PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a physician's prescription only

Varilrix

Powder and solvent for solution for injection

Each dose (0.5 ml) contains:
Live attenuated varicella virus ≥ $10^{3.3}$ PFU

For a list of inactive and allergenic ingredients in the preparation, see section 6 – "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Active immunization against varicella (chickenpox) in the following populations, where there is no history of varicella:

- Healthy individuals from the age of 12 months.
- Patients at high risk of severe varicella, such as patients with acute leukemia or a chronic condition, those on immunosuppressive therapy or those for whom an organ transplant is being considered.
- Healthy individuals living in close contact with patients with varicella and high-risk patients.

Therapeutic group: Viral vaccines, Varicella zoster vaccines

How does the vaccine work?

When a person is vaccinated with Varilrix, the immune system (the body's natural defense system) will make antibodies to protect the person from being infected by chickenpox (varicella) virus.

Varilrix contains weakened virus that is highly unlikely to cause chickenpox in healthy individuals. As with all vaccines, Varilrix may not fully protect all individuals who are vaccinated.

2. BEFORE USING THE MEDICINE

Do not use Varilrix if:

- you or your child are sensitive (allergic) to the active ingredient or any of the additional ingredients contained in the vaccine (detailed in section 6). Signs of an allergic reaction may include: itchy skin rash, shortness of breath and swelling of the face or tongue.
- you or your child have any illness (such as blood disorders, cancer, human immunodeficiency virus (HIV) infection, or Acquired Immunodeficiency Syndrome (AIDS)) or take any medicine (including high-dose corticosteroids) that weakens the immune system. Whether

you or your child receive the vaccine will depend upon the level of your immune defenses. See section 2 “Special warnings regarding use of this medicine”.
- you or your child are known to be allergic to neomycin (a type of antibiotic). A known contact dermatitis (skin rash when the skin is in direct contact with allergens such as neomycin) should not be a reason not to be vaccinated but talk to your physician first.
- you or your child have previously had an allergic reaction to any vaccine against varicella.
- you are pregnant. In addition, pregnancy should be avoided for 1 month following vaccination.

Special warnings regarding use of this medicine

Before you or your child are vaccinated with Varilrix, tell the physician if:
- you or your child have a severe infection with a high temperature. It might be necessary to postpone the vaccination until recovery. A minor infection such as a cold should not require postponement of the vaccination but talk to your physician first.
- you or your child have a weakened immune system due to diseases (e.g., human immunodeficiency virus (HIV) infection) and/or treatments. You or your child should be closely monitored as the response to the vaccine may not be sufficient to ensure protection against the illness (see section 2 “Do not use Varilrix if”).
- you have bleeding problems or bruise easily.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore, tell the physician or nurse if you or your child fainted with a previous injection.

Like other vaccines, Varilrix may not completely protect you or your child against catching chickenpox. However, individuals who have been vaccinated and catch chickenpox usually have a very mild disease, compared with individuals who have not been vaccinated.

In rare cases, the weakened virus can be passed on from a vaccinated person to others. This has usually occurred when the person vaccinated had some spots or blisters. Healthy individuals who become infected in this way usually only develop a mild rash, which is not harmful.

Once vaccinated, you or your child should attempt to avoid for up to 6 weeks after vaccination, whenever possible, close association with the following individuals:
- individuals with a weakened immune system.
- pregnant women who either have not had chickenpox or have not been vaccinated against chickenpox.
- newborn infants of mothers who either have not had chickenpox or have not been vaccinated against chickenpox.

Drug interactions

If you or your child are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the physician or pharmacist.
Tell the physician if you or your child are due to have a skin test for possible tuberculosis. If this test is done within 6 weeks after receiving Varilrix, the result may not be reliable.

Vaccination should be delayed for at least 3 months if you or your child have received a blood transfusion or human antibodies (immunoglobulins).

The use of aspirin or other salicylates (a substance present in some medicines used to lower fever and relieve pain) should be avoided for 6 weeks following vaccination with Varilrix as this may cause a serious disease called Reye's Syndrome which can affect all body organs.

Varilrix can be administered at the same time as other vaccines. A different injection site will be used for each vaccine.

Pregnancy and breastfeeding
Varilrix should not be administered to pregnant women.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult with a physician or pharmacist before being vaccinated with this medicine.
Also, it is important that you do not become pregnant within one month after having the vaccine. During this time you should use an effective method of birth control to avoid pregnancy.
Inform the physician if you are breastfeeding or if you intend to breastfeed. Your physician will decide if you should receive Varilrix.

Driving and operating machinery
Varilrix has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4 "Side Effects" may temporarily affect the ability to drive or use machines.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the physician only.

