ZOSTAVAX®

Zoster Virus Vaccine Live, Refrigerator Stable.

Consumer Medicine Information

WARNINGS
ZOSTAVAX is a live vaccine and should not be used in people with a weakened immune system, as it can cause serious illness and death from infection with the vaccine virus.
Tell your doctor if you are taking medicines that may weaken your immune system including high-dose corticosteroids or cancer medicines, or other treatment.
If you become unwell after vaccination, you should seek medical attention and tell your doctor that you have recently received ZOSTAVAX.
Seek immediate medical attention if you:
- develop a chickenpox-like rash within 2 to 4 weeks of vaccine administration
- feel unwell
- develop a fever.

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 expected benefits it will have for you.

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

Keep this leaflet.
You may need to read it again.

What ZOSTAVAX is used for

ZOSTAVAX is a vaccine used to help prevent shingles (zoster). It can be given to adults 50 years of age and older.

ZOSTAVAX boosts your immune system to help protect you from shingles and its complications. ZOSTAVAX cannot be used to treat existing shingles or the pain associated with existing shingles.

ZOSTAVAX can reduce the intensity and length of time your pain from shingles will last. If you are 70 years of age or older and you get shingles even though you have been vaccinated, ZOSTAVAX can help prevent the long-lasting nerve pain that can follow shingles.

Symptoms of shingles include 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 (varicella-zoster virus). 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 may become active again. If this happens, it can cause a blistering and painful rash that may result in scarring. The blisters can persist for several weeks. They often break out in one part of the body.

Shingles can be serious. Sometimes the nerve pain caused by shingles can be severe and last for months or years. For some people, this nerve pain can get in the way of normal day-to-day activities such as walking, sleeping, and social activities.

The pain from shingles can also lead to emotional distress. People who suffer from shingles have described their pain in many ways. Some say the pain burns or throbs. Others say it feels like stabbing, shooting pain, and/or that it feels sharp. Severe pain can result from things as minor as a breeze or the touch of clothing against the skin.

In addition to severe pain, people with shingles may have other complications. These include:

- scarring
- bacterial skin infections
- weakness
- muscle paralysis
- loss of hearing or vision.

Almost every adult has had chickenpox and so is at risk for shingles. The risk increases as you get older. This is especially true if you are over 50 years of age.

How it works

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 must not be given it

Do not receive ZOSTAVAX if you:

- **are allergic to any of its ingredients listed at the end of this leaflet. This includes allergies to gelatin or neomycin.**
  Symptoms of an allergic reaction may include swelling of the face, lips, tongue, throat, difficulty in breathing, or hives.
- **are pregnant**
  ZOSTAVAX is not recommended to be given to pregnant women.
- **have a blood disorder or any type of cancer that weakens your immune system.**
- **have been told by your doctor that you have a weakened immune system as a result of a disease, medications, (including high-dose corticosteroids or cancer medicines), or other treatment.**
- **have active tuberculosis (TB) which is not being currently treated**
- **the expiry date on the pack has passed.**
  If the vaccine is used after the expiry date has passed, it may not work.

If you are not sure whether you should be given ZOSTAVAX, talk to your doctor.

Before you are given it

Tell your doctor if you:

1. **you have or have had any medical problems**
2. **are taking or have taken any medications that might weaken your immune system**
3. **have any allergies including allergies to gelatin or neomycin**
4. **have a fever**
5. **have HIV infection**
6. **become pregnant or plan to become pregnant in the next three months, are breast-feeding, or plan to start breast-feeding**
   Your doctor will decide if ZOSTAVAX should be given
7. **have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you are given an injection of ZOSTAVAX

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Use with other vaccines

ZOSTAVAX can be administered at the same time as inactivated influenza vaccine using a separate syringe.

ZOSTAVAX should not be given at the same time as PNEUMOVAX 23, a vaccine used to help prevent infections caused by certain types of germs or bacteria called pneumococcus. For more information about these vaccines, talk to your doctor, because it may be better to get these vaccines at least 4 weeks apart.

How ZOSTAVAX is given

ZOSTAVAX is given as a single dose (0.65 ml) by injection just under the skin (subcutaneously) of the upper arm by a doctor or trained nurse.

The vaccine should not be injected directly into a blood vessel (intravascularly).

After you have been given ZOSTAVAX

Things you must do

If you are a woman of child-bearing age, avoid falling pregnant for 3 months after vaccination.

Things to be careful of

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

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well during or after having received a dose of ZOSTAVAX

ZOSTAVAX helps protect most people, but it may have unwanted side effects in a

few people. All medicines and vaccines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Tell your doctor and seek immediate medical care if you:

- develop a chickenpox-like rash within 2 to 4 weeks of vaccine administration
- feel unwell
- develop a fever.

Tell your doctor if you notice any of the following if they worry you:

- redness, pain, swelling, hard lump, itching, warmth, or bruising, at the site you had the injection
- headache
- pain in your arm or leg

These were the most common side effects reported during studies.

The following additional side effects have been reported in general use with ZOSTAVAX:

- allergic reactions which may be serious and may include difficulty in breathing or swallowing (see also Allergic Reaction below)
- 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 promptly about any unusual or severe symptoms that develop after you receive ZOSTAVAX. If the condition persists or gets worse, seek medical attention.

Allergic Reaction

As with all vaccines given by injection, there is a very small risk of a serious allergic reaction.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing
- wheezing or shortness of breath
- severe skin reactions
- pinkish, itchy swellings on the skin, also called hives or nettlerash

These are serious side effects. If you have them, you may have had a serious allergic reaction to ZOSTAVAX. You may need urgent medical attention or hospitalisation. Most of these side effects occur within the first few hours of vaccination.

Other side effects not listed above may also occur in some patients.

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°C to 8°C.

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. ZOSTAVAX when reconstituted is a semi-hazy to translucent, off white to pale yellow liquid.

Ingredients

Each 0.65-mL dose of ZOSTAVAX contains a minimum of 19,400 PFU (plaque-forming units) of Oka/Merck strain of varicella-zoster virus when reconstituted with the diluent and stored at room temperature for 30 minutes.

Inactive ingredients:

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

The diluent contains water for injections.

During initial passage of the virus, tissue culture materials sourced from human embryonic stem cells may have been used in the research undertaken in the development of this vaccine.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Supplier

ZOSTAVAX is supplied in Australia by:

Seqirus (Australia) Pty Ltd
63 Poplar Road
PARKVILLE VIC 3052

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Australian Registration Numbers:

AUST R 130225: vaccine vial

AUST R 130229: vaccine vial + diluent syringe

AUST R 130241: vaccine vial + diluent vial

Not all presentations and pack sizes may be marketed.

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