

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

The medicine is dispensed according to a physician's prescription only

## **Varilrix**

### **Powder and solvent for solution for injection**

Each dose (0.5 ml) contains:

Live attenuated varicella virus  $\geq 10^{3.3}$  PFU

For the list of inactive and allergenic ingredients in the medicine, see section 2 – “Important information about some of the ingredients in the medicine” and section 6 – “Additional 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 a weakened virus that is highly unlikely to cause chickenpox in healthy individuals. As with other 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 that weakens the immune system (such as blood disorders, cancer, Human Immunodeficiency Virus [HIV] infection, or Acquired Immunodeficiency Syndrome [AIDS]), or have

recently received or are still taking any medicine that weakens the immune system (except low-dose corticosteroid therapy for asthma or replacement therapy).

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 (an antibiotic agent). A known contact dermatitis (skin rash that occurs when the skin is in direct contact with allergens such as neomycin) should not be a reason not to be vaccinated, but you should 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 the 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 you should 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, or will be starting a treatment with a medicine that weakens the immune system. In this case, 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, whenever possible, close association with the following individuals for up to 6 weeks after vaccination:

- 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 or vaccines, 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 breast-feeding**

Varilrix should not be administered to pregnant women.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician or pharmacist before the vaccination is given.

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 breast-feeding or if you intend to breast-feed. Your physician will decide if you should receive Varilrix.

### **Driving and using machines**

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

### **Important information about some of the ingredients in the medicine**

#### **Varilrix contains sorbitol and phenylalanine**

The preparation contains 6 mg of sorbitol per dose.

The preparation contains 331 micrograms of phenylalanine per dose. Phenylalanine may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up in the body because the body cannot remove it properly.

## **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 preparation dosage and treatment regimen.

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 recommended dosage is usually:

### **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 after the first dose, but under no circumstances less than 4 weeks.

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 dose.**

### **If you or your child accidentally have received 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 abnormal drowsiness and fits (seizures) were 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 your physician.

**Do not take medicines in the dark! Check the label and the dose each time you take a 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°C 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 the 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:

- infection or inflammation of the brain (encephalitis) has been observed following vaccination with live attenuated varicella vaccines. In a few cases, this condition has been fatal, especially in people with a weakened immune system (as noted in section 2, the Varilrix vaccine must not be given to patients with a weakened immune system). Seek immediate medical attention if you or your child develop loss or reduced levels of consciousness, convulsions, or loss of control of bodily movements, accompanied by fever and headache, as these might be signs of infection or inflammation of the brain. Inform your doctor or pharmacist that you or your child received a live attenuated varicella vaccine.

- infection or inflammation of the spinal cord and peripheral nerves resulting in temporary difficulty when walking (unsteadiness) and/or temporary loss of control of bodily movements.
- stroke (damage to the brain caused by an interruption to its blood supply).
- fits or seizures.
- 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 clinic. However, if you or your child get any of these symptoms, you should contact the physician immediately.
- inflammation, narrowing or blockage of blood vessels. This may include unusual bleeding or bruising under the skin (Henoch schonlein purpura), or a fever lasting more than five days associated with a rash on the trunk, sometimes followed by peeling of the skin on the hands and fingers, and red eyes, lips, throat and tongue (Kawasaki disease).
- erythema multiforme (symptoms are red, often itchy spots, similar to the rash of measles, which starts to develop 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](http://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 TO STORE THE MEDICINE?**

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed 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).
- Store in the original package in order to protect from light.
- After reconstitution, the vaccine should be administered promptly.  
If this is not possible, the reconstituted vaccine may be kept for up to 90 minutes at room temperature (25°C) or for up to 8 hours in the refrigerator (between 2°C to 8°C). If not used within the recommended in-use storage timeframes and conditions, the reconstituted vaccine must be discarded.

- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

## 6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains:  
Powder: Anhydrous lactose, mannitol, amino acids for injection (containing phenylalanine), sorbitol.  
Solvent: Water for injection.  
Traces of: Neomycin sulphate.
- 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.  
Not all package sizes may be 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 V4A*

## **The following information is intended for healthcare professionals only:**

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine since they can inactivate the attenuated viruses in the vaccine.

Varilrix must not be administered intravascularly or intradermally.

