which is not harmful.

People injected with VARILRIX should avoid contact for at least 14 days after vaccination with persons who have a poor immune system (e.g., due to HIV infection or other immune system disorder).

#### **Other medicines and VARILRIX:**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

If you have recently had a blood transfusion, or been given human immunoglobulin, your doctor may delay vaccination with VARILRIX for at least 3 months.

Aspirin or aspirin-type products (also known as salicylates) should not be taken for 6 weeks after vaccination with VARILRIX as this may cause a serious disease called Reye's Syndrome which can affect all your body organs.

If another vaccine is due to be given at the same time as VARILRIX, your doctor or nurse will advise you whether this can be given or whether it must be delayed.

A different place for the injection will be used for each vaccine.

### **Pregnancy, breastfeeding and fertility:**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice, before you are given VARILRIX.

VARILRIX **must not** be given to pregnant women.

If you are pregnant, think you may be pregnant or are trying to become pregnant, tell your doctor before VARILRIX is given.

It is also important that you do not become pregnant **within one month** after being vaccinated with VARILRIX. During this time, you should use an effective method of birth control to avoid pregnancy.

Ask your doctor for advice about breastfeeding before receiving VARILRIX.

### **VARILRIX contains lactose and neomycin:**

Patients who are intolerant to lactose should note that VARILRIX contains a small amount of lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before you are given VARILRIX.

VARILRIX contains traces of neomycin. Tell your doctor if you have had an allergic reaction to this antibiotic.

### **3. How to use VARILRIX:**

You will not be expected to give yourself VARILRIX. It will be given to you by a person who is qualified to do so. Your doctor or nurse will inject the recommended dose of vaccine. If more than one dose is necessary, the doctor will tell you.

VARILRIX will be given as an injection under the skin or into the muscle, either in the upper arm or in the outer thigh. The vaccine must never be injected into a vein. Your doctor may wipe the skin with alcohol or other disinfecting agents and will let the skin dry before the injection.

#### **4. Possible side effects:**

VARILRIX can have side effects.

As with all injectable vaccines, there is a small risk of allergic reactions. The signs of allergy may include symptoms such as difficulty in breathing or swallowing, itchy rash of the hands and feet, swelling of the eyes and face. Such reactions will usually occur before leaving the doctor's surgery, but in any event, you should seek immediate treatment.

**Frequent** side effects include:

- pain and redness at the injection site
- rash (spots and/or blisters)
- swelling at the injection site
- fever of 38 °C or more (rectal).

**Less frequent** side effects include:

- upper respiratory tract infection
- sore throat and discomfort when swallowing
- swollen glands in the neck, armpit or groin
- irritability
- headache
- sleepiness

- cough
- runny or blocked nose, sneezing (rhinitis)
- nausea
- vomiting
- chickenpox-like rash
- itching
- painful, swollen joints
- aching muscles, muscle tenderness or weakness, not caused by exercise
- fever greater than 39,5 °C (rectal)
- tiredness (fatigue)
- generally feeling unwell.

**Other** side effects include:

- discharge with itching of the eyes and crusty eyelids (conjunctivitis)
- stomach pain or discomfort
- diarrhoea
- hives (urticaria).

The following side effects have also been reported:

- shingles (herpes zoster)
- bleeding or bruising more easily than normal, due to a drop in a type of blood cells called platelets
- allergic reactions
- fits or seizures
- infection or inflammation of the brain, spinal cord and peripheral nerves, resulting in temporary difficulty when walking (unsteadiness) and/or temporary loss of control of body movements

- stroke
- narrowing or blockage of blood vessels. This may include unusual bleeding or bruising under the skin (Henoch Schonlein purpura) or fever which lasts for more than five days, associated with a rash on the trunk sometimes followed by a peeling of the skin on the hands and fingers, red eyes, lips, throat and tongue (Kawasaki disease)
- severe condition of the skin that may affect the mouth and other parts of the body.

If you or your child develops any other symptom within days following the vaccination, tell the doctor as soon as possible.

Not all side effects reported for this vaccine are included in this leaflet. Should your general health worsen while taking this vaccine, please consult your doctor, pharmacist or healthcare professional for advice.

#### **Reporting of side effects:**

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of VARILRIX.

#### **5. How to store VARILRIX:**

Store your vaccine in a refrigerator between +2 °C and +8 °C.

Keep in the original packaging to protect from light.

Discard any unused portion.

Store all medicines out of reach of children.

The expiry date is indicated on the packaging. The vaccine should not be used after this date.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. Contents of the pack and other information:**

### **What VARILRIX contains:**

After reconstitution, 1 dose (0,5 ml) of vaccine contains not less than 2 000 plaque forming units (PFU) of the live attenuated varicella-zoster (OKa strain) virus.

The other ingredients are amino acids, lactose, mannitol, sorbitol and water for injections.

