

VARILRIX (human albumin free)

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about receiving this vaccine, speak to your doctor, nurse or pharmacist.

1. Why are my child or I being given VARILRIX?

VARILRIX is used to prevent and immunise against the varicella virus, which causes chickenpox in infants (from the age of 9 months), children, adolescents and adults. VARILRIX contains the active ingredient of a live attenuated (weakened) strain of the varicella-zoster virus.

For more information, see Section [1. Why are my child or I being given VARILRIX?](#) in the full CMI.

2. What should I know before my child or I are given VARILRIX?

Do not receive this vaccine if you or your child have ever had an allergic reaction to VARILRIX or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you or your child have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before my child or I are given VARILRIX?](#) in the full CMI.

3. What if my child or I are taking other medicines?

Some medicines may interfere with VARILRIX and affect how it works.

A list of these medicines is in Section [3. What if my child or I are taking other medicines?](#) in the full CMI.

4. How is VARILRIX 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).

More instructions can be found in Section [4. How is VARILRIX given?](#) in the full CMI.

5. What should I know while my child or I are being given VARILRIX?

| | |
|-----------------------------------|---|
| Driving or using machines | <ul style="list-style-type: none">• Be careful driving or operating machinery until you know how VARILRIX affects you.• VARILRIX in some people can cause dizziness or lightheadedness. |
| Looking after your vaccine | <ul style="list-style-type: none">• VARILRIX is usually stored at the doctor's clinic or surgery, or at the pharmacy.• If you need to store VARILRIX, keep it 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. |

For more information, see Section [5. What should I know while my child or I are being given VARILRIX?](#) in the full CMI.

6. Are there any side effects?

Side effects that have been reported include pain, redness and swelling at the injection site, rash (spots and/or blisters), fever of 37.5°C or more (oral/axillary) or 38°C or more (rectal), 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 or swollen joints, aching muscles, muscle tenderness or weakness (not caused by exercise), tiredness (fatigue) and generally feeling unwell.

There is a rare risk of convulsions, loss of control of bodily movement, or 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

VARILRIX (human albumin free)

Active ingredient: *Live attenuated (weakened) strain of the varicella zoster virus*

Consumer Medicine Information (CMI)

This leaflet provides important information about VARILRIX. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about VARILRIX.**

Where to find information in this leaflet:

- [1. Why are my child or I being given VARILRIX?](#)
- [2. What should I know before my child or I are given VARILRIX?](#)
- [3. What if my child or I are taking other medicines?](#)
- [4. How is VARILRIX given?](#)
- [5. What should I know while my child or I are being given VARILRIX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why are my child or I being given VARILRIX?

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

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.

2. What should I know before my child or I are given VARILRIX?

Warnings

Do not use VARILRIX if:

- you or your child are allergic to live attenuated (weakened) strain of the varicella-zoster virus, or any of the ingredients 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. Always check the ingredients to make sure you or your child can use this vaccine
- you or your child have previously had an allergic reaction to any vaccine against varicella
- 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 being vaccinated
- you or your child have a low white blood cell count or have severe problems with the immune system
- you or your child are sensitive to an antibiotic known as neomycin
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- you or your child has had VARILRIX before and became unwell, tell your doctor or nurse before the dose is given
- you or your child have a history or a family history of allergies
- you or your child has had a blood transfusion in the last 3 months
- you and 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 or your child has allergies to any other medicines or substances, such as dyes, foods or preservatives
- you or 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 or 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 or your child have a weakened immune system or will be starting a medicine that weakens the immune

system. You and your child should be closely monitored as the responses to the vaccine may not be sufficient to ensure a protection against the illness

- 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.

During treatment, you or your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use VARILRIX if you are pregnant or plan to become pregnant one month after vaccination.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if VARILRIX passes into breast milk. There is no data regarding use in breastfeeding women.

3. What if my child or I are taking other medicines?

Tell your doctor or pharmacist if you or your child are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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.

Some medicines may interfere with VARILRIX and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VARILRIX.

4. How is VARILRIX given?

How much is given

- The dose of 0.5 mL is given.

How is it given

- The doctor or nurse will give VARILRIX as an injection.
- 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).

