

ZOSTAVAX®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this vaccine, speak to your doctor, nurse or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I being given ZOSTAVAX?

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

For more information, see Section [1. Why am I being given ZOSTAVAX?](#) in the full CMI.

2. What should I know before I am given ZOSTAVAX?

Do not get if you have ever had an allergic reaction to ZOSTAVAX or any of the ingredients listed at the end of the CMI.

Do not get ZOSTAVAX if you 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 that may impact your immune system.

Talk to your doctor if you have any other medical conditions, take any other medicines or vaccines, or are pregnant or plan to become pregnant in the next three months or are breastfeeding.

For more information, see Section [2. What should I know before I am given ZOSTAVAX?](#) in the full CMI.

3. What if I am taking other medicines or vaccines?

Some medicines or vaccines may interfere with ZOSTAVAX and affect how it works.

For more information, see Section [3. What if I am taking other medicines or vaccines?](#) in the full CMI.

4. How am I given ZOSTAVAX?

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.

More instructions can be found in Section [4. How am I given ZOSTAVAX?](#) in the full CMI.

5. What should I know after being given ZOSTAVAX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, nurse or pharmacist you
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	<p>visit that you have been given ZOSTAVAX.</p> <ul style="list-style-type: none"> ● Call your doctor straight away if you do not feel well during or after having received a dose of ZOSTAVAX, or if you develop a chickenpox-like rash within 2 to 4 weeks of vaccine administration, or develop a fever. ● If you are a woman of child-bearing age, avoid becoming pregnant for 3 months after vaccination.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● There is no information to suggest that ZOSTAVAX affects the ability to drive or operate machinery.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● ZOSTAVAX is usually stored in the doctor's surgery or clinic or at the pharmacy. However, if you need to store ZOSTAVAX, keep ZOSTAVAX in the refrigerator between 2°C

	and 8°C. Do not freeze. Protect from light.
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For more information, see Section [5. What should I know after being given ZOSTAVAX?](#) in the full CMI.

6. Are there any side effects?

Common side effects are: redness, pain, swelling, hard lump, itching, warmth, or bruising, at the site you had the injection, headache, pain in your arm or leg.

Serious side effects can include signs of allergy such as 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING:

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

ZOSTAVAX

Active ingredient: *Zoster Virus Vaccine Live, Refrigerator Stable.*

Consumer Medicine Information (CMI)

This leaflet provides important information about ZOSTAVAX. **You should also speak to your doctor, nurse or pharmacist if you would like**

further information or if you have any concerns or questions about ZOSTAVAX.

Where to find information in this leaflet:

- [1. Why am I being given ZOSTAVAX?](#)
- [2. What should I know before I am given ZOSTAVAX?](#)
- [3. What if I am taking other medicines or vaccines?](#)
- [4. How am I given ZOSTAVAX?](#)
- [5. What should I know after being given ZOSTAVAX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given ZOSTAVAX?

ZOSTAVAX contains the active ingredient varicella-zoster virus.

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.

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

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.

2. What should I know before I am given ZOSTAVAX?

Warnings

Do not get ZOSTAVAX if you:

- **are allergic to Zostavax, or any of the 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.

- Always check the ingredients to make sure you can use this medicine.
- **you are pregnant or plan to become pregnant in the next 3 months**
- **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 (for example, HIV infection), 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 given 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.

Check with your doctor if you:

- **have or have had any medical problems**
- **have a fever**
- **have any allergies to any other vaccines or 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

After getting ZOSTAVAX, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant in the next three months.

ZOSTAVAX is not recommended to be given to pregnant women.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will decide if ZOSTAVAX should be given.

3. What if I am taking other medicines or vaccines?

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

Getting Zostavax 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZOSTAVAX.

4. How am I given ZOSTAVAX?

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).

5. What should I know after being given ZOSTAVAX?

Things you should do

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

Call your doctor straight away if you:

- do not feel well during or after having received a dose of ZOSTAVAX.

Remind any doctor, nurse or pharmacist you visit that you have been given ZOSTAVAX.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZOSTAVAX affects you.

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

Looking after your vaccine

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.
- Do not freeze ZOSTAVAX.
- Protect from light by keeping it in the original pack until it is time for it to be given.

Follow the instructions in the carton on how to take care of the vaccine properly.

Getting rid of any unwanted vaccine

It is unlikely that you will be asked to dispose of ZOSTAVAX. However, if you no longer need to be given this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not get this vaccine after the expiry date.

6. Are there any side effects?

All medicines, including vaccines, can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>These were the most common side effects reported during studies:</p> <ul style="list-style-type: none">• redness, pain, swelling, hard lump, itching, warmth, or bruising, at the site you had the injection• headache• pain in your arm or leg <p>The following additional side effects have been reported in general use with ZOSTAVAX:</p> <ul style="list-style-type: none">• allergic reactions which may be serious and	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<p>may include difficulty in breathing or swallowing (see also Serious Side effects)</p> <ul style="list-style-type: none"> ● 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.

Serious side effects

Serious side effects	What to do
<p data-bbox="201 443 772 748">Allergic Reaction As with all vaccines given by injection, there is a very small risk of a serious allergic reaction.</p> <ul data-bbox="201 779 778 1433" style="list-style-type: none">● 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 <p data-bbox="201 1460 778 1899">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</p>	<p data-bbox="807 443 1378 833">Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>occur within the first few hours of vaccination.</p> <p>Other serious side effects:</p> <ul style="list-style-type: none"> ● develop a chickenpox-like rash within 2 to 4 weeks of vaccine administration ● feel unwell ● develop a fever 	

Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

7. Product details

This vaccine is only available with a doctor's prescription.

What ZOSTAVAX contains

<p>Active ingredient (main ingredient)</p>	<p>Oka/Merck strain of varicella-zoster virus</p>
<p>Other ingredients (inactive ingredients)</p>	<p>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. *contains sulfites The diluent contains water for injections.</p>

Potential allergens	neomycin, gelatin
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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.

Do not get this vaccine if you are allergic to any of these ingredients.

What ZOSTAVAX 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.

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 supplied.

Who sponsors ZOSTAVAX

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road
Macquarie Park NSW 2113

Who distributes ZOSTAVAX

Seqirus (Australia) Pty Ltd

Melbourne, Victoria

Australia

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