Package leaflet: Information for the user

VARIVAX® powder and solvent for suspension for injection in a pre-filled syringe
Varicella Vaccine (live)

Read all of this leaflet carefully before you or your child is vaccinated 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 your pharmacist.
- This vaccine has been prescribed for you or your child. 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 VARIVAX is and what it is used for

VARIVAX is a vaccine to help protect adults and children against chickenpox (varicella). Vaccines are used to protect you or your child against infectious diseases.

VARIVAX can be administered to persons 12 months of age or older.

VARIVAX may also be administered to infants from 9 months of age under special circumstances, such as to conform with national vaccination schedules or in outbreak situations.

It may also be given to persons who have no history of chickenpox, but who have been exposed to someone who has chickenpox.
Vaccination within 3 days of exposure may help prevent chickenpox or reduce the severity of disease, resulting in fewer skin lesions and shorter duration of illness. In addition, there is limited information that being vaccinated up to 5 days after exposure may reduce disease severity.

As with other vaccines, VARIVAX does not completely protect all individuals from naturally acquired chickenpox.

2. What you need to know before you or your child receives VARIVAX

Do not use VARIVAX if:

- you or your child are allergic to any varicella vaccine, to any of the ingredients of this vaccine (listed in section 6), or neomycin (which may be present as a trace residue).
- you or your child have a blood disorder or any type of malignant cancers including leukaemia and lymphomas that affects the immune system.
- you or your child are receiving immunosuppressive therapy (including high doses of corticosteroids).

- you or your child 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 or your child receives the vaccine will depend upon the level of your immune defences.
- you or your child have a family member born with immunodeficiency, or there is a family history of immunodeficiency.
- you or your child have active untreated tuberculosis.
- you or your child have a temperature higher than 38.5°C; however, low-grade fever itself is not a reason not to be vaccinated.
- you are pregnant. In addition, pregnancy should be avoided for 1 month after vaccination.

Warnings and precautions:

In rare circumstances, it is possible to catch chickenpox, including severe chickenpox, from a person who has been vaccinated with VARIVAX. This may occur in persons who have not previously been vaccinated or have not had chickenpox, as well as persons who fall into one of the following categories:
- individuals with a weakened immune system.
- pregnant women who have never had chickenpox.
- newborn babies whose mothers have never had chickenpox.

Whenever possible, individuals who have been vaccinated with VARIVAX should attempt to avoid close contact, for up to 6 weeks following the vaccination, with anyone who falls into one of the categories above. Tell your doctor if there is anyone who falls into one of the categories above and is expected to be in close contact with the person being vaccinated.

Talk to your doctor or pharmacist before you or your child receive VARIVAX:
- if you or your child have a weakened immune system (such as HIV infection). 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 VARIVAX if").

Other medicines (or other vaccines) and VARIVAX:

Tell your doctor or pharmacist if you or your child are taking or have recently taken any other medicines (or other vaccines).

If any type of vaccine is due to be given at the same time as VARIVAX, your doctor or health care professional will advise you whether this can be given or not. VARIVAX may be given at the same time as the following routine childhood vaccinations: measles, mumps and rubella vaccine (MMR), vaccines against *Haemophilus influenza* type b, hepatitis B, diphtheria, tetanus, pertussis (whooping cough) and polio vaccine that is given by mouth.

Vaccination should be deferred for at least 5 months after any blood or plasma transfusions, or administration of normal human immune globulin (a sterile solution of naturally produced antibodies taken from donated human blood) or varicella zoster immune globulin (VZIG) have been given.

Following vaccination with VARIVAX, you or your child should not receive any immune globulin, including VZIG, for 1 month thereafter unless your doctor decides it is necessary.

Vaccine recipients should avoid products that contain aspirin (salicylates) for 6 weeks after vaccination with VARIVAX as this may cause a serious condition called Reye syndrome which can affect all your body organs.

Pregnancy and breast-feeding

VARIVAX 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 for advice 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 VARIVAX.

Driving and using machines

There is no information to suggest that VARIVAX will affect your ability to drive or use machines.

VARIVAX contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

VARIVAX contains potassium

This medicine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

3. How to use VARIVAX

VARIVAX will be administered by your doctor or health care professional.

