

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

ZOSTAVAX®

(zoster vaccine live, attenuated [Oka/Merck])

This leaflet is part III of a three-part "Product Monograph" published when ZOSTAVAX® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ZOSTAVAX®. Contact your doctor or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE

What the vaccine is used for:

ZOSTAVAX® is indicated for the prevention of shingles (zoster).

ZOSTAVAX® is indicated for vaccination of individuals 50 years of age or older.

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

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

What it does:

Your doctor has recommended or administered ZOSTAVAX® to prevent shingles (also known as zoster).

If you do get shingles even though you have been vaccinated, ZOSTAVAX® can reduce the intensity and length of time your pain from shingles will last.

When it should not be used:

- if you are allergic to any of the components of the vaccine (see ingredients), including gelatin or neomycin
- if you have a blood disorder or any type of cancer that weakens your immune system
- if you have been told by your doctor that you have a weakened immune system as a result of a disease, medications, or other treatment
- if you have active untreated tuberculosis
- if you are pregnant (see **Pregnancy**)

What the medicinal ingredient is:

Active ingredient: a weakened form of the varicella-zoster virus

What the important nonmedicinal ingredients are:

Powder:

Sucrose, hydrolyzed porcine gelatin, sodium chloride, potassium dihydrogen phosphate, potassium chloride,

monosodium L-glutamate and anhydrous disodium phosphate.

Solvent:

Water for injection

What dosage forms it comes in:

ZOSTAVAX® is supplied as a white to off-white powder in a single-dose vial.

The diluent for reconstitution is supplied as a clear, colourless liquid in a single-dose vial.

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

WARNINGS AND PRECAUTIONS

BEFORE you use ZOSTAVAX® talk to your doctor or pharmacist if:

- you have or have had any medical problems and about any allergies
- you are taking any medications that might weaken your immune system
- you have a fever
- you have HIV infection
- you have had shingles in the past.

It is not known how long ZOSTAVAX® will protect you from shingles. Studies with ZOSTAVAX® beyond 4 years have not been completed. It is not known if you will need to be vaccinated again in the future.

ZOSTAVAX® does not protect all individuals against the development of shingles or its consequences.

There may be a small chance of spreading the weakened vaccine virus to other people after receiving ZOSTAVAX®.

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.

Ask the doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Inform your doctor if you are breast-feeding or intending to breast-feed. Your doctor will decide if ZOSTAVAX[®] should be given.

Ask the doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

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

INTERACTIONS WITH THIS VACCINE

Important information about the ingredients of ZOSTAVAX[®]:

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

Using other medicines and other vaccines:

ZOSTAVAX[®] should not be given at the same time as PNEUMOVAX[®] 23 (pneumococcal vaccine, polyvalent, MSD Std.). For more information about these vaccines, talk to your doctor or healthcare provider.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

PROPER USE OF THIS VACCINE

Usual dose:

Individuals should receive a single dose.

The vaccine is to be given as a single dose by injection under the skin.

ZOSTAVAX[®] is not a treatment for shingles or the pain associated with shingles. If you get shingles, even though you have been vaccinated, see your health care provider promptly.

It is recommended that the vaccine be administered immediately after reconstitution to minimize loss of potency. Discard if reconstituted vaccine is not used within 30 minutes.

Do not freeze the reconstituted vaccine.

DO NOT INJECT INTRAVASCULARLY.

Any unused product or waste material should be disposed of in accordance with local requirements.

Overdose:

There are no data with regard to overdose.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Not applicable

HOW TO STORE IT

Keep this vaccine out of the reach and sight of children.

Vial of powder: Store and transport frozen at -15°C or below (especially when taken from the pharmacy to the physician's office) and keep the vial in the outer carton in order to protect from light.

Diluent: Store separately from the vaccine vial in a refrigerator (2 to 8°C) or at room temperature (20 to 25°C). Do not freeze.

Do not use after the expiry date stated on the label.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all vaccines, ZOSTAVAX[®] can have side effects.

In studies, the most common side effects reported were at the injection site. These side effects included redness, pain, swelling, hard lump, itching, warmth, and bruising at the injection site. Headache and pain in an arm or leg were also reported.

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.
- fever
- hives at the injection site
- joint pain
- muscle pain
- nausea
- rash
- rash at the injection site
- swollen glands near the injection site (that may last a few days to a few weeks)

Your doctor or pharmacist has a more complete list of side effects for ZOSTAVAX[®].

If you noticed any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

If any of the conditions above persists or worsens, seek medical attention.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

For health care professionals:

If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in **your province/territory**.

For the General Public:

Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada.

By toll-free telephone: 1-866-844-0018

By toll-free fax: 1-866-844-5931

By e-mail: caefi@phac-aspc.gc.ca

Web: <http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php>

Mail:

The Public Health Agency of Canada
Vaccine Safety Section
130 Colonnade Road, A/L 6502A
Ottawa, ON K1A 0K9

or at Merck Canada Inc. by one of the following 2 ways:

- Call toll-free at 1-800-567-2594:
- Complete a Canada Vigilance Reporting Form and
 - Fax toll-free to 1-800-369-3090, or
 - Mail to: Merck Canada Inc.
Pharmacovigilance
P.O. Box 1005
Pointe-Claire–Dorval, QC H9R 4P8

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada or Merck do not provide medical advice.

MORE INFORMATION

Disease information on shingles:

Why should I receive ZOSTAVAX®?

Shingles can be a very painful and potentially debilitating disease. Shingles can cause long-lasting nerve pain and other serious complications. It is an unpredictable disease that can occur at any time, with no warning. 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.

ZOSTAVAX® is the only product approved to prevent shingles. If you do get shingles even though you have been vaccinated, ZOSTAVAX® can help reduce the intensity and length of time your nerve pain will last.

What is shingles?

Shingles is a painful, blistering rash. It usually occurs in one part of the body and can last for several weeks. It may result in scarring. The nerve pain that comes from shingles can last for months or even years after the rash heals.

What causes shingles?

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, for unknown reasons, it becomes active again and causes shingles.

Is shingles serious?

Shingles can be serious. In addition to the rash-associated pain, the nerve pain caused by shingles may be severe and last for months or years (postherpetic neuralgia). 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 stabs, shoots, and/or 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.

Shingles can result in hospitalization. In rare cases, shingles can even result in death.

Am I at risk for shingles?

Almost every adult has had chickenpox and so is at risk for shingles. The risk increases as you get older, especially if you are over 50 years of age. It is estimated that in the general population, the lifetime risk of getting shingles is as high as 30%. For people who reach 85 years of age, one out of every two will have had shingles.

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.merck.ca>

or by contacting the sponsor, Merck Canada Inc.,
at: 1-800-567-2594.

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