PRODUCT MONOGRAPH

VARILRIX®

Varicella virus vaccine, live, attenuated (oka-strain)

Lyophilized vaccine for reconstitution

Active immunizing agent against infection by varicella-zoster virus

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Date of Revision:
June 2, 2006

Submission Control No:

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VARILRIX®

varicella virus vaccine, live, attenuated (oka-strain)

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Subcutaneous injection	Injection / 0.5 mL of reconstituted vaccine	amino acids, human albumin, lactose, neomycin sulphate and polyalcohols.

DESCRIPTION

VARILRIX® (varicella virus vaccine, live, attenuated (oka-strain)) is a live-attenuated varicella vaccine which contains the oka-strain of the attenuated varicella-zoster virus. VARILRIX® has been reformulated through the addition of a stabilizer, without modification of the viral strain, to permit storage at 2 to 8ºC.

Epidemiology

Varicella is a very common and highly communicable disease of childhood which is experienced by most children. An epidemiological report of Chickenpox in Canada reported that at least 90% of the population will likely contract the infection by late adolescence . Therefore, at steady state conditions, the actual number of cases that occur annually should approximate the number of annual births . Approximately 50% of cases occur in children 5 - 9 years old, 20% in preschool children, 20% in children 10-14 years of age, 10% in children ≥ 15-19 years old and < 2% in adults .

Based on epidemiological evidence, varicella-zoster virus (VZV) spreads by airborne droplets , however, the source of infectious virus remains controversial. Whether it originates primarily from skin or respiratory tract secretions is not clear but it is known that infectivity is maximal in the early stages of the illness . Among household contacts, 70-90% of susceptible individuals may become infected .

The symptoms of varicella in otherwise healthy children are usually mild and self limiting, however, complications such as secondary bacterial infections and otitis media have been reported in as many as 5-10% and 5% of children, respectively . More serious complications include pneumonia, encephalitis, Guillain-Barr Syndrome and Reye's Syndrome .

The severity of varicella and the potential for varicella-related complications increases substantially with age. Although less than 2% of all chickenpox cases occur in adults, a third of all varicella-zoster (VZ) deaths are in adults . In addition, in children with impaired immunity the disease is often severe and can be fatal. Children with malignant disease who are receiving chemotherapy and/or radiotherapy appear to be at greatest risk.

INDICATIONS AND CLINICAL USE

VARILRIX® (varicella virus vaccine, live, attenuated (oka-strain)) is indicated for:

- the active immunization against varicella of healthy subjects from 12 months of age and up.

- the active immunization against varicella of susceptible high-risk patients and their susceptible healthy close contacts.

Patients with acute leukemia
Patients suffering from leukemia have been recognized to be at special risk when they develop varicella, and should receive the vaccine if they have no history of the disease or are found to be seronegative.

When vaccinating patients in the acute phase of leukemia, maintenance chemotherapy should be withheld one week before and one week after immunization. Patients under radiotherapy should normally not be vaccinated during the treatment phase.

Generally patients are immunized when they are in complete hematological remission from the disease. It is advised that the total lymphocyte count should be at least 1,200 per mm^3, or that no other evidence of lack of cellular immune competence exists.

Patients under immunosuppressive treatment
Patients under immunosuppressive treatment (including corticosteroid therapy) for malignant solid tumor or for serious chronic diseases (such as chronic renal failure, auto-immune diseases, collagen diseases, severe bronchial asthma) are predisposed to severe varicella.

It is advised that the total lymphocyte count should be at least 1,200 per mm^3, or that no other evidence of lack of cellular immune competence exists at the time of vaccination.

Patients with planned organ transplantation
If organ transplantation (e.g. kidney transplant) is being considered, vaccination should be carried out 6-8 weeks before the administration of the immunosuppressive treatment.

Patients with chronic diseases
Other chronic disease, such as metabolic and endocrine disorders, chronic pulmonary and cardiovascular diseases, mucoviscidosis and neuromuscular abnormalities may also predispose to severe varicella.

Healthy close contacts
Susceptible healthy close contacts should be vaccinated in order to reduce the risk of the transmission of virus to high-risk patients. These include parents and siblings of high-risk patients, and medical, paramedical personnel and other people who are in close contact with varicella patients or high-risk patients.

