Package Leaflet: Information for the User

Varilrix
$10^{3.3}$ PFU/0.5 ml, powder and solvent for solution for injection.

Varicella/chickenpox vaccine

Read all of this leaflet carefully before you are given this vaccine 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 or pharmacist.
- This vaccine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. 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

Varilrix is a chickenpox or 'varicella' vaccine. It is used to boost the body's immune system to stop infection from chickenpox.

This vaccine can be given to both adults and children older than 9 months. In this leaflet any reference to 'you' can also mean 'your child'.

How Varilrix works
Varilrix contains a small amount of a live but weakened 'varicella-zoster' virus which is the cause of chickenpox.
- There is not enough virus in the vaccine to make you ill.
- There is just enough to trigger the body's immune system to prepare itself to protect against these viruses in the future.
- Varilrix does not always completely protect you from catching chickenpox. People who catch chickenpox after receiving the vaccine usually get a mild form. They will have very few spots and blisters compared to people who have not had the vaccine.
- Varilrix is normally given to healthy children (as of 9 months), teenagers and adults.
- Varilrix may sometimes be given to healthy individuals who live with, or spend a lot of time with, people who have poor immune systems and who are likely to become seriously ill if they were to catch chickenpox.
- If you come in contact with someone who has chickenpox or shingles before both doses of Varilrix have been given or about 6 weeks after the second dose, the vaccine may not be able to prevent chickenpox.

2 What you need to know before you receive Varilrix

Do not have Varilrix :

- if you are allergic (hypersensitive) to Varilrix or any of the ingredients (listed in section 6)
- if you are allergic (hypersensitive) to any other chickenpox vaccine or neomycin, an antibiotic used to treat skin infections
- if you have a high temperature (fever)
- if you have any illness (such as Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS)) or take any medicine that weakens the immune system. Whether you receive the vaccine will depend on the level of your immune defences.
- if you are pregnant. In addition, pregnancy should be avoided for 1 month following vaccination.

Do not have Varilrix if any of the above apply to you. If you are not sure, talk to your doctor, nurse, or pharmacist before receiving Varilrix.

Warnings and precautions

If you answer "Yes" to any of the following questions, talk to your doctor or nurse before the vaccine is given:

- do you have an existing skin condition that has damaged your skin?
- do you come into regular contact with pregnant women?
- do you have a history or family history of allergies?
- do you come into regular contact with people for whom the chickenpox virus could cause serious health risks? This includes people who have a weak immune system or people receiving any treatment that can weaken the immune system.
- you 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

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.

People with very poor immune systems (e.g. such as HIV infection) and pregnant women who have not previously had chickenpox have a small risk of developing severe chickenpox from the weakened virus. You should be closely monitored as the responses to the vaccines may not be sufficient to ensure a protection against the illness (see section 2).

Also, depending on the stage of pregnancy, there is a risk of the mother passing on a severe infection to the unborn child or newborn baby.

In rare cases the weakened virus can be passed on from a vaccinated person to others. However, in the absence of a rash in the vaccinated person, the risk of transmission of the vaccine viral strain to others appears to be extremely small.

Other medicines or vaccines and Varilrix

Please tell your doctor, nurse or pharmacist if you are taking, about to be taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Varilrix can affect the way some other medicines work. Also some other medicines can affect the way Varilrix works.

Varilrix can be given at the same time as most other routine vaccines, such as travel vaccines. The doctor will ensure that the vaccines are injected separately and into different parts of the body. If you are due to have, or have had any other vaccines near to when you have Varilrix, talk to your nurse before Varilrix is given. If you have received a measles vaccination recently, vaccination with Varilrix should be delayed until at least one month after the measles vaccination. Varilrix should not be mixed with other vaccines in the same syringe.

In particular talk to your doctor if:

- you are taking a medicine that can affect the way that your body fights disease. You should not have Varilrix if you are taking this type of medicine
- you are taking aciclovir, a drug used to treat herpes viruses
- you have had a blood transfusion or received blood proteins. It is not recommended to receive Varilrix for 3 months after this treatment
- your child is under the age of 16 and they are due to take aspirin or an aspirin-type product (also known as salicylates), especially if they have a fever after receiving Varilrix. Aspirin should not be taken unless on the advice of your doctor.

