Package Leaflet: Information for the user

ZOSTAVAX
Powder and solvent for suspension for injection in a pre-filled syringe
shingles (herpes zoster) vaccine (live)

Read all of this leaflet carefully before you are vaccinated because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What ZOSTAVAX is and what it is used for

ZOSTAVAX is a vaccine used to prevent shingles (zoster) and zoster-related post-herpetic neuralgia (PHN), the long-lasting nerve pain that follows shingles.

ZOSTAVAX is used to vaccinate individuals 50 years of age or older.

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

Disease information on shingles:

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 lead to severe and long-lasting pain and scarring. Less commonly, bacterial skin infections, weakness, muscle paralysis, loss of hearing or vision can occur. Shingles is caused by the same virus that causes chickenpox. After you have had chickenpox, the virus that caused it stays in your body in nerve cells. Sometimes, after many years, the virus becomes active again and causes shingles.

What is PHN?

After the shingles blisters heal, pain can last for months or years and may be severe. This long-lasting nerve pain is called post-herpetic neuralgia or PHN.

2. What you need to know before you receive ZOSTAVAX

Do not receive ZOSTAVAX

- if you are allergic (hypersensitive) to any of the components of this vaccine (including neomycin or any of the other ingredients listed in section 6)
- 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, medicines, or other treatment
- if you have active untreated tuberculosis
- if you are pregnant (in addition, pregnancy should be avoided for 1 month after vaccination, see **Pregnancy and breast-feeding**).

Warnings and precautions

If you have experienced any of the following, talk to your doctor or pharmacist before receiving ZOSTAVAX:
- if you have or have had any medical problems or any allergies
- if you have a fever
- if you have HIV infection

As with many vaccines, ZOSTAVAX may not completely protect all persons who are vaccinated.

Other medicines and ZOSTAVAX

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines or vaccines.

ZOSTAVAX can be administered at the same time as inactivated influenza vaccine. The two vaccines should be given as separate injections at different body sites.

ZOSTAVAX should not be given at the same time as the 23-valent pneumococcal polysaccharide vaccine. For more information about these vaccines, talk to your doctor or health care provider.

Pregnancy and breast-feeding

ZOSTAVAX should not be given to pregnant women. Women of child-bearing age should take the necessary precautions to avoid pregnancy for 1 month following vaccination.

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

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before receiving this vaccine.

Driving and using machines

There is no information to suggest that ZOSTAVAX affects the ability to drive or use machines.

Tell your doctor if you have ever had an allergic reaction to any of the ingredients (including neomycin or any of the ingredients listed under “the other ingredients are”- see section 6. Contents of the pack and other information - what ZOSTAVAX contains) before you receive this vaccine.

ZOSTAVAX contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium- free'.

3. How to use ZOSTAVAX

ZOSTAVAX should be injected under the skin, preferably in the upper arm.

ZOSTAVAX is given as a single dose.

Reconstitution instructions intended for healthcare professionals are included at the end of the leaflet.

4. Possible side effects

Like all vaccines and medicines, this vaccine can cause side effects, although not everybody gets them.

In studies, the most commonly reported side effects (occurring in at least 1 in 10 individuals) were at the injection site. These side effects included redness, pain, swelling and itching at the injection site. Headache, pain in arm or leg and warmth, bruising hard lump at the injection site were also commonly reported (occurring in at least 1 of 100 and less than 1 of 10 individuals). Varicella (chicken pox) was very rarely reported (occurring in less than 1 of 10,000 individuals).

The following additional side effects have been reported in general use with ZOSTAVAX: nausea; joint pain; muscle pain; fever; swollen gland (neck, armpit); shingles; rash; rash at the injection site; hives at the injection site; 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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In Ireland
You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

In the UK
You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this vaccine.

5. How to store ZOSTAVAX

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

Do not use this vaccine after the expiry date which is stated on the outer carton after EXP. The expiry date refers to the last day of that month.

Store and transport refrigerated (2°C - 8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ZOSTAVAX contains

After reconstitution, 1 dose (0.65 ml) contains:
The active substance is:
Varicella-zoster virus[1], Oka/Merck strain, (live, attenuated) not less than 19400 PFU (plaque-forming units).
[1]Produced in human diploid (MRC-5) cells

The other ingredients are:

Powder
Sucrose, hydrolysed gelatin, sodium chloride, potassium dihydrogen phosphate, potassium chloride, monosodium L-glutamate, anhydrous disodium phosphate, sodium hydroxide (to adjust pH), and urea.

Solvent
Water for injections

What ZOSTAVAX looks like and contents of the pack

The vaccine is a powder for suspension for injection contained in a single-dose vial, which should be reconstituted with the solvent provided with the vial of powder.

The solvent is a clear and colourless liquid. Before mixing with the solvent, the powder is a white to off-white compact crystalline plug.
One pack of ZOSTAVAX contains a vial and a prefilled syringe with or without attached needles. One or 2 separate needles may be available in the secondary packaging of the presentation containing the pre-filled syringe without the attached needle
ZOSTAVAX is available in packs of 1, 10 or 20 with or without needles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Sanofi Pasteur MSD SNC, 162 avenue Jean Jaurès, 69007 Lyon, France

Manufacturer: Merck Sharp and Dohme, B.V., Waarderweg, 39, 2031 BN Haarlem, The Netherlands

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu.

The following information is intended for healthcare professionals only:

Reconstitution instructions

The solvent is a clear and colourless liquid. Before mixing with the solvent, the powder is a white to off-white compact crystalline plug. When completely reconstituted, the vaccine is a semi-hazy to translucent, off-white to pale yellow liquid.

Inject the entire content of the pre-filled syringe into the vial containing the powder. Gently agitate to dissolve completely. Withdraw the entire content of the reconstituted vaccine using the same syringe. Inject the vaccine. One or 2 separate needles may be available in the packaging of the presentation containing the pre-filled syringe without attached needle. The needle should be pushed into the extremity of the syringe and rotated a quarter of a turn (90°) to secure the connection.

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 use the reconstituted vaccine if you notice any particulate matter or if the appearance of the solvent or powder or of the reconstituted vaccine differs from that described above.
Any unused product or waste material should be disposed of in accordance with local requirements.

See also section 3. How to use ZOSTAVAX.