Varilrix is injected under the skin either in the upper arm or in the outer thigh.

The usual dose is generally:

In healthy individuals
Children aged 12 months to 12 years:
Two doses of Varilrix. It is preferable to administer the second dose at least 6 weeks, but under no circumstances less than 4 weeks, after the first dose.

Adolescents aged 13 years and over and adults:

Two doses of Varilrix. An interval of at least 6 weeks, but under no circumstances less than 4 weeks, should be maintained between the two doses.

In patients at high risk
The dosage regimen described for healthy individuals is also applicable to high-risk patients, but additional doses may be necessary.

Interchangeability
A single dose of Varilrix may be administered to individuals who have already received a single dose of another varicella-containing vaccine.
A single dose of another varicella-containing vaccine may be administered to individuals who have already received a single dose of Varilrix.

Do not exceed the recommended dosage.

If you or your child accidentally receive too high a dose
Overdose is very unlikely because the vaccine is provided in a single dose vial and is administered by a physician or nurse. Few cases of accidental administration were reported and only in some of them were abnormal drowsiness and fits (seizures) reported.

If you or your child miss a dose
Contact your physician, who will decide if a dose is required and when to give it.
Adhere to the treatment regimen recommended by the physician.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Varilrix may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

The following side effects may occur with this vaccine:

Very common side effects
May occur in **more than 1 in 10 people**:
- pain and redness at the injection site

Common side effects
May occur in **up to 1 in 10 people**:
- rash (spots and/or blisters)
- swelling at the injection site*
- fever of 38 degrees or higher (rectal)*

Uncommon side effects
May occur in **up to 1 in 100 people**:
- upper respiratory tract infection

- sore throat and discomfort when swallowing (pharyngitis)
- swollen lymph glands
- irritability
- headache
- feeling drowsy
- cough
- itchy, runny or blocked nose, sneezing (rhinitis)
- nausea
- vomiting
- chickenpox-like rash
- itching
- joint pain
- muscle pain
- fever higher than 39.5°C (rectal)*
- lack of energy (fatigue)
- generally feeling unwell

Rare side effects
May occur in **up to 1 in 1,000 people**:
- inflammation of eye (conjunctivitis)
- stomach pain
- diarrhea
- itchy, bumpy rash (hives)

*Swelling at the injection site and fever may happen very commonly in adolescents and adults. Swelling may also happen very commonly after the second dose in children under 13 years of age.

The following side effects have been reported on a few occasions during routine use of Varilrix:
- shingles (herpes zoster).
- small spotted bleeding, or bruising more easily than normal, due to a drop in a type of blood cells called platelets.
- allergic reactions. Rashes that may be itchy or blistering, swelling of the eyes and face, difficulty in breathing or swallowing, a sudden drop in blood pressure and loss of consciousness. Such reactions may occur before leaving the physician's clinic. However, if you or your child get any of these symptoms, you should contact the physician immediately.
- infection or inflammation of the brain, spinal cord and peripheral nerves resulting in temporary difficulty when walking (unsteadiness) and/or temporary loss of control of body movements, stroke (damage to the brain caused by an interruption to its blood supply).
- fits or seizures.
- inflammation, narrowing or blockage of blood vessels. This may include unusual bleeding or bruising under the skin (Henoch Schonlein purpura) or fever which lasts for more than five days, associated with a rash on the trunk sometimes followed by peeling of the skin on the hands and fingers, red eyes, lips, throat and tongue (Kawasaki disease).

- erythema multiforme (symptoms are red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body).

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report side effects of drug treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in the refrigerator (between 2°C to 8°C).
- After reconstitution, inject the vaccine as soon as possible.
  However, it has been demonstrated that the reconstituted vaccine can be stored for up to 90 minutes at room temperature (25°C) and for up to 8 hours in the refrigerator (between 2°C to 8°C). If the reconstituted vaccine is not used within these timeframes, it must be discarded.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Powder: Anhydrous lactose, mannitol, amino acids for injection, sorbitol
  Traces of: Neomycin sulphate
  Solvent: Water for injection
- What the medicine looks like and contents of the package:
  Powder: A cream to yellowish or pinkish colored powder, in a glass vial.
  Solvent: A clear, colorless liquid, with no visible particles, in a pre-filled syringe or in an ampule.
  After reconstitution with the solvent: A clear solution, peach to pink in color.

Package sizes:
1 and 10 doses. The package may also contain needles.
It is possible that not all package sizes are marketed.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Biologicals S.A., Rixensart, Belgium.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 115-15-29677

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Varilrix PT V1.0B