CONTRAINDICATIONS

VARILRIX® (varicella virus vaccine, live, attenuated (oka-strain)):

- should not be administered to subjects with known hypersensitivity to any component of the vaccine or to subjects who developed an unacceptable reaction to a previous dose, including anaphylactic reaction.

- is contraindicated in subjects with known systemic hypersensitivity to neomycin, but a history of contact dermatitis to neomycin is not a contraindication.

- is contraindicated in subjects with total lymphocyte count less than 1,200 per mm^3 or presenting other evidence of lack of cellular immune competence.

- administration to pregnant women, is contraindicated because the possible effects on fetal development are unknown. Furthermore, pregnancy should be avoided for three months after vaccination.

- as with other vaccines, administration of VARILRIX® should be postponed in subjects suffering from acute severe febrile illness. In healthy subjects the presence of a minor infection, however, is not a contraindication for vaccination.

WARNINGS AND PRECAUTIONS

Salicylates should be avoided for 6 weeks after varicella vaccination, as Reye's Syndrome has been reported following the use of salicylates during natural varicella infection.

General

As with any parenteral vaccine, appropriate medication (i.e., epinephrine 1:1000) and supervision should be readily available for immediate use in case of anaphylaxis or anaphylactoid reactions following administration of the vaccine .

Transmission of the oka vaccine virus has been shown to occur at a very low rate in seronegative contacts of vaccine recipients.

VARILRIX®(varicella virus vaccine, live, attenuated (oka-strain)) can be administered at the same time as any other vaccine. Different injectable vaccines should be administered at different injection sites.

Inactivated vaccines can be administered in any temporal relationship to VARILRIX®.

If a measles vaccine cannot be administered at the same time as VARILRIX®, it is recommended that an interval of at least one month be allowed between the administration of the two vaccines as it is recognized that measles vaccination may lead to short lived suppression of the cell mediated immune response.

Skin

The mild nature of the rash in the healthy contacts indicates that the virus remains attenuated after passage through human hosts.

Special Populations

Pregnant Women: Administration to pregnant women is contraindicated because the possible effects on fetal development are unknown. Furthermore, pregnancy should be avoided for three months after vaccination.

Nursing Women: It is not known whether VARILRIX® is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when VARILRIX® is administered to a nursing woman.

High-risk patients

VARILRIX® should not be administered at the same time as other live attenuated vaccines. Inactivated vaccines may be administered in any temporal relationship to VARILRIX® given that no specific contraindication has been established.

Different injectable vaccines should always be administered at different injection sites.

ADVERSE REACTIONS

VARILRIX® (varicella virus vaccine, live, attenuated (oka-strain)) is a vaccine of low overall reactogenicity in all age groups.

Clinical Trial Adverse Drug Reactions

> *Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates*.

The incidence of solicited local and general symptoms reported after vaccination is presented in Tables 1 and 2. Reactions at the site of injection of VARILRIX® were the most commonly observed adverse events. These reactions tended to be mild and transient. There was no difference in either local or general reactogenicity between the vaccine groups and the placebo group.

In clinical studies involving more than 2000 subjects from the age of 9 months, papulo-vesicular eruptions were reported in approximately 5% of the vaccinees. Most of them occur during the first three weeks after vaccination, and the number of lesions was generally below ten. Temperature above 37.5ºC (axillary) / 38ºC (rectal) was reported in approximately 5% of subjects during a six week follow-up of the vaccinees. The reactogenicity after the second dose in adolescents and adults was not higher than after the first dose. No difference was seen between the reactogenicity in initially seropositive and seronegative subjects.

In a four-week follow-up double-blind placebo-controlled study including 513 children between 12-30 months of age, there was no significant difference in nature or incidence of symptoms in subjects receiving vaccine or placebo.

Table 1: Incidence of Solicited Symptoms Reported after Vaccination in Children < 13 yrs of age (using diary cards)

Solicited Symptoms:	Incidence in Vaccine group (%) (n=1367)
Local symptoms:	
Pain	15.1
Redness	22.8
Swelling	11.2
Any	31.2
General symptoms:	
Any general symptom*	47.0
Fever**	11.0
Rash: total	10.3
Rash: varicella – like	1.0

Cumulative data from 7 studies
* follow-up varied from 30-42 days after vaccination
** follow-up period for fever 4-42 days

Table 2: Incidence of Solicited Symptoms Reported after Vaccination in Adolescents and Adults (using diary cards)

Solicited Symptoms:	Vaccine – dose 1 (%) (n=548)	Vaccine – Dose 2 (%) (n=379)
Local symptoms:		
Any	12.2	16.6
General symptoms:		
Any general symptom	34.1	22.2
Fever*	29.3	20.7
Rash: total	4.5	4.2
Rash: varicella – like	0.9	1.3

Cumulative data from 5 studies
* fever assessed in one study

High-risk patients
Reactions at the site of injection of VARILRIX® are usually mild.

