

**Patient Information about
VARIVAX® (pronounced “VAR ih vax”)
Generic name: Varicella Virus Vaccine Live**

This is a summary of information about VARIVAX®. You should read it before you or your child get the vaccine. If you have any questions about the vaccine after reading this leaflet, you should ask your healthcare professional. This is a summary only. It does not take the place of talking about VARIVAX with your doctor, nurse, or other healthcare professional. Only your healthcare professional can decide if VARIVAX is right for you or your child.

What is VARIVAX and how does it work?

VARIVAX is also known as Varicella Virus Vaccine Live. It is a live virus vaccine that is given as a shot. It is meant to help prevent chickenpox. Chickenpox is sometimes called varicella (pronounced VAR ih sell a).

VARIVAX contains a weakened form of chickenpox virus.

VARIVAX works by helping the immune system protect you or your child from getting chickenpox.

VARIVAX may not protect everyone who gets it.

VARIVAX does not treat chickenpox once you or your child have it.

What do I need to know about chickenpox?

Chickenpox is an illness that occurs most often in children who are 5 to 9 years old. It can be passed to others. The illness can include headache, fever, and general discomfort. Then an itchy rash occurs, which can turn into blisters. The most common complication is that the blisters can get infected. Less common but very serious complications can occur. These include pneumonia, inflammation of the brain, Reye syndrome (which affects the liver and the brain), and death. Severe disease and serious complications are more likely to occur in adolescents and adults.

Who should not get VARIVAX?

Do not get VARIVAX if you or your child:

- are allergic to any of its ingredients. (This includes gelatin or neomycin. See the ingredient list at the end of this leaflet.)
- have a weakened immune system, such as an immune deficiency, an inherited immune disorder, leukemia, lymphoma, or HIV/AIDS.
- take high doses of steroids by mouth or in a shot.
- have active tuberculosis that is not treated.
- have a fever.
- are pregnant or plan to get pregnant within the next three months.

What should I tell my healthcare professional before getting VARIVAX?

Tell your healthcare professional if you or your child:

- have or have had any medical problems.
- have received blood or plasma transfusions or human serum globulin within the last 5 months.
- take any medicines. (This includes non-prescription medicines and dietary supplements.)
- have any allergies. (This includes allergies to neomycin or gelatin.)

- had an allergic reaction to any other vaccine.
- are pregnant or plan to become pregnant within the next three months.
- are breast-feeding.

How is VARIVAX given?

VARIVAX is given as a shot to people who are 12 months old or older. If your child is 12 months to 12 years old and your doctor gives a second dose, the second dose must be given at least 3 months after the first shot.

A second dose should be given to those who first get the vaccine when they are 13 years old or older. This second dose should be given 4 to 8 weeks after the first dose.

Your doctor or healthcare professional will use the official recommendations to decide the number of shots needed and when to get them.

If a dose is missed, your healthcare professional will let you know when you should have it.

What should you or your child avoid when getting VARIVAX?

Do not take aspirin or aspirin-containing products for 6 weeks after getting VARIVAX.

It is rare, but possible, that once you have the vaccine, you could spread the chickenpox virus to others. Whenever possible, try to avoid contact with certain groups of people for up to six weeks after receiving the vaccine. This is because the disease for these groups may be quite serious. These groups include:

- people who have a weakened immune system.
- pregnant women who have never had chickenpox.
- newborn babies whose mothers have never had chickenpox.
- newborn babies born at less than 28 weeks of pregnancy.

Tell your doctor or healthcare professional if you or your child expect to have contact with someone who falls into one of these groups.

What are the possible side effects of VARIVAX?

The most common side effects reported after taking VARIVAX are:

- Fever
- Pain, swelling, itching, or redness at the site of the shot
- Chickenpox-like rash on the body or at the site of the shot
- Irritability

Other less common side effects have also been reported.

- Tingling of the skin
- Shingles (herpes zoster)*

Tell your healthcare professional if you have any of the following problems within a short time after getting VARIVAX because they may be signs of an allergic reaction:

- Shortness of breath or wheezing
- Rash or hives

Other side effects have been reported. Some of them were serious. These include bruising more easily than normal; red or purple, flat, pinhead spots under the skin; severe paleness; difficulty walking; severe skin disorders; skin infection; and chickenpox. Rarely, swelling of the brain (encephalitis)*, stroke, inflammation of the coverings of the brain and spinal cord (meningitis)*, inflammation of the lungs (known as pneumonia or pneumonitis), and seizures with or without a fever have been reported. It is not known if these rare side effects are related to the vaccine.

*Can be from naturally occurring chickenpox or the vaccine in healthy individuals or individuals with lowered immunity.

Your doctor has a more complete list of side effects for VARIVAX.

Tell your doctor or healthcare professional if you or your child have any new or unusual symptoms after getting VARIVAX.

Report the following to your doctor or your child's doctor:

- any adverse reactions following vaccination
- exposure to VARIVAX during pregnancy
- exposure to VARIVAX during the 3 months before getting pregnant.

You may also report these events to Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231, or directly to the Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to www.vaers.hhs.gov.

What are the ingredients of VARIVAX?


Active Ingredient: a weakened form of chickenpox virus.

Inactive Ingredients: sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, residual components of MRC-5 cells including DNA and protein, sodium phosphate monobasic, EDTA, neomycin, fetal bovine serum.

What else should I know about VARIVAX?

This leaflet summarizes important information about VARIVAX.

If you would like more information, talk to your healthcare professional, visit the web site at www.merckvaccines.com, or call 1-800-Merck-90.

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