Neomycin sulphate is present in trace amounts.

### **What VARILRIX looks like and contents of the pack:**

**Vaccine:** cream to yellowish or pinkish coloured cake or powder.

**Diluent:** clear and colourless liquid.

**Reconstituted vaccine:** clear peach to pink coloured solution.

The vaccine is presented in a 3 ml clear glass vial with a rubber stopper.

The diluent is presented in a clear glass ampoule or a pre-filled syringe, including 2 needles.

### **Holder of Certificate of Registration:**

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

### **This leaflet was last revised in:**

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## Pasiëntinligtingsvoubiljet

**SKEDULERINGSSTATUS:** S4

### **VARILRIX- geliofiliseerde virusvaksien. Poeier vir oplossing en inspuiting**

Varisella-vaksien

Bevat suiker. Elke 0,5 ml van die hersaamgestelde entstof bevat:

Bevat suiker (watervrye laktose 32 mg/dosis) en suiker alkohol (mannitol 8 mg/dosis, sorbitol 6 mg/dosis)

### **Lees hierdie hele voubiljet aandagtig deur voordat VARILRIX aan u gegee word:**

VARILRIX is nie as selfmedikasie bedoel nie en moet deur 'n gesondheidsorgkundige toegedien word.

- Hou hierdie voubiljet. U sal dit moontlik weer moet lees.
- Vra asseblief u dokter of u apteker as u verdere vrae het.
- VARILRIX is vir u persoonlik voorgeskryf, en u moenie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs as hulle simptome dieselfde as u simptome is.

Hierdie voubiljet is so geskryf dat daar aangeneem word dat die persoon wat die vaksien ontvang, die voubiljet lees, maar dit kan ook aan volwassenes en kinders gegee word, en dit is moontlik dat u dit aan u kind sal moet voorlees.

### **Wat in hierdie voubiljet vervat word:**

1. Wat VARILRIX is en waarvoor dit gebruik word
2. Wat u moet weet voordat u VARILRIX gebruik
3. Hoe om VARILRIX te gebruik
4. Moontlike neue-effekte

5. Hoe om VARILRIX te bewaar
6. Inhoud van die pakkie en ander inligting.

### **1. Wat VARILRIX is en waarvoor dit gebruik word:**

VARILRIX is 'n vaksien wat vanaf die ouderdom van 9 maande gebruik word om beskerming te bied teen siekte wat deur die varisellavirus (waterpokkievirus) veroorsaak word. Wanneer 'n persoon met VARILRIX gevaksineer word, sal die immuunstelsel (die liggaam se natuurlike verdedigingstelsel) teenliggaampies maak om die persoon teen infeksie deur die varisellavirus (waterpokkievirus) te beskerm.

### **2. Wat u moet weet voordat u VARILRIX gebruik:**

#### **VARILRIX moenie aan u toegedien word nie as u:**

- enige ernstige siekte het wat die immuunstelsel verswak (soos bloedversteurings, kanker of infeksies)
- onlangs behandeling ontvang het wat die immuunstelsel verswak (insluitend 'n hoë dosis kortikosteroïede) of as u dit steeds ontvang
- tevore 'n allergiese reaksie op VARILRIX, neomisien ('n antibiotikum), of enige komponent in hierdie vaksien ervaar het. As u egter 'n veluitslag (dermatitis) ervaar het nadat u met neomisien behandel is, kan u steeds met VARILRIX gevaksineer word
- 'n bloedingsprobleem het of maklik kneusplekke opdoen.

VARILRIX moenie gedurende swangerskap gegee word nie. Swangerskap moet vir een maand ná die vaksinering, vermy word.

Maak seker by u dokter as u dink dat enige hiervan op u van toepassing is.

## **Waarskuwings en voorsorgmaatreëls:**

### **Wees in die volgende gevalle besonder versigtig met VARILRIX:**

Sê vir u dokter of gesondheidsorgverskaffer van die volgende voordat die inspuiting aan u toegedien word:

- indien u 'n ernstige infeksie met 'n hoë koors het. Dit is moontlik dat die vaksinasie uitgestel sal moet word totdat u herstel het. 'n Geringe infeksie, soos 'n verkoue, behoort nie 'n probleem te wees nie, maar gesels eers met u dokter
- indien u 'n geskiedenis of 'n familiegeskiedenis van allergieë het
- indien u immuunstelsel verswak is. U moet noulettend gemonitor word omdat die reaksies op die vaksien moontlik nie voldoende kan wees om beskerming teen die siekte te verseker nie
- indien u 'n veltoets vir moontlike tuberkulose moet ondergaan. Indien hierdie toets binne 6 weke na ontvangs van VARILRIX gedoen word, is dit moontlik dat die resultaat nie betroubaar sal wees nie.