Papulo-vesicular eruptions, rarely accompanied by mild to moderate fever, have appeared a few days up to several weeks after immunization. Such reactions have occurred in less than a quarter of leukemic patients. These eruptions were generally mild and short-lived.

Eruptions tend to occur in the more immunocompromised leukemic patients such as those still in the maintenance phase of chemotherapy. The appearance of these eruptions did not influence the clinical management of the patients. There is no evidence that immunization may have an adverse effect on the course of the disease.

DRUG INTERACTIONS

Drug-Drug Interactions

In subjects who have received immune globulins or a blood transfusion, vaccination should be delayed for at least three months because of the likelihood of vaccine failure due to passively acquired varicella antibodies.

DOSAGE AND ADMINISTRATION

Recommended Dose and Dosage Adjustment

One immunizing dose contains 0.5 mL of reconstituted vaccine. Children (12 months to 12 years of age, inclusive) should receive a single 0.5 mL dose. Adolescents and adults (13 years of age and older) should receive two 0.5 mL doses with a minimum interval of 6 weeks between doses.

For high-risk patients additional doses of vaccine may be required.

Administration

VARILRIX® (varicella virus vaccine, live, attenuated (oka-strain)) should be administered by subcutaneous injection in the deltoid region.

VARILRIX® should not be injected intradermally. **VARILRIX® must under no circumstances be administered intravascularly.**

Reconstitution:

Parenteral Products:

VARILRIX® is presented as a slightly cream to yellowish or pinkish coloured pellet in a monodose glass vial. VARILRIX® must be reconstituted by adding the contents of the supplied container of diluent (sterile Water for Injection) to the vial containing the pellet. After the addition of the diluent to the pellet, the mixture should be well shaken until the pellet is completely dissolved in the diluent.

Due to minor variations in pH, the color of the reconstituted vaccine may vary from clear peach to pink coloured solution. The diluent (sterile Water for Injection) and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, discard the diluent or the reconstituted vaccine.

Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine since they may inactivate the virus.

VARILRIX® should not be mixed with other vaccines in the same syringe.

After reconstitution, it is recommended that the vaccine be injected as soon as possible. However, it has been demonstrated that the reconstituted vaccine may be kept for up to 90 minutes at room temperature (25ºC) and up to 8 hours in the refrigerator (2 to 8ºC). If not used within these timeframes, the reconstituted vaccine must be discarded.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

Varicella (chickenpox) is caused by primary infection with the varicella-zoster virus (VZV). VARILRIX® (varicella virus vaccine, live, attenuated (oka-strain)) produces an attenuated clinically inapparent varicella infection in susceptible subjects.

VARILRIX® stimulates antibodies directed against varicella-zoster virus. Some protection may be obtained by immunization up to 72 hours after exposure to natural varicella. The presence of antibodies is accepted to be an indication of protection.

STORAGE AND STABILITY

The lyophilized vaccine should be stored in a refrigerator between 2 to 8ºC. The diluent (sterile Water for Injection) may be stored in the refrigerator or at ambient temperature (maximum 25ºC). The lyophilized vaccine is not affected by freezing.

The reconstituted vaccine may be kept for up to 90 minutes at room temperature (25ºC) and up to 8 hours in the refrigerator (2 to 8ºC). If not used within these timeframes, the reconstituted vaccine must be discarded.

Do not use beyond the expiry date printed on the label.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Dosage Form

VARILRIX® (varicella virus vaccine, live, attenuated (oka-strain)) is supplied as a sterile powder and diluent (sterile Water for Injection) (prefilled syringe or ampoule) for subcutaneous injection. The vaccine must be reconstituted and shaken to ensure a uniform mixture before administration.

Composition
A 0.5 mL dose of the reconstituted vaccine contains not less than $10^{3.3}$ plaque-forming units (PFU) of the varicella-zoster virus. The reconstituted vaccine also contains amino acids, human albumin, lactose, neomycin sulfate, polyalcohols and water for injection.

