

VARIVAX® Refrigerated

Consumer Medicine Information (CMI) summary

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

1. Why is my child or I being given VARIVAX Refrigerated?

VARIVAX Refrigerated is a vaccine used to help prevent chickenpox (varicella). It can be given to children 12 months of age and older, teenagers and adults who are healthy.

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

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

Do not receive VARIVAX Refrigerated if you or your child have ever had an allergic reaction to VARIVAX Refrigerated 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 VARIVAX Refrigerated?](#) in the full CMI.

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

Some medicines may interfere with VARIVAX Refrigerated and affect how it works. A list of these medicines is in Section [3. What if my child or I am taking other medicines?](#) in the full CMI.

4. How is VARIVAX Refrigerated given?

- The usual dose of VARIVAX Refrigerated is 0.5 mL. The dose of the vaccine is the same for everyone.
- VARIVAX Refrigerated is given as an injection just under the skin (subcutaneously) or in the muscle (intramuscular) of the upper arm by a doctor or trained nurse.

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

5. What should I know after my child or I are given VARIVAX Refrigerated?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• If you are 13 years of age or older, or your doctor tells you to have a second dose, keep your follow-up appointment with your doctor or clinic.• If you are a woman of child-bearing age, avoid falling pregnant for 3 months after vaccination |
| Things you should not do | <ul style="list-style-type: none">• Do not take aspirin or other salicylate medicines for six weeks after being given VARIVAX Refrigerated. |
| Driving or using machines | <ul style="list-style-type: none">• VARIVAX Refrigerated should not normally interfere with your ability to drive a car or operate machinery. However, VARIVAX Refrigerated may cause tiredness or dizziness in some people.• Be careful driving or operating machinery until you know whether VARIVAX Refrigerated has affected you. |
| Looking after your medicine | <ul style="list-style-type: none">• It is unlikely that you would be asked to store VARIVAX Refrigerated. If you are, keep it in the refrigerator, but not in the door compartment, until ready to use.• VARIVAX Refrigerated is stable for up to 24 months when stored in the refrigerator. |

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

6. Are there any side effects?

Common side effects include: pain, soreness, swelling, itching, redness, bruising, numbness, stiffness or a hard lump where you had the injection, fever, tingling of the skin, irritability, swollen glands typically located in the neck, armpit or groin.

Serious side effects include: seizures or fits, severe skin conditions, skin infections, allergic reactions, bruising more easily than normal, red or purple, flat, pinhead spots under the skin; severe paleness, nausea, vomiting, chickenpox, difficulty walking. For a complete list of side effects and more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

VARIVAX Refrigerated

Active ingredient: *Varicella virus vaccine live (live varicella vaccine)*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why is my child or I being given VARIVAX Refrigerated?

VARIVAX Refrigerated is a vaccine used to help prevent chickenpox (varicella). It can be given to children 12 months of age and older, teenagers and adults who are healthy.

After vaccination with VARIVAX Refrigerated, most people will produce enough antibodies against the varicella virus. However, as with all vaccines, 100% protection against chickenpox cannot be guaranteed.

The chance of a severe reaction from VARIVAX Refrigerated is very small, but the risks from not being vaccinated are very serious.

What is chickenpox

Chickenpox is an infectious disease caused by the varicella-zoster virus, or otherwise known as varicella virus. It occurs in millions of people around the world each year, most often in children 5 to 9 years of age. Chickenpox is easily passed from one person to another. It is commonly spread from person to person through the air by sneezing or coughing. Once a person is infected, it usually takes about 2 to 3 weeks before symptoms of the infection start.

Symptoms of chickenpox include mild headache, moderate fever and general discomfort. These are followed by a rash of itchy, little red spots which usually start on the chest, stomach or back, but can appear anywhere on the body. There may be only a few spots or groups of spots, or even hundreds of spots that develop over the next 3 to 5 days. The spots will change into clear blisters filled with fluid which then become cloudy, break open, dry, scab and heal, usually within 5 to 20 days.

