

VARILRIX[®] (human albumin free)

Live attenuated varicella vaccine

CONSUMER MEDICINE INFORMATION LEAFLET

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about VARILRIX vaccine. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the possible risks of you or your child having VARILRIX against the expected benefits.

If you have any concerns about VARILRIX talk to your doctor, nurse or pharmacist.

Keep this leaflet with this vaccine. You may need to read it again

WHAT VARILRIX IS USED FOR

VARILRIX is a vaccine used in children aged 9 months or older, adolescents and adults to prevent chickenpox. Groups who would benefit mostly from vaccination include:

- adults not immunised (protected) against chickenpox, especially those in 'at-risk' occupations such as health care workers, teachers and workers in child care centres
- adults not immunised, who are parents of young children
- adults and children not immunised, who live in the same

house with people who have lowered immunity and have no history of chickenpox.

- The vaccine works by causing the body to produce its own protection (antibodies) against this disease.

Chickenpox is caused by a virus called the varicella-zoster virus. VARILRIX vaccine contains a weakened form of the chickenpox (varicella-zoster) virus.

Chickenpox is a highly infectious disease, which usually causes an itchy, red rash with blisters. After about 1 week, most of the blisters have normally crusted over. The rash can appear on the face, scalp, body, or in the mouth, eyes and bottom. Other symptoms can include fever, headaches, chills, and muscle and/or joint aches and pains.

Sometimes disease complications can occur such as bacterial infection of the skin (often due to itching of the rash/crusts), inflammation of the brain (varicella encephalitis), and lung infection (varicella pneumonia). Complications are not common and are mainly seen in children with lowered immunity, and sometimes in adults.

Full recovery from chickenpox generally occurs; however, later in life the virus can become active again. This condition is known as shingles or Herpes zoster.

BEFORE VACCINATION

VARILRIX SHOULD NOT BE GIVEN IF:

- you or your child has had an allergic reaction to VARILRIX, or any ingredient contained in this vaccine. The ingredients in VARILRIX are listed at the end of this leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue. VARILRIX can be used in people who have previously developed a skin rash after applying the antibiotic 'neomycin' to the skin.
- you or your child have previously had an allergic reaction to any vaccine against varicella
- you are or think you may be pregnant, or if you intend to become pregnant within one month of vaccination. Your doctor will discuss with you the risks of receiving VARILRIX during pregnancy.
- you or your child has severely lowered immunity. This can occur in persons:
 - with inherited (or family history of) immune deficiency conditions
 - with abnormal blood conditions or blood protein (immunoglobulin) disorders

- with cancer
- receiving or who have received certain drugs (ie cyclosporin, corticosteroids, and cancer medicines)
- receiving or who have received radiation therapy
- with Human Immunodeficiency Virus (HIV) infection
- you or your child has a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before vaccination.
- the expiry (EXP) date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

If you are not sure whether you or your child should have VARILRIX, talk to your doctor or nurse. Do not give this vaccine to anyone else; your doctor has prescribed it specifically for you or your child.

BEFORE VARILRIX IS GIVEN TELL YOUR DOCTOR OR NURSE IF:

- you are breast feeding. The effect on breast fed infants of the administration of VARILRIX to their mothers has not been evaluated in clinical studies.
- you or your child has allergies to any other medicines or substances, such as dyes, foods or preservatives.
- you or your child have received another vaccine within the last month.
- You or your child has a weakened immune system. In the presence of weakened immunity, careful assessment by your doctor or your child's doctor is necessary in order to minimise adverse reactions to the vaccine. You or your child should be closely monitored as the response to the vaccine may not be sufficient to

ensure protection against the illness.

- you or your child have received a blood or plasma transfusion, or been given gamma globulin or other immunoglobulins within the last 3 months. VARILRIX may be less effective if given within 3 months of these products.
- you or your child 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.
- you or your child are having any prescription or OTC (over-the-counter) medicines. In particular, mention use of any medicines that suppress the immune system, such as high-dose steroids.

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

Some vaccines may be affected by other vaccines or medicines. Your doctor, nurse or pharmacist will be able to tell you what to do if VARILRIX is to be given with another vaccine or medicine.

HOW VARILRIX IS GIVEN

The doctor or nurse will give VARILRIX as an injection.

If you have any concerns about how this vaccine is to be given, talk to your doctor, nurse or pharmacist.

HOW MUCH IS GIVEN

The dose is 0.5mL for infants (9 months or older), children, adolescents and adults.

HOW IS IT GIVEN

VARILRIX will be injected under the skin (subcutaneously) of the shoulder or thigh.

The vaccine should never be given intravenously.

WHEN IT IS GIVEN

In children from 9 months up to and including 12 years, the appropriate time and number of doses that will be given will be determined by your doctor on the basis of appropriate official recommendations. Adults and adolescents aged 13 years and older are generally given two doses at least six weeks apart. Each dose is given at a separate visit.

The need for booster doses is uncertain at present.

IF A DOSE IS MISSED

If a scheduled dose is missed, talk to your doctor or nurse and arrange another visit as soon as possible.

OVERDOSAGE

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 Poison Information Centre on 131126 (Australia).

WHILE USING VARILRIX

THINGS YOU MUST NOT DO:

Do not become pregnant for one month after receiving VARILRIX vaccination. Talk to your doctor as soon as possible, if you do become pregnant within this time.

