

GlaxoSmithKline

Package Leaflet: Information for the User

Varilrix, powder and solvent for solution for injection in pre-filled syringe

Varicella vaccine (live)

Read all of this leaflet carefully before you or your child receive this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you or your child get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Varilrix is and what it is used for
- 2 What you need to know before you or your child receive Varilrix
- 3 How Varilrix is given
- 4 Possible side effects
- 5 How to store Varilrix
- 6 Contents of the pack and other information

1 What Varilrix is and what it is used for

Varilrix is a vaccine for use in individuals from 12 months of age to protect them against chickenpox (varicella). In some circumstances, Varilrix can also be given to infants as from 9 months of age.

Vaccination within 3 days of exposure to someone with chickenpox may help prevent chickenpox or reduce the severity of disease.

How Varilrix works

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

Varilrix contains weakened viruses that are highly unlikely to cause chickenpox in healthy individuals.

As with all vaccines, Varilrix may not fully protect all individuals who are vaccinated.

2 What you need to know before you or your child receive Varilrix

Do not use Varilrix

- if 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 level of your immune defences. See section 2 "Warnings and precautions".
- if you or your child are allergic to any of the ingredients of this vaccine (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

- if you or your child are known to be allergic to neomycin (an antibiotic agent). 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 doctor first.
- if you or your child have previously had an allergic reaction to any vaccine against varicella.
- if you are pregnant. In addition, pregnancy should be avoided for 1 month following vaccination.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you or your child receive Varilrix

- 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 doctor first.
- if you or your child have a weakened immune system due to diseases (e.g. such as HIV infection) and/or treatments. You or your child should be closely monitored as the responses to the vaccines may not be sufficient to ensure a 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 doctor 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;
- new-born infants of mothers who either have not had chickenpox or have not been vaccinated against chickenpox.

Other medicines and Varilrix

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other vaccines and/or medicines.

Tell your doctor 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 doctor 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 your doctor if you are breast-feeding or if you intend to breast-feed. Your doctor 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 effects mentioned under section 4 “Possible side effects” may temporarily affect the ability to drive or use machines.

Varilrix contains sorbitol and phenylalanine.

This vaccine contains 6 mg of sorbitol per dose.

This vaccine 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 because the body cannot remove it properly.

3 How Varilrix is given

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

Individuals from 12 months of age should be administered 2 doses of Varilrix at least 6 weeks apart. The time between the first and second dose **must not** be less than 4 weeks.

In some circumstances, the first dose of Varilrix may be administered to infants from 9 to 11 months of age. In these cases, two doses are needed and should be given at least 3 months apart.

Individuals who are at risk of severe chickenpox such as those receiving treatment for cancer, may receive additional doses. The time between doses **must not** be less than 4 weeks.

The appropriate time and number of doses will be determined by your doctor on the basis of appropriate official recommendations.

If you or your child receive more Varilrix than you or your child should

Overdose is very unlikely because the vaccine is provided in a single dose vial and is administered by a doctor or nurse. Few cases of accidental administration were reported and only in some of them abnormal drowsiness and fits (seizures) were reported.

If you think you or your child have missed a dose of Varilrix

Contact your doctor who will decide if a dose is required and when to give it.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may happen with this vaccine

- Very common (may affect more than 1 in 10 people)
 - pain and redness at the injection site
- Common (may affect up to 1 in 10 people)
 - rash (spots and/or blisters)
 - swelling at the injection site*
 - fever of 38°C or higher (rectal)*
- Uncommon (may affect 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 (may affect up to 1 in 1,000 people)

- inflammation of eye (conjunctivitis)
- stomach pain
- diarrhoea
- 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 doctor's surgery. However, if you or your child get any of these symptoms you should contact a doctor urgently.
- 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 bodily 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 a

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).

Reporting of side effects

If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Varilrix

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store and transport refrigerated (2°C - 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 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.

Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6 Contents of the pack and other information

What Varilrix contains

- The active substance is varicella live attenuated virus (Oka strain, produced in MRC-5 human diploid cells). Each 0.5 mL dose of the reconstituted vaccine contains not less than $10^{3.3}$ PFU (Plaque-forming units) of varicella virus.
- The other ingredients are:
Powder: amino acids (containing phenylalanine), lactose anhydrous, sorbitol (E 420), mannitol (E 421).
Solvent: water for injections.

What Varilrix looks like and contents of the pack

Varilrix is presented as a powder and solvent for solution for injection (powder in a vial for 1 dose and solvent in a pre-filled syringe (0.5 mL)) with or without separate needles in the following pack sizes:

- with 1 separate needle: pack sizes of 1 or 10.

- with 2 separate needles: pack sizes of 1 or 10.
- without needles: pack sizes of 1 or 10.

Varilrix is supplied as slightly cream to yellowish or pinkish powder and a clear colourless solvent (water for injections) for reconstituting the vaccine.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

SmithKline Beecham Ltd, 79 New Oxford Street, London, WC1A 1DG

Manufacturer:

GlaxoSmithKline Biologicals S.A., Rue de l'Institut 89, B-1330 Rixensart, Belgium.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only).

Please be ready to give the following information:

Product name **Varilrix**

Reference number 10592/0121

This is a service provided by the Royal National Institute of Blind People.

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The following information is intended for healthcare professionals only.

Varilrix, powder and solvent for solution for injection in pre-filled syringe.

Varicella vaccine (live)

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.

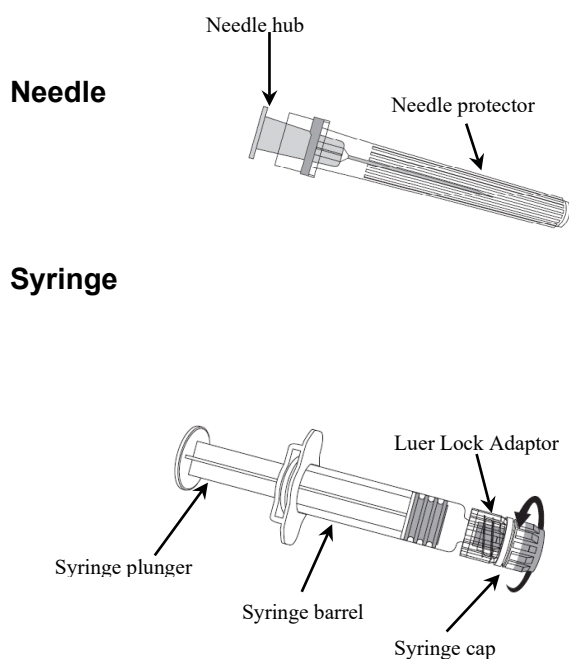
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

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.

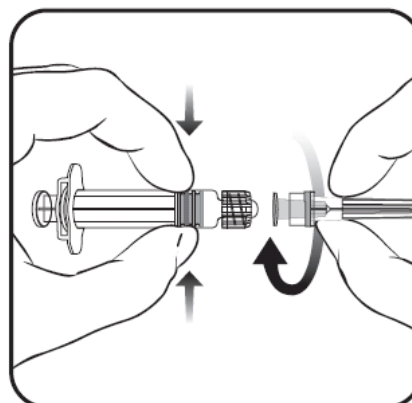
The vaccine must be reconstituted by adding the entire contents of the pre-filled syringe of solvent to the vial containing the powder..

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.



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 below steps:

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.