Although chickenpox is generally a fairly harmless infection, it may be associated with serious complications and/or rarely death. In children, the most common complications are bacterial skin infections. Less frequent but very serious complications include pneumonia, inflammation of the brain (encephalitis), Reye syndrome (which causes brain and liver damage), and death. Severe disease and serious complications are more likely to occur in teenagers and adults.

It is not known whether VARIVAX Refrigerated will prevent chickenpox if it is given after you have been exposed to the natural varicella virus. Therefore, vaccination before way exposure is the best to help protect against infection and possible serious complications.

Groups of people who would particularly benefit from being vaccinated with VARIVAX Refrigerated include those who have not been infected with chickenpox before and either:

- work in jobs where they are at high risk of being infected,
- are parents of young children, or
- live in the same household as someone who has a poor immune system (such as people with organ transplants, certain cancers, and HIV/AIDS) and has not had chickenpox before.

How does it work

VARIVAX Refrigerated contains a weakened strain of living varicella virus. This strain of live virus causes either mild or no symptoms of infection.

VARIVAX Refrigerated works by causing your body to produce its own protection against chickenpox. It does this by making disease-fighting substances called antibodies to fight the varicella virus. If a vaccinated person comes into contact with live virus, the body is usually ready to destroy it.

Your doctor will use the official recommendations to decide the number of doses needed and when to get them. At least one injection of VARIVAX Refrigerated is needed to help protect against chickenpox in children aged 12 months to 12 years. In persons aged 13 years and older, a second injection is required after the first injection.

After vaccination with VARIVAX Refrigerated, most people will produce enough antibodies against the varicella virus. However, as with all vaccines, 100% protection against chickenpox cannot be guaranteed.

The chance of a severe reaction from VARIVAX Refrigerated is very small, but the risks from not being vaccinated are very serious.

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

Warnings

Do not receive VARIVAX Refrigerated if:

- you or your child have an allergy to VARIVAX Refrigerated or any of the ingredients listed at the end of this leaflet
- you or your child have a serious allergy to the antibiotic, neomycin
Symptoms of an allergic reaction may include swelling of the face, lips, tongue, throat, difficulty in breathing, or hives.
- you or your child are pregnant or intend to become pregnant
- you or your child are being treated with medicines which decrease the body's immune system such as corticosteroids (e.g., prednisone), cyclosporin or cancer medicines
- you or your child have diseases which decrease the body's immune system, such as blood disorders, cancers of the blood cells or lymph system (e.g. leukaemia, lymphoma) and HIV/AIDS
- you or your child have a family history of immune deficiency
- you or your child have tuberculosis (TB) which is not being currently treated
- you or your child have an infection with a high temperature

If you are not sure whether you or your child should be given VARIVAX Refrigerated, talk to your doctor.

Check with your doctor if you or your child:

- are breast-feeding or plan to breast-feed
- have or have had any serious medical conditions
- have received blood or plasma transfusions or immune globulins within the past five months

Your doctor may decide to delay your injection of VARIVAX Refrigerated.

- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you are given an injection of VARIVAX Refrigerated.

During treatment, you 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

VARIVAX Refrigerated is not recommended to be given to pregnant women. Also women of child-bearing age should avoid becoming pregnant for 3 months after vaccination.

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

Breastfeeding

It is not known whether VARIVAX Refrigerated passes into breast milk. Your doctor will discuss the possible risks and benefits of being given VARIVAX Refrigerated when breast-feeding.

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

Children

Do not give VARIVAX Refrigerated to children under 12 months of age.

The safety and effectiveness of VARIVAX Refrigerated in children below the age of 12 months have not been established.

Close Contact with High Risk People

In rare circumstances, it is possible to catch chickenpox, including severe chickenpox, from a person who has been vaccinated with VARIVAX Refrigerated. This may occur in persons who have not previously been vaccinated or have not had chickenpox, as well as persons who fall into one of the following categories:

- individuals with a weakened immune system
- pregnant women who never had chickenpox
- newborn babies whose mothers never had chickenpox.

