VARILRIX

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 VARILIX 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 ºC (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:

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