Pregnancy, breast-feeding and fertility

- Do not have Varilrix if you are pregnant.
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before the vaccination is given. Also, it is important that you do not become pregnant within one month after receiving the vaccine. During this time you should use an effective method of birth control to avoid pregnancy.
- In case of inadvertent vaccination of pregnant women with Varilrix, this should not be a reason for termination of pregnancy.

Driving and using machines

Varilrix is not likely to affect you being able to drive or use any tools or 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.

If you have been told by your doctor that you or your child has an intolerance to some sugars, contact your doctor before receiving this vaccine.

3 How Varilrix is given

How your vaccine is given

You will never be expected to give yourself this vaccine. It will always be given to you by a person qualified to do so.

You will have Varilrix:

- as an injection under your skin, either in the upper arm or in the outer thigh.
- your doctor or nurse will usually wipe the skin clean around the place where you will have the injection using alcohol or another antiseptic.

How much is given

Children older than 9 months and adults:

- Each time you receive Varilrix, it will be given to you as a single 0.5 ml injection.
- You will have two separate doses.
- For children between 9 and 12 months of age, there will be an interval of at least 3 months between the first and second dose.

- For adults and children older than 12 months of age, there will be an interval of at least 6 weeks (never less than 4 weeks) between the first and second dose.
- If you miss the due date for the second injection, you should still be given the second dose as soon as this can be arranged. The second injection ensures that protection against chickenpox will be continued.

If you have more Varilrix than you need
It is unlikely that you will be given too much Varilrix.

4 Possible side effects

Like all vaccines, Varilrix can cause side effects although not everybody gets them. In adults and young people the second dose is not likely to cause more severe side effects than the first dose.

Allergic reactions:
If you have an allergic reaction, see your doctor straight away. Very rarely you may experience:
- facial swelling
- low blood pressure
- difficulty breathing
- your skin going blue
- loss of consciousness.

Should these reactions happen, they will usually start very soon after the injection has been given to you. Seek medical help straight away if they happen after leaving the clinic.

Other side effects include:
Very common (affects more than 1 in 10 people)
- reactions at the site of the injection. These include redness, pain and swelling.
- high temperature (fever)

Common (affects less than 1 in 10 people)
- rash

Uncommon (affects less than 1 in 100 people)
- swollen glands
- headache
- drowsiness
- sore throat or cough
- runny nose
- feeling sick or being sick
- rash with blisters
- itching
- joint or muscle pain
- very high temperature
- tiredness
- feeling generally unwell
- feeling irritable

Rare (affects less than 1 in 1,000 people)
- eye infection
- stomach ache
- diarrhoea

- hives
- painful rash with blisters (Shingles)
- reduction in platelets, increases risk of bleeding and bruising
- inflammation of blood vessels
- fits
- loss of control of body movements e.g.inability to walk or speak properly
- inflammation or infection of the brain
- stroke
- severe condition of the skin that may affect the mouth and other parts of the body

Very rare (affects less than 1 in 10,000 people)
- dizziness
- facial swelling, allergic reactions

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Reporting of side effects
If you 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.

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

5 How to store Varilrix

- Keep out of the sight and reach of children.
- Store between 2°C and 8°C in a refrigerator.
- Varilrix in powder form is not affected by freezing but must not be frozen after being made up.
- Do not store for more than 60 minutes at room temperature (25°C) or 8 hours if kept in a refrigerator after the injection has been made up.
- Do not use Varilrix after the expiry date which is stated on the label and carton.
- Store in the original package with this leaflet.
- Do not throw away 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 ingredient is live attenuated Varicella zoster (Oka strain) virus prepared in MRC_5 human diploid cells.
- Each 0.5 ml dose contains not less than $10^{3.3}$ plaque forming units (PFU) of this virus.
- The other ingredients are amino acids, human albumin, lactose, mannitol and sorbitol.

