

# 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 or pharmacist.

### 1. Why am I receiving VARILRIX?

VARILRIX is used in children aged 9 months or older, adolescents and adults to prevent chickenpox. VARILRIX contains the active ingredient of a live weakened varicella-zoster virus (Oka strain).

For more information, see Section [1. Why am I receiving VARILRIX?](#) in the full CMI.

### 2. What should I know before I receive VARILRIX?

Do not use if you or your child have ever had an allergic reaction to VARILRIX, any vaccine against varicella, 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 if you are pregnant, plan to become pregnant, or are breastfeeding. Tell your doctor if you or your child have received a vaccine within the last month, or received a blood or plasma transfusion, gamma globulin, or other immunoglobulins within the last 3 months.**

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

### 3. What if I am 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 I am taking other medicines?](#) in the full CMI.

### 4. How is VARILRIX given?

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

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

### 5. What should I know while receiving VARILRIX?

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

For more information, see Section [5. What should I know while receiving 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, headache, fever and upper respiratory tract infection, 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 or swollen joints and aching muscles or muscle tenderness or weakness (not caused by exercise).

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.

Post commercialisation, infection or inflammation of the nervous system resulting in temporary loss of control of bodily movements, walking or sensation changes has been rarely reported in people vaccinated with VARILRIX.

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 weakened varicella-zoster virus (Oka strain)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about VARILRIX. **You should also speak to your doctor 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 am I receiving VARILRIX?](#)
2. [What should I know before I receive VARILRIX?](#)
3. [What if I am taking other medicines?](#)
4. [How is VARILRIX given?](#)
5. [What should I know while receiving VARILRIX?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I receiving VARILRIX?

**VARILRIX is a vaccine used in children aged 9 months or older, adolescents and adults to prevent chickenpox.**

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

Groups who would benefit mostly from vaccination include:

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

## 2. What should I know before I receive VARILRIX?

### Warnings

**Do not use VARILRIX if:**

- you or your child are allergic to VARILRIX or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you or your child can use this vaccine. 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 or your child have 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 (i.e. cyclosporin, corticosteroids, and cancer medicines)
  - receiving or who have received radiation therapy
  - with Human Immunodeficiency Virus (HIV) infection
- you or your child have 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.

If you are not sure whether you should receive 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.

**Check with your doctor if you or your child:**

- have any other medical conditions
- take any medicines for any other condition
- have allergies to any other medicines or substances, such as dyes, foods or preservatives
- have received another vaccine within the last month
- have a weakened immune system. In the presence of weakened immunity, careful assessment by your doctor is necessary in order to minimise adverse

reactions to the vaccine. You or child should be closely monitored as the response to the vaccine may not be sufficient to ensure protection against the illness.

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.

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**

Check with your doctor if you are pregnant or intend to become pregnant.

#### **Do not use VARILRIX if:**

- 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.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The effect on breast fed infants of the administration of VARILRIX to their mothers has not been evaluated in clinical studies.

### **Fainting**

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

## **3. What if I am 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.

Tell your doctor or pharmacist if:

- you 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 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 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.

## **4. How is VARILRIX given?**

### **How much is given**

- The doctor or nurse will give VARILRIX as an injection.
- The dose is 0.5 mL for infants (9 months or older), children, adolescents and adults.

### **How it is given**

- VARILRIX will be injected under the skin (subcutaneously) of the shoulder or thigh.
- The vaccine should never be given into a vein (intravenously).

### **When is it VARILRIX given**

- For 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.

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

The need for booster doses is uncertain at present.

### **If you are given too much VARILRIX**

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.

If you think that you or your child have used too much VARILRIX, you may need urgent medical attention.

#### **You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), 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 receiving VARILRIX?**

### **Things you should do**

#### **Call your doctor straight away if you or your child:**

- develop 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

- 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
- are to have another vaccine within 1 month after vaccination.

Remind any doctor, nurse or pharmacist you visit that you or child have received VARILRIX.

Where possible, avoid contact with people who have lowered immunity for up to 6 weeks. The disease may be more serious in these people.

