

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 Is VARILRIX Used For

VARILRIX is a vaccine used to prevent and immunise against the varicella virus, which causes chickenpox in infants (from the age of 9 months), children, adolescents and adults.

Varicella, commonly known as chickenpox, is a highly infectious viral infection, caused by varicella zoster virus.

Sufferers usually experience a rash, fever, loss of appetite, headache and sore throat. The spots of the rash are initially flat and become blisters with fluid in them which eventually forms a crust.

Some groups of people are at a higher risk of exposure to the varicella virus. Vaccination is recommended for these people:

- some healthcare workers
- school teachers
- people in contact with children
- children who have working mothers

The virus can be spread by patients with chickenpox or the herpes zoster virus. The virus is spread through the air or direct contact with the lesions or blisters. It can also be transmitted from an infected mother to her unborn child.

Vaccination is the best way to protect against infection in the longer term. The risk of complications and death are greater in people whose immunity is impaired by illness or by treatment with drugs known as immunosuppressants.

VARILRIX will not protect a person if they are already infected with the varicella virus at the time of vaccination. VARILRIX may not prevent the disease in these people.

Before Receiving VARILRIX

When you must not have VARILRIX

- you have/your child has had an allergic reaction to VARILRIX, or any ingredient contained in this vaccine. The ingredients 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.

- you or your child have previously had an allergic reaction to any vaccine against varicella.
- you have/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 being vaccinated.
- you or your child have a low white blood cell count or have severe problems with the immune system.
- you / your child are sensitive to an antibiotic known as neomycin.
- you are pregnant or plan to become pregnant one month after vaccination.
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

If you are not sure whether VARILRIX should be given, talk to your doctor or nurse.

Tell your doctor if:

- you are breast-feeding. It is not known if VARILRIX passes into breast milk. There is no data regarding use in breastfeeding women.
- you/your child has had VARILRIX before and became

unwell, tell your doctor or nurse before the dose is given.

- you/your child have a history or a family history of allergies
- you/your child has had a blood transfusion in the last 3 months.
- you/your child has any medical conditions, such as:
 - a bleeding disorder.
Sometimes VARILRIX may need to be given differently in people with bleeding problems.
 - an immune deficiency condition (eg. are HIV positive).
- you/your child has allergies to any other medicines or substances, such as dyes, foods or preservatives.
- you/your child has received another vaccine. VARILRIX can be given at the same time as other vaccines. VARILRIX will always be given separately from other injections.
- you/your child is taking any prescription or OTC (over-the-counter) medicines or any medicine you have bought from a supermarket or health food shop.
- you/your child have a weakened immune system. You/your child should be closely monitored as the responses to the vaccine may not be sufficient to ensure a protection against the illness.
- you/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.

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.

VARILRIX can be given 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.

Use in children

VARILRIX is recommended for use in healthy infants (from the age of 9 months), children and adolescents.

Giving VARILRIX

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.

When it will be given

VARILRIX is generally given as a single dose on an elected date. If a second dose is given, it will be administered 6 weeks after the first dose.

In children from the age of 9 months up to 12 years of age, two doses of VARILRIX administered at least six weeks apart are recommended.

From 13 years and up, 2 doses should be given, with an interval of at least 6 weeks between the first and second dose.

How is it given

VARILRIX will be injected into the upper arm in adults and older children, and into the thigh muscle in infants. The injection is given subcutaneously (under the skin).

The vaccine should never be given intravenously (into a vein) or intradermally (into the skin).

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 0800 POISON or 0800 764 766 (New Zealand).

While You Are Getting VARILRIX

Things you must do

Keep your visits with the doctor or clinic. It is important VARILRIX doses are given at the correct times. This will ensure the best effect of the vaccine in protecting you (or your child) against varicella virus.

If you develop the chicken pox blisters within the first 4 weeks after vaccination, avoid contact with people who are immune suppressed (have problems with their immune system) for the duration of the rash.

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 light-headedness. 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 light-headed.

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, nurse or pharmacist as soon as possible if you (or your child) do not feel well during or after having had a dose of VARILRIX.

VARILRIX helps protect most people from varicella virus, 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 such as tenderness, soreness and redness.

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 and redness at the injection site

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

- rash (spots and/or blisters)
- swelling at the injection site
- fever of 37.5°C or more (oral/axillary) or 38°C or more (rectal)

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

- 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°C (oral/axillary) or greater than 39.5°C (rectal)
- tiredness (fatigue)
- generally feeling unwell

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

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

After the marketing of VARILRIX, the following additional side effects have been rarely reported:

- shingles (herpes zoster)
- 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
- fits or seizures
- temporary lumpy rash that may affect the skin, mouth and other parts of the body

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 notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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. **THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.**
- 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 is a slightly pink-coloured powder, which comes in a neutral, colourless glass vial. The solution used to dilute the powder is clear and colourless and comes in ampoules and prefilled syringes.

Ingredients

VARILRIX contains a live attenuated (weakened) strain of the varicella-zoster virus.

VARILRIX also contains the following inactive ingredients:

- lactose
- mannitol

- sorbitol
- amino acids.

The diluent is water for injections.

Neomycin sulphate is present as a residual from the manufacturing process.

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

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
- a glass vial with sterile diluent (ampoule) in packs of 1 or 10

Not all pack sizes may be marketed.

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