Whenever possible, individuals who have been vaccinated with VARIVAX Refrigerated should attempt to avoid close contact, for up to 6 weeks following the vaccination, with anyone who falls into one of the categories above. Tell your doctor if there is anyone who falls into one of the categories above and is expected to be in close contact with the person being vaccinated.

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

Tell your doctor, nurse or pharmacist if you or your child have been given any other vaccines or 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.

VARIVAX Refrigerated should not be given to people who are using the following:

- **medicines that decrease the immune system**, such as corticosteroids (e.g., prednisone) cyclosporin, or cancer medicines
- **aspirin or other salicylate medicines.**

Talk to your doctor if you or your child are taking any of these medicines.

Some medicines should not be used for 6 to 8 weeks after receiving VARIVAX Refrigerated. These include:

- **aspirin or other salicylates.**

A serious condition called Reye Syndrome has been reported following the use of aspirin or other salicylate medicines during a natural chickenpox infection. Therefore, aspirin or other salicylates

should be avoided for 6 weeks following vaccination with VARIVAX Refrigerated.

- **immune globulins.**

Your doctor will discuss with you the possible risks and benefits of having immune globulin injections in the 2 months following vaccination with VARIVAX Refrigerated.

Use with other vaccines

VARIVAX Refrigerated can be given at the same time as M-M-R II (measles, mumps and rubella virus vaccine live), oral polio vaccine, and diphtheria, tetanus and pertussis vaccine. The injections should be given at different places on the body and using separate syringes. Your doctor will decide if VARIVAX Refrigerated should be given with other vaccines.

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

4. How is VARIVAX Refrigerated given?

How much is given

The usual dose of VARIVAX Refrigerated is 0.5 mL. The dose of the vaccine is the same for everyone.

VARIVAX Refrigerated can be given to persons 12 months of age and older. For children aged 12 months to 12 years, at least one injection is given. Your doctor will use the official recommendations to decide the number of doses needed and when to get them.

For persons who are first vaccinated at 13 years of age and older, a second injection should be given 4 to 8 weeks after the first injection.

How is VARIVAX Refrigerated given

VARIVAX Refrigerated is given as an injection just under the skin (subcutaneously) or in the muscle (intramuscular) of the upper arm by a doctor or trained nurse.

The vaccine should not be injected directly into veins (intravenously).

5. What should I know after my child or I are given VARIVAX Refrigerated?

Things you should do

If you are 13 years of age or older, or your doctor tells you to have a second dose, keep your follow-up appointment with your doctor or clinic.

It is important to have your follow-up injection of VARIVAX Refrigerated at the appropriate time to make sure the vaccine has the best chance of providing protection against the chickenpox virus.

If you are a woman of child-bearing age, avoid falling pregnant for 3 months after vaccination.

If you are about to be injected with any immune globulin (including varicella zoster globulin) and you have been

injected with VARIVAX Refrigerated within the past 2 months, tell your doctor.

If you or your child have been given VARIVAX Refrigerated, avoid coming into contact, for six weeks, with a person who falls into one of the following categories:

- people with a weakened immune system
- pregnant women who have never had chickenpox
- newborn babies whose mothers have never had chickenpox

These people may be at risk of catching chickenpox from you or your child.

Things you should not do

Do not take aspirin or other salicylate medicines for six weeks after being given VARIVAX Refrigerated.

A serious condition called Reye Syndrome has been reported following the use of aspirin or other salicylate medicines during a natural chickenpox infection.

Driving or using machines

Be careful driving or operating machinery until you know whether VARIVAX Refrigerated has affected you.

VARIVAX Refrigerated should not normally interfere with your ability to drive a car or operate machinery. However, VARIVAX Refrigerated may cause tiredness or dizziness in some people.

Make sure you know how you react to VARIVAX Refrigerated before you drive a car, operate machinery, or do anything else that could be dangerous if you are tired.