Floute kan voorkom ná, of selfs voor, enige inspuiting met 'n naald; vertel dus vir die dokter of verpleegkundige as u gedurende 'n vorige inspuiting flou geval het.

VARILRIX kan u nie heeltemal daarteen beskerm om waterpokkies op te doen nie. Mense wat egter gevaksineer is en waterpokkies ontwikkel, ervaar gewoonlik 'n baie ligte siekte in vergelyking met mense wat nie gevaksineer is nie.

In seldsame gevalle kan die verswakte virus van 'n gevaksineerde persoon na ander persone oorgedra word. Dit het slegs voorgekom toe die persoon wat gevaksineer is, 'n paar kolle of blasies gehad het. Gesonde persone wat op hierdie manier geïnfekteer word, ontwikkel slegs 'n ligte veluitslag, wat nie skadelik is nie.

Persone wat met VARILRIX ingespuut word, moet vir minstens 14 dae ná vaksineringskontak vermy met mense wat 'n swak immuunstelsel het (bv. as gevolg van MIV-infeksie of 'n ander immuunstelsel versteuring).

### **Ander medisyne en VARILRIX:**

Sê altyd vir u gesondheidsorgkundige as u enige ander medisyne neem. (Dit sluit aanvullende of tradisionele medisyne in.)

As u onlangs 'n bloedoortapping ondergaan het, of menslike immunoglobulien ontvang het, mag u dokter moontlik vaksineringskontak met VARILRIX vir minstens 3 maande uitstel.

Aspirien of produkte wat soos aspirien is (wat ook as salisilate bekend staan) behoort nie vir 6 weke ná vaksineringskontak met VARILRIX gegee te word nie omdat dit moontlik 'n ernstige siekte wat Reye se Sindroom genoem word, wat al die organe van u liggaam kan affekteer, mag veroorsaak..

Indien daar 'n ander vaksien terselfdertyd gegee moet word as VARILRIX, sal u dokter of verpleegkundige vir u sê of dit aan u gegee kan word en of die vaksien uitgestel moet word.

Daar sal vir elke vaksien 'n ander inspuutplek gebruik word.

### **Swangerskap, borsvoeding en vrugbaarheid:**

Raadpleeg asseblief u dokter, apteker of ander gesondheidsorgkundige vir advies voordat VARILRIX aan u gegee word as u swanger is of u baba borsvoed.

VARILRIX **moenie** aan swanger vroue gegee word nie.

As u swanger is, of dink dat u moontlik kan swanger wees, of as u probeer om swanger te raak, moet u vir u dokter daarvan sê voordat VARILRIX aan u gegee word.

Dit is ook belangrik dat u nie **binne een maand** ná vaksineringskontak met VARILRIX swanger raak nie.

U moet gedurende hierdie tydperk 'n doeltreffende geboorte beperkingsmetode gebruik om swangerskap te voorkom.

Vra u dokter vir advies oor borsvoeding voordat u VARILRIX ontvang.

### **VARILRIX bevat laktose en neomisien:**

Pasiënte wat laktose-intolerant is, moet daarop let dat VARILRIX 'n klein hoeveelheid laktose bevat. As u dokter vir u gesê het dat u 'n intoleransie vir sekere soorte suikers het, kontak u dokter voordat VARILRIX aan u gegee word.

VARILRIX bevat spore van neomisien. Sê vir u dokter as u 'n allergiese reaksie op hierdie antibiotikum gehad het.

### **3. Hoe om VARILRIX te gebruik:**

Daar sal nie van u verwag word om VARILRIX aan uself te gee nie. Dit sal aan u gegee word deur iemand wat gekwalifiseerd is om dit te doen. U dokter of verpleegkundige sal die aanbevole dosis van die vaksien inspuit. U dokter sal vir u sê as meer as een dosis nodig is.

VARILRIX sal as inspuiting onder die vel of in die spier, óf in die boarm óf in die buitekant van die bobeen, gegee word. Die vaksien moet nooit in 'n aar ingespuit word nie. U dokter kan moontlik die vel met alkohol of ander ontsmettingsmiddels afvee en sal die vel laat droog word voordat die inspuiting gegee word.

### **4. Moontlike neue-effekte:**

VARILRIX kan neue-effekte veroorsaak.

Soos vir alle inspuitbare vaksiene is daar 'n klein risiko vir allergiese reaksies. Die tekens van allergie kan moontlik simptome soos asemhaling of slukprobleme, veluitslag op die hande en voete wat jeuk, en swelling van die oë en gesig insluit. Sulke reaksies sal gewoonlik voorkom voordat u die dokter se spreekkamer verlaat. U moet in alle gevalle onmiddellik behandeling kry.

**Algemene** neue-effekte sluit in:

- pyn en rooiheid by die inspuitplek

- veluitslag (kolle en/of blasies)
- swelling by die inspuitplek
- koors van 38 °C of hoër (rektaal).