VARILRIX® is presented as a slightly cream to yellowish or pinkish coloured pellet and the diluent, sterile Water for Injection (WFI), presents as a clear and colourless solution.

Packaging
VARILRIX® is supplied in package sizes as follows: Single monodose vial with diluent (sterile WFI) in prefilled syringe with separate needle and in packages of 10 monodose vials. Diluent (sterile WFI) in ampoules in packages of 10 are available separately.

Vials/prefilled syringes are made of neutral type 1 glass.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: varicella virus vaccine, live attenuated (oka-strain)

Physicochemical properties: After reconstitution, the pH of the VARILRIX ®is between 6.9 and 7.4

Product Characteristics

VARILRIX® **(**varicella virus vaccine, live, attenuated (oka-strain)) is a live-attenuated varicella vaccine which contains the oka-strain of the attenuated varicella-zoster virus. VARILRIX®has been reformulated through the addition of a stabilizer, without modification of the viral strain, to permit storage at 2 to 8ºC.

CLINICAL TRIALS

Study results

Healthy subjects

In subjects aged 9 months to 12 years, the overall seroconversion rate when given VARILRIX® (varicella virus vaccine, live, attenuated (oka-strain)) was > 98% when measured at 6 weeks post-vaccination. In children vaccinated at 12-15 months of age, antibodies persisted for at least 7 years post vaccination.

In subjects aged 13 years and above, the seroconversion rate when given VARILRIX® was 100% when measured 6 weeks after the second dose. One year after vaccination, all subjects tested were still seropositive.

In an efficacy study in 10 to 30 month old children during a follow-up of an average of 29.3 months, the protective efficacy was 100% against common clinical cases of varicella (≥ 30 vesicles). Against any cases of varicella (mild case with at least 1 vesicle or papule) protective efficacy of VARILRIX® was 88%. However, cases were mild (median number of vesicles was 1; no fever was reported).

High-risk patients
In high-risk patients the overall seroconversion rate when given VARILRIX® was 80%, however, in leukemic patients the overall seroconversion rate was about 90%. In one study, the incidence of herpes zoster in immunized leukemic patients was lower than that observed in naturally infected non immunized leukemic patients. In highly immunosuppressed patients clinically evident varicella has occurred after immunization and vaccine-like virus has been isolated from vesicles.

In high-risk patients, periodic measurement of varicella antibodies after immunization with VARILRIX® may be indicated in order to identify those who may benefit from re-immunization.

DETAILED PHARMACOLOGY

Not applicable.

MICROBIOLOGY

Not applicable.

TOXICOLOGY

Not applicable.

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PART III: CONSUMER INFORMATION

VARILRIX ®
varicella virus vaccine, live, attenuated (oka-strain)

This leaflet is part III of a three-part "Product Monograph" published for VARILRIX® (varicella virus vaccine, live, attenuated (oka-strain)) that was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VARILRIX ®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
VARILRIX® is a vaccine against varicella, also known as chicken pox.

What it does:
VARILRIX® protects you against varicella virus (chicken pox). It works by helping the body to make its own antibodies which protect you against the disease.

When it should not be used:
You should not receive VARILRIX® if:

- you have had an allergic reaction previously to VARILRIX® or any of it constituents. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- you have a known allergy to neomycin (an antibiotic contained in the vaccine), or
- you have evidence of an inadequate immune response, including low white blood cell count.

You should inform your doctor about the above conditions. Your doctor may decide if the vaccine can be given, if the allergy to neomycin is limited to a skin reaction (contact dermatitis) or the low white blood cell count is not evidence of inadequate immune response.

In addition, you should not receive VARILRIX® if:

- you are pregnant. Furthermore, pregnancy should be avoided for three months after vaccination.
- you have a severe infection with a high temperature (over 38°C). In healthy subjects the presence of minor infection, however, is not a contraindication for vaccination.

What the medicinal ingredient is:
Each 0.5 mL dose of VARILRIX® contains as active ingredient no less than $10^{3.3}$ plaque-forming units (PFU) of the live attenuated oka-strain of varicella-zoster virus.

What the important nonmedicinal ingredients are:
The reconstituted vaccine contains the following nonmedicinal ingredients: amino acids, human albumin, lactose, neomycin sulphate and polyalcohols.
For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:
VARILRIX® is presented as a powder and diluent for solution for injection.