### Things to be careful of:

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.

### Things you should 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.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how VARILRIX affects you.**

VARILRIX may cause dizziness in some people.

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

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

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

Do not use this vaccine after the expiry date.

Do not use this vaccine if the packaging is torn or shows signs of tampering.

## 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.

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

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.

### Less serious side effects

Less serious side effects	What to do
<b>General disorders and administration site conditions:</b> <ul style="list-style-type: none"> <li>• pain, redness and swelling at the injection site</li> <li>• headache</li> <li>• fever</li> <li>• toothache</li> <li>• tiredness (fatigue)</li> <li>• generally feeling unwell</li> <li>• dizziness</li> <li>• fever greater than 39°C.</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

Less serious side effects	What to do
<b>Gastrointestinal disorders:</b> <ul style="list-style-type: none"> <li>vomiting</li> <li>diarrhoea</li> <li>stomach pain or discomfort</li> <li>indigestion</li> <li>nausea.</li> </ul> <b>Musculoskeletal disorders:</b> <ul style="list-style-type: none"> <li>painful, swollen joints</li> <li>aching muscles, muscle tenderness or weakness, not caused by exercise.</li> </ul> <b>Respiratory and mouth disorders:</b> <ul style="list-style-type: none"> <li>upper respiratory tract infection</li> <li>cough</li> <li>runny or blocked nose, sneezing (rhinitis)</li> <li>sore throat and discomfort when swallowing.</li> </ul> <b>Lymphatic disorders:</b> <ul style="list-style-type: none"> <li>swollen glands in the neck, armpit or groin.</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

Less serious side effects	What to do
<b>Skin disorders:</b> <ul style="list-style-type: none"> <li>rash (spots and/or blisters)</li> <li>itching</li> <li>hives (urticaria).</li> </ul> <b>Eye disorders:</b> <ul style="list-style-type: none"> <li>discharge with itching of the eyes and crusty eyelids (conjunctivitis).</li> </ul> <b>Ear disorders:</b> <ul style="list-style-type: none"> <li>infection of the middle ear</li> <li>earache.</li> </ul> <b>Psychiatric disorders:</b> <ul style="list-style-type: none"> <li>migraine</li> <li>sleepiness</li> <li>irritability</li> <li>nervousness.</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you</b>

<b>Cardiac disorders:</b> <ul style="list-style-type: none"> <li>chest pain.</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<b>Infection and immune system disorders:</b> <ul style="list-style-type: none"> <li>chickenpox-like rash</li> <li>shingles (herpes zoster)</li> <li>fits or seizures</li> <li>temporary lumpy rash that may affect the skin, mouth and other parts of the body</li> <li>bleeding or bruising more easily than normal which may be associated with skin rashes/peeling or fever</li> <li>infection or inflammation of the nervous system resulting in temporary loss of control of bodily movements, walking or sensation changes.</li> </ul>	<b>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.</b>

**Tell your doctor or pharmacist if you or your child notice anything else that may be making you 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 to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). 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 or your child decide to stop taking any of your medicines.**

## 7. Product details

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

### What VARILRIX contains

<b>Active ingredient (main ingredient)</b>	live weakened varicella-zoster virus (Oka Strain)
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>amino acids</li> <li>lactose</li> <li>mannitol</li> <li>sorbitol</li> <li>neomycin sulphate is present as traces</li> </ul>

Each 0.5 mL dose contains not less than 1,995 plaque-forming units of the varicella-zoster virus.

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.

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

### **What VARILRIX looks like**

VARILRIX is presented as a powder (contained in a glass vial) and a clear sterile water diluent (contained in a separate glass prefilled syringe).

The powder is slightly cream to yellowish or pinkish.

The sterile water diluent is clear and colourless.

The powder and sterile water diluent have to be mixed together, before being injected by the doctor or nurse.

AUST R 234750 - a glass vial with sterile water diluent (prefilled syringe) in packs of 1 or 10.

Not all pack sizes may be marketed.

### **Who distributes VARILRIX**

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

[www.gsk.com.au](http://www.gsk.com.au)

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