**Nie-algemene** newe-effekte sluit in:

- boonste lugweginfeksie
- seerkeel en ongemak met sluk
- swelling van die kliere in die nek, oksel of lies
- prikkelbaarheid
- hoofpyn
- slaperigheid
- hoes
- loopneus of toeneus, nies (rinitis)
- naarheid
- braking
- waterpokkies-agtige veluitslag
- jeuk
- pynlike, geswelde gewigte
- seer spiere, spierteerheid of -swakheid wat nie deur oefening veroorsaak word nie
- koors van hoër as 39,5 °C (rektaal)
- moegheid (uitputting)
- voel oor die algemeen ongesteld.

**Ander** newe-effekte sluit in:

- afskeiding met jeuk van die oë en korsvormig op die ooglede (konjunktivitis)
- maagpyn of -ongemak
- diarree

- galbulte (urtikarie).

Die volgende newe-effekte is ook aangemeld:

- gordelroos (herpes zoster)
- bloeding of doen makliker kneusplekke op as gewoonlik as gevolg van 'n vermindering in die telling van 'n soort bloedsel wat bloedplaatjies genoem word
- allergiese reaksies
- stuipe of aanvulle
- infeksie of inflammasie van die brein, rugmurg en perifere senuwees wat lei tot tydelike probleme om te loop (wankelrigheid) en/of tydelike verlies aan beheer van liggaamsbewegings
- beroerte
- vernouing of blokkasie van bloedvate. Dit kan moontlik insluit buitengewone bloeding of kneusing onder die vel (Henoch Schonlein-puntbloeding), of koors wat vir langer as vyf dae duur en gepaard gaan met 'n veluitslag op die bolyf, en soms volg afdop van die vel op die hande en voete, rooi oë, lippe, keel en tong (Kawasaki-siekte)
- ernstige veltoestand wat moontlik 'n uitwerking op die mond en ander dele van die liggaam kan hê.

Indien u of u kind binne dae ná die vaksinerings enige simptome ontwikkel, sê so gou as moontlik vir die dokter.

Nie al die newe-effekte wat vir hierdie vaksien aangemeld is, word by hierdie voubiljet ingesluit nie. Indien u algemene gesondheid agteruitgaan wanneer u hierdie vaksien ontvang, moet u asseblief u dokter, apteker of gesondheidsorgkundige vir advies raadpleeg.

**Aanmelding van newe-effekte:**

Praat met u dokter, apteker of verpleegkundige as u newe-effekte ervaar. U kan ook newe-effekte by SAHPRA aanmeld deur die “**6.04 Adverse Drug Reaction Reporting Form**” te

gebruik wat aanlyn onder SAHPRA se publikasies beskikbaar is:

<https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van VARILRIX te verskaf.

## **5. Hoe om VARILRIX te bewaar:**

Bewaar u vaksien tussen +2 °C en +8 °C in 'n yskas.

Hou dit in die oorspronklike verpakking om dit teen lig te beskerm.

Gooi enige ongebruikte gedeelte weg.

Bewaar alle medisyne buite die bereik van kinders.

Die vervaldatum word op die verpakking aangedui. Die vaksien moenie ná hierdie datum gebruik word nie.

Moenie wegdoen met medisyne in afvoerwater of huishoudelike vullis nie. Vra u apteker hoe om van medisyne ontslae te raak wat nie meer benodig word nie. Hierdie maatreëls sal die omgewing help beskerm.

## **6. Inhoud van die pakkie en ander inligting:**

### **Wat VARILRIX bevat:**

Ná hersamestelling bevat 1 dosis vaksien (0,5 mL) nie minder nie as 2 000 plaakvormende eenhede (PVE) van die lewende, verswakte varisella zoster(Oka-stam)-virus.

Die ander bestanddele is aminosure, laktose, mannitol, sorbitol en water vir inspuiting.

Neomisiensulfaat is in baie klein hoeveelhede teenwoordig.

### **Hoe VARILRIX lyk en die inhoud van die pakkie:**

**Vaksien:** roomkleurige tot geel, of pienkkleurige koekie of poeier.

**Vedunningsmiddel:** helder en kleurlose vloeistof.

**Hersaamgestelde vaksien:** helder perske- tot pienk-gekleurige oplossing.

Die vaksien word aangebied in 'n helder glasflessie van 3 ml met 'n rubberprop.

Die verdunningsmiddel word aangebied in 'n helder glasampul of voorafge vulde spuit + 2 naalde.

**Houer van die registrasiesertifikaat:**

GlaxoSmithKline South Africa (Edms) Bpk.

Hawkinslaan 39

Epping Industrie 1, 7460

**Hierdie voubiljet is laas hersien op:**

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**Registrasienommer:**

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