Looking after your vaccine

It is unlikely that you will be asked to store VARIVAX Refrigerated. However if you need to store VARIVAX Refrigerated:

- Keep it where children cannot reach it.
- Keep it in the refrigerator, but not in the door compartment.
- Do not freeze VARIVAX Refrigerated

VARIVAX Refrigerated is stable for up to 24 months when stored in the refrigerator.

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

6. Are there any side effects?

VARIVAX Refrigerated helps protect most people from chickenpox, but it may have unwanted side effects in a few people.

All medicines can have side effects. If you 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, nurse or pharmacist if you have any further questions about side effects.

Common side effects

| Common side effects | What to do |
|--|---|
| <ul style="list-style-type: none"> • pain, soreness, swelling, itching, redness, bruising, numbness, stiffness or a hard lump where you had the injection • fever • tingling of the skin • irritability • swollen glands typically located in the neck, armpit or groin • chickenpox-like rash on the body or at the injection site <p>These are the more common side effects of VARIVAX Refrigerated. For the most part these have been mild.</p> | <p>Speak to your doctor if you or your child have any of these common side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> • seizures or fits • severe skin conditions • skin infections • allergic reactions • bruising more easily than normal, red or purple, flat, pinhead spots under the skin; severe paleness • nausea • vomiting • chickenpox • difficulty walking • shingles (herpes zoster)†, an infection which causes blisters and severe pain • drooping eyelid or sagging muscles on one side of the face, also called Bell's palsy • fever, chills, shortness of breath, cough, phlegm, difficulty breathing, wheezing which may be symptoms of pneumonia or pneumonitis • inflammation of the brain (encephalitis†- symptoms include headache and fever, progressing to hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, stiff neck, and sensitivity to light) • inflammation of the coverings of the brain and spinal cord (meningitis)† • stroke | <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> |

| Serious side effects | What to do |
|---|------------|
| <p>†Can be from naturally occurring chickenpox or the vaccine in healthy individuals or individuals with lowered immunity.</p> <p>These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.</p> <p>As with all vaccines given by injection, there is a very small risk of a serious allergic reaction.</p> <ul style="list-style-type: none"> • skin rash, itchiness, or other severe skin reactions • pinkish, itchy swellings on the skin, also called hives • swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing <p>These are serious side effects. If you have them, you may have had a serious allergic reaction to VARIVAX Refrigerated. You may need urgent medical attention or hospitalisation. Most of these side effects occur within the first few hours of vaccination.</p> | |

Tell your doctor, nurse 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 have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

7. Product details

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

What VARIVAX Refrigerated contains

| | |
|--|--|
| Active ingredient (main ingredient) | A minimum of 1350 PFU (plaque forming units) of Oka/Merck varicella virus (which is the weakened strain of varicella virus) when reconstituted with the diluent and stored at room temperature for 150 minutes (2 and a half hours). |
| Other ingredients | sucrose hydrolysed porcine gelatin* |

| | |
|-------------------------------|--|
| (inactive ingredients) | sodium chloride monosodium glutamate monohydrate dibasic sodium phosphate monobasic potassium phosphate potassium chloride urea *contains sulfites |
| Potential allergens | neomycin |

Each dose contains trace amounts of bovine (beef) serum.

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.

Do not take this vaccine if you are allergic to any of these ingredients.

What VARIVAX Refrigerated looks like

VARIVAX REFRIGERATED is a white powder that comes in a glass vial. It is reconstituted with a special diluent (water for injections) to make a solution suitable for injection.

Australian Register Numbers:

VARIVAX REFRIGERATED varicella virus vaccine live powder for injection vial (AUST R 90140)

VARIVAX REFRIGERATED varicella virus vaccine live powder for injection vial with prefilled diluent syringe (AUST R 115008)

VARIVAX REFRIGERATED varicella virus vaccine live powder for injection vial with sterile diluent vial (AUST R 337387)

Who sponsors VARIVAX Refrigerated

Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A, 26 Talavera Road
Macquarie Park NSW 2113

Who distributes VARIVAX Refrigerated

Seqirus (Australia) Pty Ltd
Melbourne, Victoria
Australia

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