VARIVAX is given by injection as follows:

- Infants from 9 months to 12 months of age:
  Under special circumstances (to conform with national vaccination schedules or in outbreaks of chickenpox), VARIVAX may be administered between 9 and 12 months of age. To ensure optimal protection against chickenpox, two doses of VARIVAX are needed and should be given at least three months apart.
- Children from 12 months to 12 years of age:
  To ensure optimal protection against chickenpox, two doses of VARIVAX should be given at least one month apart.
- Children from 12 months to 12 years of age with asymptomatic HIV:
  VARIVAX should be given as two doses by injection 12 weeks apart. Please ask your healthcare provider for more information.
- Teenagers 13 years of age and older and adults:
  VARIVAX is given as two doses by injection. The second dose should be given 4 to 8 weeks after the first dose.

The number and timing of doses should be determined by your doctor, using the official recommendations.

VARIVAX should not be given to children under 9 months of age.

VARIVAX should be injected into the muscle or under the skin either in the area of the outer thigh or of the upper arm. Usually for injections into the muscle, the thigh area is preferred in young children, whereas for older individuals, the upper arm area is the preferred injection site.

If you have a blood clotting disorder or low levels of platelets in your blood, the injection will be given under the skin.

Your doctor or health care professional will take care that VARIVAX is not injected into the bloodstream.

If you use more VARIVAX than you should

Overdose is very unlikely because the vaccine is provided in single dose vials and is given by a doctor or health care professional.

If you think you have missed a dose of VARIVAX

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

4. Possible side effects

Like all vaccines and medicines, this vaccine can cause side effects, although not everybody gets them.

Very rarely (reported in less than 1 in 10,000 people), a severe allergic reaction may occur with symptoms that may include facial swelling, low blood pressure, and difficulty breathing, with or without rash. These reactions often occur very soon after the injection. If any of these symptoms or other serious symptoms are noticed after vaccination, you must seek immediate medical attention.

Tell your doctor if you notice any of the following rare or very rare side effects:
- bruising or bleeding more easily than normal; red or purple, flat, pinhead spots under the skin, severe paleness
- severe skin rash (ulcers and blistering that may involve the eyes, mouth, and/or genitals; red, often itchy spots which start on the limbs and sometimes on the face and the rest of the body) (Stevens-Johnson syndrome; erythema multiforme)
- muscle weakness, abnormal sensations, tingling in the arms, legs, and upper body (Guillain-Barré syndrome)
- fever, feeling sick, vomiting, headache, stiff neck and sensitivity to light (meningitis)
- stroke
- seizures (fits) with or without a fever

The following side effects have been observed:

Very common reactions (*reported by more than 1 out of 10 people*) were:
- fever
- injection site redness of the skin, pain/sensitivity to touch/soreness, and swelling

Common reactions *(reported by less than 1 out of 10 but more than 1 out of 100 people)* were:
- upper respiratory tract infection (nose, throat, airway)
- irritability
- rash, rash with flat, red skin and small confluent bumps, varicella-like rash
- injection site rash, itching at the injection site

Uncommon reactions *(reported by less than 1 out of 100 but more than 1 out of 1,000 people)* were:
- headache, drowsiness
- discharge and itching of the eyes with crusting of eyelids (conjunctivitis)
- cough, nasal congestion, chest congestion, runny nose, loss of appetite
- upset stomach with vomiting, cramps, diarrhoea caused by a virus
- diarrhoea, vomiting (gastroenteritis)
- ear infection, sore throat
- crying, inability to sleep, sleep disorders
- varicella skin rash caused by virus (chicken pox), illness caused by a virus, inflammation of the skin, redness of the skin, hives

- weakness/fatigue, generally feeling unwell, injection site reactions including numbness, bleeding, bruising, hardened raised area of the skin, warm feeling, warm to touch

Rare reactions (*reported by less than 1 out of 1,000 people but more than 1 out of 10,000 people*) were:
- swollen glands, bruising or bleeding more easily than normal
- agitation, sleeping too much, difficulty walking, seizures with a fever, shaking
- swelling of eyelid, irritation of eye
- ear pain
- feeling of fullness in the nose sometimes with throbbing ache and facial pressure or pain (sinusitis), sneezing, congestion in the lung, runny nose (rhinitis), wheezing, swelling of the tubes relating to the lungs (bronchitis), lung infection, severe lung infection with fever, chills, cough, congestion and shortness of breath (pneumonia)
- flu-like illness
- stomach pain, upset stomach and feeling sick, blood in the stool, mouth ulcer
- flushing, blisters, skin disorders (including bruising, and hives)
- muscle/bone pain, aching muscles, stiffness
- injection site reactions including changes in skin colour and hive-like rash

