

ZOSTAVAX[®]

Zoster Vaccine Live (Oka/Merck)

Refrigerator stable

What is in this leaflet

This leaflet answers some common questions about ZOSTAVAX. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the risks of you being given ZOSTAVAX against the benefits they expect it will have for you.

If you have any concerns about being given this vaccine, ask your doctor.

Keep this leaflet with the medicine. You may need to read it again.

What ZOSTAVAX is used for

Your doctor has recommended or administered ZOSTAVAX to prevent shingles (also known as zoster). ZOSTAVAX is an injectable live virus vaccine that is used to prevent shingles.

Shingles is a painful, blistering rash that may result in scarring. The blisters can persist for several weeks. They often break out in one part of the body. The nerve pain that comes from shingles can last for months or even years after the rash heals.

Shingles is caused by the same virus that causes chickenpox. After your chickenpox blisters heal, the virus that caused them stays in your body in nerve cells. The virus may be there for many years and not cause a problem. Sometimes, though, it becomes active again. If this happens, it can cause a blistering and painful rash.

If you do get shingles even though you have been vaccinated, ZOSTAVAX can help prevent the long-lasting nerve pain that can follow shingles. ZOSTAVAX can also reduce the intensity and length of time your pain from shingles will last.

ZOSTAVAX cannot be used to treat existing shingles or the pain associated with existing shingles.

ZOSTAVAX can be administered at the same time as inactivated influenza vaccine.

ZOSTAVAX is used in adults 50 years of age or older.

ZOSTAVAX boosts your immune system to help protect you from shingles.

As with any vaccine, ZOSTAVAX may not protect all people who receive the vaccine.

Before you are given ZOSTAVAX

When you should not be given it

Do not receive ZOSTAVAX if you:

- are allergic to any of its ingredients. This includes allergies to gelatin or to neomycin.
- have a weakened immune system as a result of a disease, medicines, or other treatment

- have active TB (tuberculosis) that is not being treated
- are pregnant.

Before you are given it

Tell your doctor if you:

- have or have had any medical problems
- are taking or have taken any medications that might weaken your immune system
- have any allergies including allergies to gelatin or neomycin
- have a fever
- have HIV infection.

Use in pregnancy

ZOSTAVAX should not be given to pregnant women. Women of child-bearing age should take the necessary precautions to avoid pregnancy for 3 months following vaccination.

Use in breast-feeding

Inform your doctor or health care provider if you are breast-feeding or intending to breast-feed. Your doctor or health care provider will decide if ZOSTAVAX should be given.

Use in Children

ZOSTAVAX is not recommended for use in children.

Can I drive or operate machinery following vaccination with ZOSTAVAX?

There is no information to suggest that ZOSTAVAX affects the ability to drive or operate machinery.

What should I know about the inactive ingredients in ZOSTAVAX?

Tell your doctor if you have ever had an allergic reaction to any of the ingredients before you receive this vaccine.

Can I receive ZOSTAVAX with other vaccines?

ZOSTAVAX can be given at the same time as the inactivated flu vaccine.

ZOSTAVAX should not be given at the same time as the PNEUMOVAX[®] 23 vaccine. For more information about these vaccines, talk to your doctor or health care provider because it may be better to get these vaccines at least 4 weeks apart.

How ZOSTAVAX is given

How much is given

ZOSTAVAX is given as a single dose by injection.

How it is given

ZOSTAVAX is given as an injection under the skin (subcutaneously), usually into your upper arm, by a doctor or trained nurse. The vaccine should not be injected directly into a blood vessel (intravascularly).

ZOSTAVAX can be administered at the same time as inactivated influenza vaccine.

Adverse Effects

ZOSTAVAX helps protect most people from shingles, but it may have unwanted adverse effects in a few people. All medicines and vaccines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

In studies, the most common side effects reported were at the injection site. These side effects included:

- redness
- pain
- swelling
- hard lump
- itching
- warmth
- bruising

Other side effects also reported:

- headache
- pain in arm or leg

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.
- chicken pox
- 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)
- Guillain-Barré syndrome (muscle weakness, abnormal sensations, tingling in the arms, legs and upper body)
- loss of facial muscle movements

Tell your doctor or pharmacist promptly about any unusual or severe symptoms that develop after you receive ZOSTAVAX. If the condition persists or gets worse, seek medical attention.

Don't be alarmed by this list of possible adverse effects. You may not experience any of them.

Storage

ZOSTAVAX is usually stored in the doctor's surgery or clinic, or at the pharmacy. However if you need to store ZOSTAVAX:

- Keep it where children cannot reach it.
- Keep it in the refrigerator where the temperature is 2 to 8°C or colder.
- Protect from light by keeping it in the original pack until it is time for it to be given.

Product description

What it looks like

ZOSTAVAX comes as a white to off-white powder in glass vials. It is reconstituted with a special diluent to make a solution suitable for injection.

Ingredients

Active ingredient:

- zoster vaccine live (Oka/Merck), a weakened form of the varicella-zoster virus

Inactive ingredients:

- sucrose
- hydrolysed porcine gelatin
- urea
- sodium chloride
- monosodium L-glutamate
- sodium phosphate dibasic
- potassium phosphate monobasic
- potassium chloride
- residual components of MRC-5 cells including DNA and protein
- trace quantities of neomycin and bovine calf serum

There are no preservatives.

Supplier

ZOSTAVAX is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99851
Newmarket
Auckland
NEW ZEALAND

Pack size

Vial of vaccine and pre-filled diluent syringe (composite pack) in packs of 1 or 10

Vial of vaccine and vial of diluent (composite pack) in packs of 1* or 10*

* These presentations are not currently available in New Zealand.

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