

VARIVAX[®] Refrigerated

Varicella virus vaccine live (live varicella vaccine)

Consumer Medicine Information

What is in this leaflet

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

All medicines and vaccines have risks and benefits. Your doctor has weighed the risks of you being given VARIVAX Refrigerated against the benefits they expect it will have for you.

If you have any concerns about being given this vaccine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What VARIVAX Refrigerated is used for

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.

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.

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

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 exposure is the best way 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 it works

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.

Before you are given VARIVAX Refrigerated

When you or your child must not be given it

Do not have VARIVAX Refrigerated if:

- you have an allergy to VARIVAX Refrigerated or any of the ingredients listed at the end of this leaflet
- you 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 are pregnant or intend to become pregnant
VARIVAX Refrigerated is not recommended to be given to pregnant women. Also women of child-bearing age should avoid falling pregnant for 3 months after vaccination.
- you are being treated with medicines which decrease the body's immune system such as corticosteroids (eg. prednisone), cyclosporin, cancer medicines
- have diseases which decrease the body's immune system, such as blood disorders, cancers of the blood cells or lymph system (eg. leukaemia, lymphoma) and HIV/AIDS
- you have a family history of immune deficiency
- you have tuberculosis (TB) which is not being currently treated
- you have an infection with a high temperature
- the expiry date on the pack has passed.

If the vaccine is used after the expiry date has passed, it may not work.

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

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.

Before you or your child are given it

Tell your doctor if:

1. you are breast-feeding or plan to breast-feed

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.

2. you have or have had any medical conditions

3. you 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.

4. you 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.

Taking other medicines

Tell your doctor if you or your child are taking any other medicines, including any 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 (eg. prednisone) cyclosporin, or cancer medicines
- aspirin or other salicylate medicines.

Your doctor will advise you whether you are receiving 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.

How VARIVAX Refrigerated is 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 it is given

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

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

If you miss a dose

If you miss a scheduled dose, talk to your doctor and arrange another visit as soon as possible.

After you have been given VARIVAX Refrigerated

Things you must 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 must 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.

Things to be careful of

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.

Side Effects

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well during or after having had a dose of VARIVAX Refrigerated.

VARIVAX Refrigerated 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. You or your child may need medical treatment if you get some of the side effects.

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

Tell your doctor if you or your child have any of the following and they are troublesome or ongoing:

- 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

These are the more common side effects of VARIVAX Refrigerated. For the most part these have been mild.

Tell your doctor immediately if you or your child notice any of the following:

- 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

†Can be from naturally occurring chickenpox or the vaccine in healthy individuals or individuals with lowered immunity.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Allergic Reaction:

As with all vaccines given by injection, there is a very small risk of a serious allergic reaction.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice any of the following:

- skin rash, itchiness, or other severe skin reactions
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing

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.

Other side effects not listed above may also occur in some patients.

Tell your doctor 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

VARIVAX Refrigerated is usually stored in the doctor's surgery or clinic, or at the pharmacy. 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.**

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.**

Product description

What it looks like

VARIVAX Refrigerated is a white powder that comes in a glass vial. It is reconstituted with a special diluent to make a solution suitable for injection.

Ingredients

Active ingredient:

Each 0.5 mL dose of VARIVAX Refrigerated contains 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).

Inactive ingredients:

- sucrose
- hydrolysed porcine gelatin
- sodium chloride
- monosodium glutamate monohydrate
- dibasic sodium phosphate
- monobasic potassium phosphate
- potassium chloride
- urea

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

The diluent contains water for injections.

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.

Supplier

VARIVAX Refrigerated is supplied in Australia by:

Seqirus (Australia) Pty Ltd
63 Poplar Road
PARKVILLE VIC 3052

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