


Varilrix[®]

**(varicella/chickenpox)
Vaccine**

Patient Information Leaflet

Read all of this leaflet before this vaccine is given.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.

In this leaflet:

1. What Varilrix is and what it is used for
2. Before having Varilrix
3. How Varilrix is given
4. Possible side effects
5. Storing Varilrix

The name of this vaccine is **Varilrix, 10^{3.3} PFU/0.5 ml, powder and solvent for solution for injection.**

The active ingredient in Varilrix is a live but weakened varicella-zoster virus, which is the cause of chickenpox. This specially weakened virus is called the Oka strain.

Varilrix also contains inactive ingredients. These are amino acids, human albumin, lactose, neomycin sulphate, sorbitol and mannitol.

The Product Licence holder is SmithKline Beecham plc, Brentford, UK trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex UB11 1BT, UK.

This vaccine is manufactured by GlaxoSmithKline Biologicals S.A., Rixensart, Belgium.

1. What Varilrix is and what it is used for

Varilrix is a vaccine containing the varicella-zoster virus that causes chickenpox. The virus in the vaccine has been weakened so that it does not cause chickenpox in normal healthy people. When a person is given the vaccine, the immune system (the body's natural defence against infections) makes antibodies against the chickenpox virus and also reacts to the virus in other ways to develop what is called cell-mediated immunity. These antibodies and cell responses help to protect you against getting chickenpox.

Many people get chickenpox during childhood, but some get it only as teenagers or adults when it may be a much more severe infection, even in healthy people. Varilrix is intended to prevent chickenpox in people who did not get the illness in childhood, so it is usually only given to teenagers and adults.

Varilrix may sometimes be given to healthy children between 1 and 12 years of age who live with, or spend a lot of time with, people who have poor immune systems and who are likely to be very seriously ill if they catch chickenpox. Vaccinating these healthy children to prevent them getting chickenpox means that they will not then pass the infection on to people in whom chickenpox can be a very serious disease.

Like other vaccines, Varilrix cannot completely protect you against catching chickenpox. However, people who have had the vaccine and still catch chickenpox usually have a very mild disease with very few spots and blisters compared with people who have not had the vaccine.

If a teenager or adult comes into contact with a case of chickenpox or shingles before both doses of Varilrix have been given or within about 6 weeks after the second dose, the vaccine may not be able to prevent chickenpox. Similarly, a child who comes into contact with a case of chickenpox just before or within about 6 weeks after vaccination may still get chickenpox.

Varilrix is supplied as a slightly cream to yellowish or pinkish coloured pellet in a single dose glass vial with a separate glass ampoule of clear colourless sterile liquid (Water for Injections) for making up the vaccine. After mixing with the water the vaccine is clear peach to pink in colour.

Each 0.5 millilitre (ml) dose contains not less than 10^{3.3} plaque forming units (Oka strain) of chickenpox virus.

2. Before having Varilrix

Varilrix is not suitable for everyone.

If the answer is "YES" to any of the following questions either the vaccine will not be given at all or the injection will be delayed. If you are the parent of a child who is to be vaccinated you should check that none of the following applies to your child.

If you are not sure, ask your doctor or nurse.

Varilrix must not be given if the answer is "Yes" to any of the following :

Has the person who is to receive Varilrix:

- had an allergic reaction to Varilrix following the first dose?
- had an allergic reaction to any other chickenpox vaccine, or to neomycin, or to any of the ingredients listed above?
- any illness that weakens the immune system (such as blood disorders, or infections)?
- recently received or still taking any treatment that can weaken the immune system?

Also, is the person who is to receive Varilrix:

- pregnant or even possibly pregnant?
- breastfeeding?
- under 13 years of age? Varilrix will not usually be given to children who are less than 13 years old. It may be given to children between the ages of 1 and 12 years of age to prevent them getting chickenpox and passing the infection on to people in whom chickenpox infections can be a very serious disease.

Varilrix will, or may be, delayed if the answer to the following is "Yes":

- Does the person who is to receive Varilrix have a high temperature or an infection?
- Has the person who is to receive Varilrix had a blood or plasma transfusion, or human immunoglobulin within the last 3 months? If so, the antibody response to Varilrix may be low so it is usual to wait for 3 months before giving Varilrix.
- Is the person who is to receive Varilrix due to undergo treatment that might weaken their immune system?

Take special care with Varilrix

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

Does the person who is to receive Varilrix:

- come into regular contact with pregnant women?
- come into regular contact with people for whom the chickenpox virus could cause serious health risks, such as people who have a weak immune system or people receiving any treatment that can weaken the immune system?

These questions are important because although the weakened virus in Varilrix does not cause widespread chickenpox in healthy people, healthy people can very rarely (in less than 1 in 10,000 people) pass on the vaccine virus to others. This has only been proven to happen when the healthy person has developed some spots and blisters, and these usually appear only near the site of the injection. Additionally, spots and blisters only develop in between 1 in 10 and 1 in 100 healthy people after having the vaccine, but the spots and blisters heal quickly and the person is then no longer infectious to others.

Passing on the weakened vaccine virus from a vaccinated person to another healthy person is not harmful to them. Very rarely, they may develop a mild rash but this is much less severe than natural chickenpox infection.