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

### **Instructions for reconstitution of the vaccine with solvent presented in ampoules**

The solvent and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance before administration. In the event of either being observed, do not administer the vaccine.

The vaccine must be reconstituted by adding the entire contents of the supplied ampoule of solvent to the vial containing the powder. The mixture should be well shaken until the powder is completely dissolved in the solvent.

The colour of the reconstituted vaccine may vary from clear peach to pink due to minor variations of its pH. This is normal and does not impair the performance of the vaccine. In the event of other variation being observed, do not administer the vaccine.

Withdraw the entire contents of the vial.

A new needle should be used to administer the vaccine.

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 (25°C) and up to 8 hours in the refrigerator (2°C to 8°C). If not used within the recommended in-use storage timeframes and conditions, the reconstituted vaccine must be discarded.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

### **Instructions for reconstitution of the vaccine with solvent presented in a pre-filled syringe**

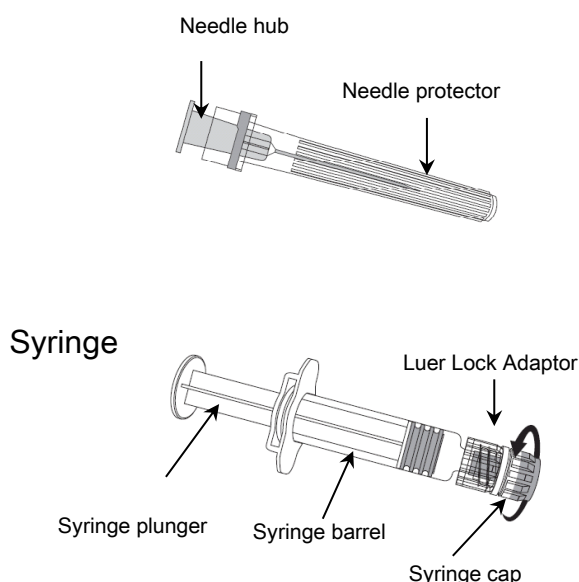
The solvent and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance before administration. In the event of either being observed, do not administer the vaccine.

The vaccine must be reconstituted by adding the entire contents of the pre-filled syringe of solvent to the vial containing the powder.

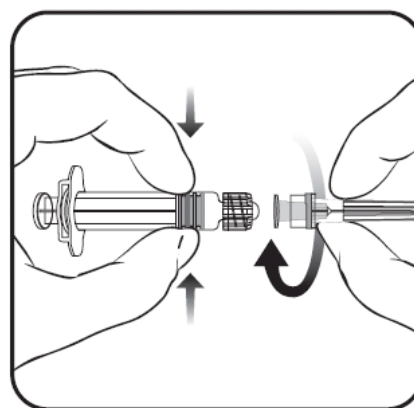
To attach the needle to the syringe, carefully read the instructions given with pictures 1 and 2. However, the syringe provided with Varilrix might be slightly different (without screw thread) than the syringe illustrated.

In that case, the needle should be attached without screwing.

## Needle



**Picture 1**



**Picture 2**

Always hold the syringe by the barrel, not by the syringe plunger or the Luer Lock Adaptor (LLA), and maintain the needle in the axis of the syringe (as illustrated in picture 2). Failure to do this may cause the LLA to become distorted and leak.

During assembly of the syringe, if the LLA comes off, a new vaccine dose (new syringe and vial) should be used.

1. Unscrew the syringe cap by twisting it anticlockwise (as illustrated in picture 1).  
Whether the LLA is rotating or not, please follow the steps below:
2. Attach the needle to the syringe by gently connecting the needle hub into the LLA and rotate a quarter turn clockwise until you feel it lock (as illustrated in picture 2).
3. Remove the needle protector, which may be stiff.
4. Add the solvent to the powder. The mixture should be well shaken until the powder is completely dissolved in the solvent.  
The colour of the reconstituted vaccine may vary from clear peach to pink due to minor variations of its pH. This is normal and does not impair the performance of the vaccine. In the event of other variation being observed, do not administer the vaccine.
5. Withdraw the entire contents of the vial.

6. A new needle should be used to administer the vaccine. Unscrew the needle from the syringe and attach the injection needle by repeating step 2 above.

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 (25°C) and up to 8 hours in the refrigerator (2°C to 8°C). If not used within the recommended in-use storage timeframes and conditions, the reconstituted vaccine must be discarded.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.