When is VARILRIX given

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

- VARILRIX is generally given as a single dose on an elected date. If a second dose is given, it will be administered at least 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.

If you miss receiving VARILRIX

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

If you received too much VARILRIX

If you think that you have received too much VARILRIX, you may need urgent medical attention.

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.

You should immediately:

- phone the Poisons Information Centre (**by calling 0800 POISON or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while my child or I are being given VARILRIX?

Things you and your child should do

- Keep your visits with the doctor or clinic. It is important that 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.
- It is advised to remain in the clinic for about 15 minutes after receiving the injection. There is a rare risk of allergic reactions.
- 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.

Remind any doctor, dentist or pharmacist you visit that you or your child are using VARILRIX.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Looking after your vaccine

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 VARILRIX in the original pack until it is time for it to be given.

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

Follow the instructions in the carton on how to take care of your vaccine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted vaccine

If you no longer need to use this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this vaccine after the expiry date.

6. Are there any side effects?

All vaccines can have side effects. If you or your child do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| <p>General disorders and administration site conditions:</p> <ul style="list-style-type: none"> • pain and redness at the injection site • swelling at the injection site • headache • fever of 37.5°C or more (oral/axillary) or 38°C or more (rectal) • tiredness (fatigue) • generally feeling unwell. <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • nausea vomiting • diarrhoea • stomach pain or discomfort. <p>Musculoskeletal disorders:</p> <ul style="list-style-type: none"> • painful, swollen joints • aching muscles, muscle tenderness or weakness, not caused by exercise. <p>Skin disorders:</p> <ul style="list-style-type: none"> • rash (spots and/or blisters) • itching. <p>Eye disorders:</p> <ul style="list-style-type: none"> • discharge with itching of the eyes and crusty eyelids (conjunctivitis). <p>Respiratory and mouth disorders:</p> <ul style="list-style-type: none"> • nose and throat infection • cough • runny or blocked nose, sneezing (rhinitis) • sore throat and discomfort when swallowing. <p>Psychiatric disorders:</p> <ul style="list-style-type: none"> • irritability • sleepiness. <p>Lymphatic disorders:</p> <ul style="list-style-type: none"> • swollen glands in the neck, armpit or groin. | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <p>Infection and immune system disorders:</p> <ul style="list-style-type: none"> chickenpox-like rash fever greater than 39°C (oral/axillary) or greater than 39.5°C (rectal) hives (urticaria) 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 damage to the brain caused by an interruption to its blood supply (stroke) fits or seizures temporary lumpy rash that may affect the skin, mouth and other parts of the body. <p>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.</p> <p>Inflammation of the brain (encephalitis) has been observed following vaccination with live attenuated varicella vaccines including VARILRIX. Fatal cases have been observed, especially in people with weakened immune systems. If you develop any of the following symptoms, contact your doctor urgently and inform them that you have received Varilrix:</p> <ul style="list-style-type: none"> loss or reduced levels of consciousness, convulsions or loss of control of bodily movements, accompanied by fever and headache. | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you or your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you or your child have received medical advice for any side effects experienced, you can report side effects via <https://pophealth.my.site.com/carmreportnz/>.

By reporting side effects, you can help provide more information on the safety of this vaccine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This vaccine is only available with a doctor's prescription.

What VARILRIX contains

| | |
|---|---|
| Active ingredient (main ingredient) | live attenuated (weakened) strain of the varicella-zoster virus |
| Other ingredients (inactive ingredients) | lactose mannitol sorbitol amino acid |

Do not receive this vaccine if you or your child are allergic to any of these ingredients.

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.

What VARILRIX looks like

VARILRIX is presented as a powder (contained in a glass vial) and a sterile diluent (contained in a separate glass ampoule or pre-filled syringe) for solution for injection.

The powder is slightly cream to yellowish or pinkish.

The sterile diluent is clear and colourless.

The powder and the sterile diluent have to be mixed together before vaccination.

VARILRIX (TT50-4173/2) comes in:

- 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.

Who distributes VARILRIX

GlaxoSmithKline NZ Ltd
Private Bag 106600
Downtown

Auckland 1143
New Zealand

Phone: (09) 367 2900

Facsimile: (09) 367 2910

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