Passing on the weakened vaccine virus from a vaccinated person to people with very poor immune systems or to pregnant women who have never had chickenpox can cause problems. People with very poor immune systems and pregnant women have a small risk of developing severe chickenpox from the weakened virus. 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 infant.

If you regularly come into contact with anyone who might be at risk of severe chickenpox if they catch the vaccine strain from you, your doctor or nurse will discuss with you whether you should have the vaccine. Your doctor or nurse will also advise you what to do if you develop any spots or blisters at the site of the injection.

Pregnancy

Varilrix must not be given to pregnant women.

Women must be especially careful to avoid getting pregnant between the two doses and for 3 months after the second dose. Talk to your doctor or nurse about effective contraception.

Breastfeeding

Women should not be vaccinated while they are breastfeeding.

Driving and using machines

It is very unlikely that Varilrix would affect driving or operating machinery skills.

Taking other medicines and having other vaccines

- Varilrix must not be given to persons who are taking medicines that can weaken the immune system.
- You should speak to your doctor if you are taking aciclovir, a drug used to treat herpes viruses, as the virus in Varilrix can be affected by this drug so that the vaccine does not work properly.
- If your child is under the age of 16, aspirin or aspirin-type products (also known as salicylates) should not be taken, unless on the advice of a doctor, since we now know that Reye's Syndrome, a rare disease of the brain and liver could occur. This advice is particularly important if your child has fever after vaccination with Varilrix, since Reye's Syndrome has been reported in children who have taken aspirin when they have had chickenpox.
- Varilrix may be given with other routine vaccines that may be due to be given at the same time. If any other vaccines (for example, travel vaccines) are to be given at the same time as, or very near in time to Varilrix, talk to your doctor or nurse before Varilrix is given.
- Make sure that your doctor or nurse is told about all medicines that are being taken by the person who is to receive Varilrix and about all vaccines that may have been given a few weeks before or are due to be given within a few weeks after Varilrix.

3. How Varilrix is given

Adults and adolescents from 13 years of age

Two doses, each of 0.5 ml, are given to complete the course with an interval of approximately 8 weeks (minimum 6 weeks) between the first and second doses. There is no information on the use of Varilrix in the elderly.

Children between 1 and 12 years of age

Only one dose of 0.5 ml is given.

Although Varilrix is not intended for routine use in children, it may be given to children between 1 and 12 years of age to prevent them getting chickenpox and passing the infection on to people in whom chickenpox can be a very serious disease.

Varilrix must be injected under the skin usually in the upper arm. Your nurse or doctor may wipe the skin with alcohol or other disinfecting agents and will let the skin dry before the injection.

Your doctor or nurse will take care that Varilrix is not injected into skin or the bloodstream.

Because the vaccine is supplied in single dose vials, and because it is then made up and injected by a doctor or nurse, it is very unlikely that you could be given too much.

If the appointment for the second injection is missed, the second dose should still be given as soon as this can be arranged after the due date. The second injection will ensure that protection against chickenpox will be continued.

4. Possible side effects

Like all vaccines, Varilrix can have side effects.

In teenagers and adults, the second dose was not more likely than the first dose to cause side effects.

Very rarely, a severe allergic reaction may occur with symptoms that may include facial swelling, low blood pressure, difficulty breathing, going blue and loss of consciousness. Urgent medical attention is needed in these cases. These reactions often occur very soon after the injection, while still in the clinic. If any of these symptoms or other serious symptoms are noticed after vaccination, you must seek urgent medical help.

The commonest side effects (reported in greater than 1 in 10 persons) seen in clinical trials with Varilrix were reactions at the site of the injection. These included local redness, local pain and swelling.

Side effects that were commonly reported during clinical trials (in more than 1 in 100 but less than 1 in 10 persons) were tiredness, raised temperature, headache, and spots or blisters that usually occurred near the site of the injection but sometimes at other sites.

Side effects that were uncommonly reported during clinical trials (in more than 1 in 1000 but in less than 1 in 100 persons) were: inflammation or a small lump under the skin at the site of injection, chest pain, feeling generally unwell, pain at other sites, dizziness, migraine, stomach upset, feeling sick, joint pain, back pain, muscle pain, drowsiness, coughing, sore throat, runny nose, itching, and swelling of the glands.

Other side effects that have been reported very rarely (in less than 1 in 10,000 persons) during routine use of the vaccine are rashes with spots and blisters, loss of movement or sensation in one or more parts of the body, inability to walk properly, and low numbers of a type of blood cell called thrombocytes that are needed for normal blood clotting.

If you notice any side effects not mentioned in this leaflet please tell your doctor or nurse.

5. Storing Varilrix

Your doctor or nurse will usually have supplies of Varilrix and will have stored it correctly. However, if you have been given a prescription to get the vaccine and have been asked to store it until the injection is given, you should store Varilrix in a refrigerator between 2°C and 8°C until it is given. The vaccine in powder form is not affected by freezing. The doctor or nurse should check that the expiry date on the outer package label has not passed.

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

Once the vaccine has been mixed with the water supplied, it should not be frozen and should be injected as soon as possible. It may, however, be kept for up to 90 minutes at room temperature (25°C) and up to 8 hours in the refrigerator (2°C-8°C). If not used within these time limits, the vaccine must be discarded.

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