PART III: CONSUMER INFORMATION

VARIVAX® III
(varicella virus vaccine, live, attenuated [Oka/Merck])

This leaflet is part III of a three-part "Product Monograph" published when VARIVAX® III was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VARIVAX® III. Contact your doctor or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE

What the vaccine is 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.

What it does:
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.

When it should not be used:
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)

What the medicinal ingredient is:
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).

What the important nonmedicinal ingredients are:

Powder: sucrose, hydrolyzed gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, and trace quantities of neomycin.

Diluent: water for injection.

What dosage forms it comes in:
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.

WARNINGS AND PRECAUTIONS

What should I tell my doctor before vaccination with VARIVAX® III?
Tell your doctor about any medical problems you or your child have or have had, and about any allergies (especially to gelatin or neomycin). VARIVAX® III contains gelatin and a trace amount of neomycin as inactive ingredients.

Tell your doctor if there is anyone who comes in close contact with the person being vaccinated who falls into one of the following categories, since these individuals may be at risk of catching chickenpox from the person who was vaccinated:

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

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.

Can I drive or operate machinery following vaccination with VARIVAX® III?
There is no information to suggest that VARIVAX® III affects your ability to drive or operate machinery.

What other important information about VARIVAX® III should I know?

As with other vaccines, VARIVAX® III may not fully protect all those who receive it.

INTERACTIONS WITH THIS VACCINE

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.

PROPER USE OF THIS VACCINE

Usual dose:
VARIVAX® III is given by subcutaneous injection as follows:

- Children 12 months to 12 years of age should receive a single dose. The dose of the vaccine is the same for everyone.
- Adolescents and adults 13 years of age and older 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:

In case of overdose, contact a health care practitioner, 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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.

This is not a complete list of side effects. For any unexpected effects while taking VARIVAX® III contact your doctor or pharmacist.

HOW TO STORE IT

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.

Reporting Suspected Vaccine Adverse Events

For the general public:
If you suspect you have had a serious or unexpected event following receipt of a vaccine, please ask your healthcare professional to complete the Adverse Events Following Immunization (AEFI) Form and send it to your local health unit in your province/territory.

For healthcare professionals:
If a patient experiences an adverse event following immunization, please complete the Adverse Events Following Immunization (AEFI) Form and send it to your local health unit in your province/territory.

If you have any questions or have difficulty contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada:

Toll-free telephone: 1-866-844-0018
Toll-free fax: 1-866-844-5931
By email: caefi@phac-aspc.gc.ca

NOTE: Should you require information related to the management of the adverse events, please contact your health professional before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

MORE INFORMATION

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 Consumer Information by visiting the Health Canada website or Merck Canada website www.merck.ca or by calling Merck Canada at 1-800-567-2594

To report an adverse event related to VARIVAX® III, please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

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