Patient Information about ZOSTAVAX® (pronounced "ZOS tah vax") Generic name: Zoster Vaccine Live

You should read this summary of information about ZOSTAVAX before you are vaccinated. If you have any questions about ZOSTAVAX after reading this leaflet, you should ask your health care provider. This information does not take the place of talking about ZOSTAVAX with your doctor, nurse, or other health care provider. Only your health care provider can decide if ZOSTAVAX is right for you.

What is ZOSTAVAX and how does it work?

ZOSTAVAX is a vaccine that is used for adults 50 years of age or older to prevent shingles (also known as zoster).

ZOSTAVAX contains a weakened chickenpox virus (varicella-zoster virus).

ZOSTAVAX works by helping your immune system protect you from getting shingles.

If you do get shingles even though you have been vaccinated, ZOSTAVAX may help prevent the nerve pain that can follow shingles in some people. ZOSTAVAX does not protect everyone, so some people who get the vaccine may still get shingles.

ZOSTAVAX cannot be used to treat shingles, or the nerve pain that may follow shingles, once you have it

What do I need to know about shingles and the virus that causes it?

Shingles is caused by the same virus that causes chickenpox. Once you have had chickenpox, the virus can stay in your nervous system for many years. For reasons that are not fully understood, the virus may become active again and give you shingles. Age and problems with the immune system may increase your chances of getting shingles.

Shingles is a rash that is usually on one side of the body. The rash begins as a cluster of small red spots that often blister. The rash can be painful. Shingles rashes usually last up to 30 days and, for most people, the pain associated with the rash lessens as it heals.

Who should not get ZOSTAVAX?

You should not get ZOSTAVAX if you:

- are allergic to any of its ingredients.
- are allergic to gelatin or neomycin.
- have a weakened immune system (for example, an immune deficiency, leukemia, lymphoma, or HIV/AIDS).
- take high doses of steroids by injection or by mouth.
- are pregnant or plan to get pregnant.

You should not get ZOSTAVAX to prevent chickenpox.

Children should not get ZOSTAVAX.

How is ZOSTAVAX given?

ZOSTAVAX is given as a single dose by injection under the skin.

What should I tell my health care provider before I get ZOSTAVAX?

You should tell your health care provider if you:

- have or have had any medical problems.
- take any medicines, including non-prescription medicines, and dietary supplements.
- have any allergies, including allergies to neomycin or gelatin.
- had an allergic reaction to another vaccine.
- are pregnant or plan to become pregnant.
- · are breast-feeding.

Tell your health care provider if you expect to be in close contact (including household contact) with newborn infants, someone who may be pregnant and has not had chickenpox or been vaccinated against chickenpox, or someone who has problems with their immune system. Your health care provider can tell you what situations you may need to avoid.

Can I get ZOSTAVAX with other vaccines?

Talk to your health care provider if you plan to get ZOSTAVAX at the same time as the flu vaccine.

Talk to your health care provider if you plan to get ZOSTAVAX at the same time as PNEUMOVAX® 23 because it may be better to get these vaccines at least 4 weeks apart.

What are the possible side effects of ZOSTAVAX?

The most common side effects that people in the clinical studies reported after receiving the vaccine include:

- redness, pain, itching, swelling, hard lump, warmth, or bruising where the shot was given.
- headache

The following additional side effects have been reported with ZOSTAVAX:

- allergic reactions, which may be serious and may include difficulty in breathing or swallowing. If you have an allergic reaction, call your doctor right away.
- chickenpox
- fever
- hives at the injection site
- joint pain
- muscle pain
- nausea
- rash
- rash at the injection site
- shingles
- swollen glands near the injection site (that may last a few days to a few weeks)

Tell your healthcare provider if you have any new or unusual symptoms after you receive ZOSTAVAX. For a complete list of side effects, ask your health care provider.

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

- any adverse reactions following vaccination
- exposure to ZOSTAVAX during pregnancy
- exposure to ZOSTAVAX 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 ZOSTAVAX?

Active Ingredient: a weakened form of the varicella-zoster virus.

Inactive Ingredients: sucrose, hydrolyzed porcine gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride.

This leaflet summarizes important information about ZOSTAVAX. If you would like more information, talk to your health care provider or visit the website at www.ZOSTAVAX.com or call 1-800-622-4477.



For patent information: www.merck.com/product/patent/home.html

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