The vaccine is provided as slightly cream to yellowish or pinkish coloured pellet in a monodose glass vial.

The sterile diluent (0.5 mL) is clear and colourless and presented in ampoules and prefilled syringes.

The colour of the reconstituted vaccine may vary from clear peach to pink coloured solution.

WARNINGS AND PRECAUTIONS

VARILRIX® can be administered at the same time as any other vaccine. Different injectable vaccines should be administered at different injection sites.

Inactivated vaccines can be administered at any time in relationship to VARILRIX®.

If a measles vaccine cannot be administered at the same time as VARILRIX®, it is recommended that at least one month be allowed between the administration of the two vaccines as it is recognized that measles vaccination could effect the effectiveness of VARILRIX®.

Salicylates (medications derived from salicylic acid, including aspirin) should be avoided for 6 weeks after varicella vaccination, as Reye's Syndrome (a potentially fatal disease that causes numerous detrimental effects to many organs) has been reported following the use of salicylates during natural varicella infection.

Different injectable vaccines should always be administered at different injection sites.

BEFORE you use VARILRIX® talk to your doctor or pharmacist if:

- you think you may be pregnant.
- you think you have had an allergic reaction previously to VARILRIX® or any of its constituents.
- you are in any of above mentioned situation.
- you are taking any other medicine or have recently received any other vaccine.
- you are breastfeeding.

High risk patients
VARILRIX® should not be administered at the same time as other live attenuated vaccines. Inactivated vaccines may be administered at any time in relationship to VARILRIX® given that no specific contraindication has been established.

INTERACTIONS WITH THIS MEDICATION

In subjects who have received immune globulins or a blood transfusion, vaccination should be delayed for at least three months because of the likelihood of vaccine failure due to passively acquired varicella antibodies.

PROPER USE OF THIS MEDICATION

The vaccine must be administered by a health care professional.

VARILRIX® should not be mixed with any other vaccine in the same syringe.

Make sure you finish the complete vaccination course. If not you may not be fully protected against infection.

Usual dose:
VARILRIX® will be injected subcutaneously.

The upper arm (deltoid region) is the preferred site of injection. VARILRIX® should not be administered intradermally.

VARILRIX® must under no circumstances be administered intravascularly.

The doctor or nurse will inject the recommended dose of vaccine, namely one or two dose(s) of 0.5 mL, according to your age.

Children from the age of 12 months up to and including 12 years of age should receive 1 dose. Adolescents and adults from 13 years up should receive 2 doses with an interval of at least 6 weeks between each dose. In high risk patients additional doses of vaccine might be required.

It is important to follow the instructions from the doctor/nurse so that you complete the course of injections.

Administration:
If you forget to go back to the doctor/nurse at the scheduled time, ask the doctor/nurse for advice

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all vaccines, VARILRIX® may occasionally cause unwanted effects.

As with other vaccines, you may feel pain or discomfort at the injection site, or you may see some redness and swelling at this site. These reactions are usually mild and transient.

Other reactions which can occur are skin rash and fever.

If these discomforts continue or become severe, tell the doctor or nurse.

If you develop any other symptom within days following the vaccination, tell the doctor as soon as possible.

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

HOW TO STORE IT

VARILRIX® should be stored in a refrigerator between 2 to 8°C.

The reconstituted vaccine may be kept for up to 90 minutes at room temperature (25ºC) and 8 hours in the refrigerator (2 to 8ºC). If not used within these timeframes, the reconstituted vaccine must be discarded.

Store all vaccines out of the reach of children.

The expiry date is shown on the label and packaging. The vaccine should not be used after this date.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

For Vaccines:
toll-free telephone: 1-800-363-6456
local telephone: 613-957-1340
fax: 613-998-6413

By regular mail:
Health Canada
Division of Immunization
L.C.D.C., Tunney's Pasture 0603E1
Ottawa, ON K1A 0L2

For Drugs:
toll-free telephone: 866-234-2345
toll-free fax 866-678-6789
By email: cadrmp@hc-sc.gc.ca

By regular mail:
National AR Centre
Marketed Health Products Safety and Effectiveness Information Division
Marketed Health Products Directorate
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://www.gsk.ca or by contacting the sponsor,
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This leaflet was prepared by GlaxoSmithKline Inc.

Last Revised: June 2, 2006
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