PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

VARIVAX® III

varicella virus vaccine, live, attenuated [Oka/Merck]

Read this carefully before you or your child is vaccinated with **VARIVAX® III**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VARIVAX® III**.

What is VARIVAX® III used for?
VARIVAX® III is an injectable live virus vaccine to help prevent chickenpox (varicella). The vaccine can be administered to persons 12 months of age or older.

How does VARIVAX® III work?
Your doctor has recommended or administered VARIVAX® III to help protect you or your child against chickenpox.

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. Although chickenpox is generally a fairly harmless disease, it may be associated with serious complications (such as bacterial skin infections, pneumonia, inflammation of the brain, Reye syndrome) and/or rarely death.

What are the ingredients in VARIVAX® III?
Medicinal ingredients: Each 0.5 mL dose contains as active ingredient a minimum of 1350 PFU (plaque-forming units) of live attenuated varicella virus (Oka/Merck strain).
Non-medicinal ingredients:
Powder: hydrolyzed gelatin, monosodium L-glutamate, neomycin (trace quantities), potassium chloride, potassium phosphate monobasic, sodium chloride, sodium phosphate dibasic, sucrose, urea,

Diluent: water for injection.

VARIVAX® III comes in the following dosage forms:
VARIVAX® III is supplied as a sterile white powder in a single-dose vial.

The diluent for reconstitution is supplied as a sterile, clear, colourless fluid in a single-dose vial.

When reconstituted, VARIVAX® III is a clear, colourless to pale yellow fluid.

Do not use VARIVAX® III if:
VARIVAX® III should not be used by anyone who:
- is allergic to any of its ingredients (including gelatin and neomycin). A list of ingredients can be found below
- has a blood disorder or any type of cancer that affects their immune system
- is taking medications to suppress their immune system
- has an immune deficiency, including one as a result of a disease (such as AIDS)
- has active untreated tuberculosis

- has a fever > 38.5°C (> 101.3°F)
- is pregnant (in addition, pregnancy should be avoided for 3 months after vaccination)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you or your child gets VARIVAX® III. Talk about any health conditions or problems you or your child may have, including if you or your child:

- has any allergies (especially to gelatin or neomycin)
- has a family member with a weakened immune system

In rare circumstances, it is possible to catch chickenpox, including severe chickenpox, from a person who has been vaccinated with VARIVAX® III. This may occur in persons who have not previously been vaccinated or never 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® III 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.

Use in children
VARIVAX® III can be used in children 12 months of age and older.

Use in pregnancy
VARIVAX® III should not be administered to pregnant women. Women of child-bearing age should take the necessary precautions to avoid pregnancy for 3 months following vaccination.

Use in breast-feeding
Tell your doctor if you are breast-feeding or intend to breast-feed. Your doctor will decide if you should receive VARIVAX® III.

Other warnings you should know about:
As with other vaccines, VARIVAX® III may not fully protect all those who receive it.

Tell your healthcare professional about all the medicines you or your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with VARIVAX® III:

- Vaccine recipients should avoid salicylates (medications derived from salicylic acid, including aspirin) for 6 weeks after vaccination with VARIVAX® III as Reye syndrome (a serious condition which can affect all your body organs) has been reported following use of salicylates during natural varicella infection.

- Vaccination should be deferred for at least 5 months after any blood or plasma transfusions, or administration of immune globulin or varicella zoster immune globulin (VZIG).
- Following vaccination with VARIVAX® III, you or your child should not receive any immune globulin, including VZIG, for 2 months thereafter, unless your doctor decides it is necessary.
- VARIVAX® III can be given at the same time as measles, mumps and rubella vaccine (M-M-R® II) and vaccines against Haemophilus influenzae type b, diphtheria, tetanus and pertussis (whooping cough). If VARIVAX® III 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.

How to take VARIVAX® III:

- VARIVAX® III will be given to you or your child by a healthcare professional in a healthcare setting

Usual dose:

- VARIVAX® III is given by subcutaneous injection as follows:

    - Children 12 months to 12 years of age should receive a 0.5 mL dose. The dose of the vaccine is the same for everyone. If your child is 12 months to 12 years old and your doctor gives a second dose, the second dose should be given at least 3 months after the first dose.
    - Adolescents 13 years of age and older and adults should receive two doses. The second dose should be given 4 to 8 weeks after the first dose.

See your doctor for more details.

Overdose:

If you think you, or a person you are caring for, have received too much VARIVAX® III, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:
If you miss a dose, your doctor will decide when to give the missed dose.

What are possible side effects from using VARIVAX® III?
These are not all the possible side effects you or your child may have when receiving VARIVAX® III. If you or your child experience any side effects not listed here, tell your healthcare professional.

Any vaccine may have unintended or undesirable effects, so-called side effects. The most common are injection site complaints such as pain, swelling, itching and redness. Occasionally, fever, irritability, tingling of the skin, shingles (herpes zoster)†, or a chickenpox-like rash on the body or at the injection site may occur.

Other side effects such as nausea, vomiting, and chickenpox have been reported. Some reported side effects were serious, including allergic reactions (in individuals with or without an allergic history); bruising more easily than normal; red or purple, flat, pinhead spots under the skin; severe paleness; difficulty walking; severe skin disorders; and skin infection. Rarely, inflammation of the brain

(encephalitis)†, stroke (cerebrovascular accident), inflammation of the coverings of the brain and spinal cord (meningitis)†, inflammation of the lung (pneumonia/pneumonitis) and seizures with or without a fever have been reported. The relationship of these rare side effects to the vaccine has not been established.

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

Tell your doctor promptly about any of these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

If you or your child has a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with his daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.
Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Merck Canada Inc. cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html) and send it to your local Health Unit.

Storage:
Vial of powder: Store refrigerated at 2°C to 8°C. The vaccine may also be stored in a freezer at temperatures above -50°C; if subsequently transferred to a refrigerator, the vaccine may be placed back in the freezer. Keep the vial in the outer carton in order to protect from light.

Diluent: Store separately from the vaccine vial at room temperature (20°C to 25°C) or in the refrigerator at 2°C to 8°C

All vaccines must be discarded after the expiration date.

Keep out of reach and sight of children.

If you want more information about VARIVAX® III:
- Talk to your healthcare professional

- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.merck.ca, or by calling at 1-800-567-2594.

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