What Varilrix looks like and contents of the pack
Varilrix is a creamy yellowish or pinkish coloured pellet or powder in 3 ml vials. The pack also contains a separate 1 ml glass ampoule or pre-filled syringe containing a colourless sterile liquid (Water for Injections). Once made up Varilrix is clear peach to pink coloured solution. The vaccine is available in packs of 1. Not all listed packs are marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
SmithKline Beecham Ltd, Stockley Park West, Uxbridge, Middlesex, UB11 1BT

Manufacturer:
GlaxoSmithKline Biologicals s.a., 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.
This leaflet was revised in September 2017.

Instructions for use
The following information is intended for medical or healthcare professionals only.

Varilrix
$10^{3.3}$ PFU/0.5 ml, powder and solvent for solution for injection.
Varicella/chickenpox vaccine

- The diluent 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.
- Due to minor variations of its pH, the colour of the reconstituted vaccine may vary from clear peach to pink coloured solution.
- Varilrix must not be mixed with any other medicinal product in the same syringe.
- Varilrix is for subcutaneous administration only, in the upper arm (deltoid region) or the anterolateral area of the thigh.
- Varilrix should not be administered intradermally.
- Varilrix must under no circumstances be administered intravascularly.
- There are no data on the immune responses when different Varicella zoster vaccines are used for the first and second doses. Therefore, it is recommended that the same vaccine should be used for both doses.

Instructions for reconstitution of the vaccine with diluent presented in ampoules
Varilrix must be reconstituted by adding the entire contents of the supplied ampoule of water for injections diluent to the vial containing the powder. After the addition of the diluent to the powder, the mixture should be well shaken until the powder is completely dissolved in the diluent. After reconstitution, the vaccine should be used promptly.

A new needle should be used to administer the vaccine.

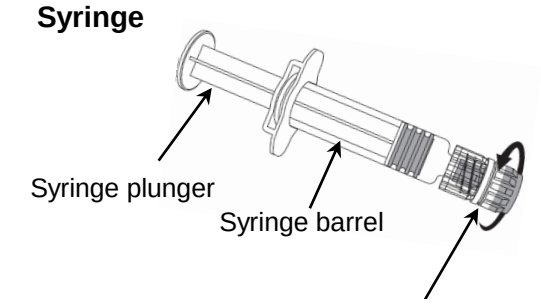
Withdraw the entire contents of the vial.

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

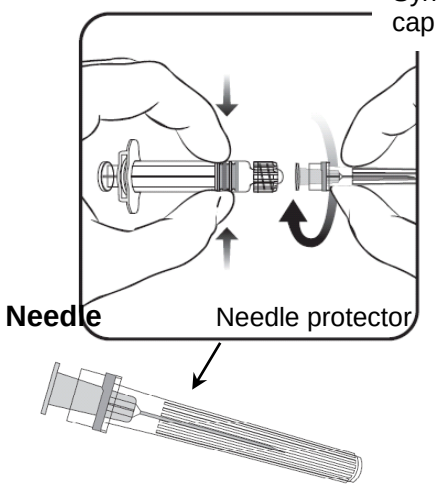
Instructions for reconstitution of the vaccine with diluent presented in pre-filled syringe
Varilrix must be reconstituted by adding the entire content of the pre-filled syringe of diluent to the vial containing the powder.

To attach the needle to the syringe, refer to the below drawing. However, the syringe provided with Varilrix might be slightly different (without screw thread) than the syringe described in the drawing. In that case, the needle should be attached without screwing.

1. Holding the syringe barrel in one hand (avoid holding the syringe plunger), unscrew the syringe cap by twisting it anticlockwise.



2. To attach the needle to the syringe, twist the needle clockwise into the syringe until you feel it lock. (see picture).
3. Remove the needle protector, which on occasion can be a little stiff.



Add the diluent to the powder. After the addition of the diluent to the powder, the mixture should be well shaken until the powder is completely dissolved in the diluent.
After reconstitution, the vaccine should be used promptly.

A new needle should be used to administer the vaccine.
Withdraw the entire contents of the vial.

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

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