THINGS YOU MUST DO:

- Tell your doctor that you or your child has received VARILRIX if another vaccine is to be given within 1 month after vaccination.
- Tell your doctor if you or your child develops a rash within 4 weeks after vaccination. Some individuals develop symptoms of mild chickenpox several weeks after vaccination with VARILRIX. While the rash lasts, you or your child should avoid contact with people who have low immunity.
- Where possible, avoid contact with people who have lowered immunity for up to 6 weeks. The disease may be more serious in these people.
- Tell your doctor if you or your child are to have a tuberculin skin test for tuberculosis within 4-6 weeks after vaccination. The vaccine may affect the results of the tuberculin skin test.
- Tell your doctor if you or your child are to have another vaccine within 1 month after vaccination.

THINGS TO BE CAREFUL OF:

Be careful driving or operating machinery until you know how VARILRIX affects you. VARILRIX should not normally interfere with your ability to drive a car or operate machinery. But in some people vaccination can cause dizziness or lightheadedness. Make sure you know how you react to VARILRIX before you drive a car or operate machinery, or do anything that could be dangerous if you are dizzy or lightheaded.

It is advised to remain in the clinic for about 15 minutes after receiving the injection. There is a rare risk of allergic reactions. These may be local or widespread rashes that may be itchy or blistering, swelling of the eyes and face, difficulty in breathing or swallowing, a sudden drop in

blood pressure and loss of consciousness. These reactions will usually occur before leaving the doctor's surgery. If these symptoms occur, you should contact a doctor immediately.

SIDE EFFECTS

Tell your doctor or nurse as soon as possible if you or your child have troublesome symptoms after having had a dose of VARILRIX.

VARILRIX helps protect most people from chickenpox, but it may have unwanted side effects in a few people. All medicines and vaccines can have side effects. Sometimes they are serious; most of the time they are not. Some side effects may need medical treatment.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Most unwanted effects with VARILRIX are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site. However, some children develop symptoms of mild chickenpox several weeks after vaccination with VARILRIX.

Side effects that occurred during clinical trials with VARILRIX were as follows:

Very common (these may occur with more than 1 in 10 doses of the vaccine):

- pain, redness and swelling at the injection site
- headache
- fever
- upper respiratory tract infection

Common (these may occur with up to 1 in 10 doses of the vaccine):

- rash (spots and/or blisters)
- itching
- vomiting
- diarrhoea

- stomach pain or discomfort
- toothache
- nervousness
- cough
- runny or blocked nose, sneezing (rhinitis)
- sore throat and discomfort when swallowing
- discharge with itching of the eyes and crusty eyelids (conjunctivitis)
- infection of the middle ear
- tiredness (fatigue)
- chest pain
- generally feeling unwell
- nausea
- dizziness
- migraine
- sleepiness
- swollen glands in the neck, armpit or groin
- painful, swollen joints
- aching muscles, muscle tenderness or weakness, not caused by exercise

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):

- irritability
- chickenpox-like rash
- fever greater than 39°C
- earache
- indigestion

Rare (these may occur with up to 1 in 1,000 doses of the vaccine):

- hives (urticaria)

After commercialisation, the following additional side effects have been rarely reported in people vaccinated with VARILRIX:

- shingles (herpes zoster)
- fits or seizures
- temporary lumpy rash that may affect the skin, mouth and other parts of the body
- bleeding or bruising more easily than normal which may be

associated with skin rashes/peeling or fever

- infection or inflammation of the nervous system resulting in temporary loss of control of bodily movements, walking or sensation changes

Other side effects not listed above, can also occur during or soon after a dose of VARILRIX.

Check with your doctor or nurse if you or your child has any other effects.

STORAGE

VARILRIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store VARILRIX always:

- Keep VARILRIX in the refrigerator stored between 2°C and 8°C. Do not store it in the bathroom, near the sink, or leave it in the car on hot days. Avoid exposing the vaccine to sunlight. The water diluent can be kept in a refrigerator or at room temperature. It must not be frozen.
- Keep the vaccine out of the reach of children.
- Keep VARILRIX in the original pack until it is time for it to be given.

Ask your pharmacist what to do with any left over VARILRIX that has expired or has not been used.

PRODUCT DESCRIPTION

WHAT IT LOOKS LIKE

VARILRIX comes as a slightly cream to yellowish or pinkish coloured powder in a glass vial. The clear sterile water diluent comes in prefilled syringes or ampoules. It is made into a clear peach to pink

coloured liquid, before being injected by the doctor or nurse.

INGREDIENTS

The active ingredient of VARILRIX is a live weakened varicella-zoster virus (Oka strain). Each 0.5 mL dose contains not less than 1,995 plaque-forming units of the varicella-zoster virus.

The inactive ingredients in the vaccine are: amino acids, lactose, mannitol and sorbitol. Neomycin sulphate is present as traces.

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 does not contain a preservative, sucrose, gluten, tartrazine or any other azo dyes.

FURTHER INFORMATION

VARILRIX is only available if prescribed by a doctor.

VARILRIX comes in the following:

- a glass vial with sterile water diluent (prefilled syringe) in packs of 1 or 10 - AUST R 234750. Needles may or may not be provided, subject to availability.
- a glass vial with sterile water diluents (ampoule) in packs of 1 or 10 – AUST R 234751 Needles are not provided.

Not all pack sizes may be marketed.

MANUFACTURER

GlaxoSmithKline Biologicals S.A
rue de l'Institut 89,
1330 Rixensart, Belgium.

DISTRIBUTED IN AUSTRALIA BY

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

Date of Preparation:

16 March 2017

Version 2.0

VARILRIX is a registered trade mark of the GSK group of companies.

© 2016 GSK group of companies. All rights reserved.