

## **VARIVAX®**

*Varicella Virus Vaccine Live (Oka/Merck)*

Single dose vial

### **What is in this leaflet**

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

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

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

Keep this leaflet. You may need to read it again.

### **What VARIVAX is used for**

VARIVAX is a vaccine used to help prevent chickenpox. It can be given to children 12 months of age and above, teenagers and adults.

Chickenpox is easily passed from one person to another and occurs in millions of people worldwide each year, most often in children 5 to 9 years of age. It is primarily spread from person to person through the air by sneezing or coughing. Once a person has been infected, it usually takes about 2 to 3 weeks before symptoms 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 clusters 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 disease, 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, and death. Severe disease and serious complications are more likely to occur in adolescents and adults.

### **Before you are given VARIVAX**

#### **When you or your child must not be given it**

Do not have VARIVAX if:

- you have an allergy to VARIVAX or any of the ingredients listed at the end of this leaflet
- you have a blood disorder or any type of cancer that affects your immune system
- you are taking any medicine that suppresses your immune system
- you have any other disease that affects your immune system (such as AIDS)
- you have active untreated tuberculosis
- you currently have a fever of more than 38.5°C
- you are or may potentially be pregnant (pregnancy should also be avoided for 3 months after vaccination)
- 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, talk to your doctor.

VARIVAX must not be given to children under 12 months of age. The safety and effectiveness of VARIVAX in these children have not been established.

### **Before you or your child are given it**

Tell your doctor if:

- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes, especially gelatin or neomycin.
- you are breastfeeding or you intend to breastfeed, your doctor will decide if you should receive the vaccine.

In rare circumstances, it is possible to catch chickenpox, including severe chickenpox, from a person who has been vaccinated with VARIVAX. This may occur in persons who have not previously been vaccinated or 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 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.

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

### **Taking other medicines**

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

Medicines that fall under the category of salicylates such as Aspirin should not be taken for at least 6 weeks after vaccination with VARIVAX. If you are not sure if your medicine is within this class, ask your doctor or pharmacist.

Tell your doctor if you or your child are taking corticosteroids (e.g., prednisone). Your doctor will advise you if you or your child are taking any of these or other medicines that decrease the immune system, and the doctor will decide whether or not to give the vaccine.

### **Use with other vaccines**

VARIVAX may be given at the same time as M-M-R<sup>®</sup> II (measles, mumps, and rubella virus vaccine live), diphtheria and tetanus toxoids and pertussis vaccine adsorbed and *Haemophilus influenzae* type b conjugate combined vaccine, *Haemophilus influenzae* type b Conjugate (Meningococcal protein Conjugate) and Hepatitis B (Recombinant) combined vaccine, OPV (oral poliovirus vaccine), DTaP (diphtheria, tetanus, acellular pertussis), or PedvaxHIB\* (*Haemophilus influenzae* type b).

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\* Not currently registered in New Zealand

If VARIVAX is not given at the same time as M-M-R II, a 1-month interval between these 2 vaccines should be observed. Your doctor will decide the vaccination schedule.

The injections should be given at different places on the body and using separate syringes.

## **How VARIVAX is given**

### **How much is given**

VARIVAX is given to individuals 12 months of age and older. The dose of the vaccine is the same for everyone. For children aged 12 months to 12 years, at least one injection is given. If your doctor gives a second dose, the second dose must be given at least 3 months after the first dose. 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 dose should be given 4 to 8 weeks after the first dose.

### **How it is given**

VARIVAX is given as an injection deep under the skin, usually in your upper arm or upper thigh by a doctor or trained nurse.

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

### **If you miss a dose**

Talk to your doctor and arrange another visit as soon as possible.

## **After you have been given VARIVAX**

### **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 dose of VARIVAX at the appropriate time to make sure the vaccine has the best chance of providing protection against the chickenpox virus.

### **Things to be careful of**

Be careful driving or operating machinery until you know whether VARIVAX has affected you. VARIVAX should not normally interfere with your ability to drive a car or operate machinery.

## **Adverse Effects**

Tell your doctor or nurse as soon as possible if you do not feel well during or after having had an injection of VARIVAX.

VARIVAX helps protect most people from chickenpox, but it may have unwanted adverse effects in a few people. All medicines and vaccines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

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

## **In children, teenagers and adults:**

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

- local reaction around the injection site such as pain, soreness, tenderness, warmth, redness or swelling

These are the more common adverse effects of VARIVAX that may occur in children, teenagers and adults. For the most part these have been mild.

Other side effects have been reported and some of these were serious.

Tell your doctor if you notice any of the following and they worry you

- skin rash, itching
- hives or nettlerash (pinkish, itchy swellings on the skin), these may be signs of an allergic reaction
- fever, tingling of the skin, shingles (herpes zoster)<sup>†</sup>, or a chickenpox-like rash on the body or at the injection site
- chest and/or ear infection
- cough
- nausea and/or vomiting
- loss of appetite
- abdominal pain
- diarrhoea
- constipation
- irritability/fatigue/malaise
- disturbed sleep
- headache
- muscle or joint pain, including stiff neck
- dizziness
- swollen lymph glands (in the neck, armpit or groin)
- eye complaint

Tell your doctor immediately if you notice any of the following

- bruising more easily than normal
- red or purple, flat, pinhead spots under the skin; severe paleness
- difficulty walking
- severe skin disorders, and skin infection
- chickenpox
- inflammation of the brain (encephalitis<sup>†</sup> -symptoms include severe headache and sensitivity to light)
- inflammation of the lung (pneumonia/pneumonitis)
- seizure with or without fever
- stroke
- inflammation of the coverings of the brain and spinal cord (meningitis)<sup>†</sup>

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

These adverse effects are rare.

Other adverse 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 adverse effects.

You may not experience any of them.

## **Storage**

VARIVAX is usually stored in the doctor's surgery or clinic, or at the pharmacy. However if you need to store VARIVAX:

- keep it where children cannot reach it
- keep it in the refrigerator, but not in the door compartment
- keep the injection in the original pack until it is time for it to be given.

## **Product description**

### **What it looks like**

VARIVAX is supplied as:

- a single dose carton containing a vial of vaccine and a vial of diluent
- a carton containing 10 single dose vials of vaccine and a carton containing 10 vials of diluent
- a single dose carton containing a vial of vaccine and a pre-filled diluent syringe
- a carton containing 10 single dose vials of vaccine and 10 pre-filled diluent syringes

It is a clear colourless to pale yellow liquid. The vials and syringes are made up using a supplied diluent which contains sterile water for injection.

## **Ingredients**

### Active ingredient

Each 0.5 mL dose contains not less than 1350 plaque forming units of varicella virus (Oka/Merck).

### Inactive ingredients

Sucrose, hydrolysed gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic and potassium chloride. The product also contains residual components of MRC-5 cells and trace quantities of neomycin and bovine calf serum.

VARIVAX does not contain any preservatives.

## **Supplier**

VARIVAX is supplied in New Zealand by:

Merck Sharp and Dohme (New Zealand) Limited  
P O Box 99851  
Newmarket  
Auckland  
NEW ZEALAND  
Tel: 0800 500 673

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