Side effects that have been reported during marketed use of VARIVAX include:
- illnesses affecting the nervous system (brain and/or spinal cord) such as sagging facial muscles and drooping eyelid on one side of the face (Bell's palsy), walking unsteadily, dizziness, tingling or numbness of the hands and feet, inflammation of the brain (encephalitis), inflammation of the coverings of the brain and spinal cord not caused by bacterial infection (aseptic meningitis), fainting
- shingles, sore throat (pharyngitis), purple or red-brown spots visible through the skin (Henoch-Schönlein purpura), secondary bacterial infections of the skin and soft tissues (including cellulitis), chickenpox (varicella), aplastic anaemia, which may include bruising or bleeding more easily than normal; red or purple, flat, pinhead spots under the skin; severe paleness

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 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 VARIVAX

Keep this vaccine out of sight and reach of children.

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

Store and transport refrigerated (2 °C – 8 °C). Do not freeze. Keep the vial in the outer carton in order to protect from light.

After reconstitution, the vaccine should be used immediately. However, the in-use stability has been demonstrated for 30 minutes between +20 °C and +25 °C.

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

6. Contents of the pack and other information

What VARIVAX contains

The active ingredient is: live attenuated varicella virus (Oka/Merck strain) (produced in MRC-5 human diploid cells).

Each 0.5 mL dose of reconstituted vaccine contains: a minimum of 1,350 PFU (plaque forming units) of varicella virus (Oka/Merck strain).

The other ingredients are:

Powder:
Sucrose, hydrolysed gelatin, urea, sodium chloride, monosodium L-glutamate, anhydrous disodium phosphate, potassium dihydrogen phosphate and potassium chloride.

Residual components in trace quantities: neomycin.

***Solvent*:**
Water for injections

What VARIVAX looks like and contents of pack

Pharmaceutical form: powder and solvent for suspension for injection

The vaccine consists of a white to off-white powder in a vial and a clear colourless liquid solvent in a pre-filled syringe. The product is available in packs of one or 10 doses.

The solvent provided is a pre-filled syringe of water for injections. The secondary packaging may also contain 2 separate needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Holder of the Marketing Authorisation:
Merck Sharp & Dohme (UK) Limited
120 Moorgate
London
EC2M 6UR
UK

Manufacturer Responsible for Batch Release
Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

This medicine is authorised in the Member States of the European Economic Area, in the United Kingdom (Northern Ireland) and Great Britain under the following names:

VARIVAX
België/Belgique/Belgien; България; Česká republika; Danmark; Deutschland; Eesti; Ελλάδα; España; France; Hrvatska; Ireland; Ísland; Italia; Κύπρος; Latvija; Lietuva; Luxembourg/Luxemburg; Magyarország; Malta; Norge; Österreich; Polska; Portugal; România; Slovenija; Slovenská republika; Suomi/Finland; Sverige; United Kingdom (Northern Ireland), Great Britain

PROVARIVAX
Nederland

This leaflet was last revised in December 2023.

The following information is intended for health care professionals only:

Instructions

Before reconstitution, the vial contains a white to off-white powder and the pre-filled syringe contains a clear, colourless liquid solvent. The reconstituted vaccine is a clear, colourless to pale yellow liquid.

Avoid contact with disinfectants.

To reconstitute the vaccine, use only the solvent provided in the pre-filled syringe.

It is important to use a separate sterile syringe and needle for each patient to prevent transmission of infectious agents from one individual to another.

One needle should be used for reconstitution and a separate, new needle for injection.

Directions for the vaccine preparation

To attach the needle, it should be firmly placed on the tip of the syringe and secured by rotating a quarter of a turn (90°).

Inject the entire content of the pre-filled syringe into the vial containing the powder. Gently agitate to mix thoroughly.

The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation in physical appearance. The vaccine must not be used if any particulate matter is noted or if the appearance is not a clear colourless to pale yellow liquid after reconstitution.

It is recommended that the vaccine be administered immediately after reconstitution, to minimise loss of potency. Discard if reconstituted vaccine is not used within 30 minutes.

Do not freeze the reconstituted vaccine.

Withdraw the entire content of the vial into a syringe, change the needle, and inject the vaccine by subcutaneous or intramuscular route.

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

See also section 3 How to use VARIVAX