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 to any of the components of this vaccine (including neomycin (which may be present as trace residue) 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

Tell your doctor if you have ever had an allergic reaction to any of the ingredients (including neomycin (which may be present as trace residue) or any of the ingredients listed under section 6) before you receive this vaccine.

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

If you have a blood clotting disorder or low levels of platelets, the vaccine should be given under the skin because bleeding may occur following administration into the muscle.

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.

For information about the administration of ZOSTAVAX and pneumococcal polysaccharide vaccine at the same time, talk to your doctor or health care provider.

Pregnancy and breast-feeding
ZOSTAVAX should not be given to pregnant women. Women of child-bearing potential 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.

ZOSTAVAX contains sodium
This medicine contains less than 1 mmol sodium (23 milligrams) per dose, that is to say essentially ‘sodium-free'.

ZOSTAVAX contains potassium
This medicine contains less than 1 mmol potassium (39 milligrams) per dose, that is to say essentially ‘potassium-free’.

3. How to use ZOSTAVAX

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

If you have a blood clotting disorder or low levels of platelets in your blood, the injection will be given under the skin.

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.

Rarely (may affect up to 1 in 1,000 people), allergic reactions may occur. Some of these reactions may be serious and may include difficulty in breathing or swallowing. If you have an allergic reaction, call your doctor right away.

The following side effects have been observed:

- Very common (may affect more than 1 in 10 people): Redness, pain, swelling and itching at the injection site*
- Common (may affect up to 1 in 10 people): Warmth, bruising, hard lump, and rash at the injection site*; headache*; pain in the arm or leg*; joint pain, muscle pain; fever; rash
- Uncommon (may affect up to 1 in 100 people): Nausea; swollen gland (neck, armpit)
- Rare (may affect up to 1 in 1,000 people): Hives at the injection site
- Very rare (may affect up to 1 in 10,000 people): Varicella (chicken pox); shingles; damage of retina caused by inflammation resulting in changes in sight (in patients under immunosuppressive therapy).

*These adverse reactions have been observed in clinical trials and through post-marketing surveillance; most of those observed in clinical trials were reported as mild in intensity.

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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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, one dose (0.65 mL) contains:
The active substance is:
Varicella-zoster virus[1], Oka/Merck strain, (live, attenuated) not less than 19,400 PFU (plaque-forming units).
[1]Produced in human diploid (MRC-5) cells

The other ingredients are:

Powder
Sucrose, hydrolysed gelatin, sodium chloride (NaCl), potassium dihydrogen phosphate, potassium chloride (KCl), monosodium L-glutamate monohydrate, disodium phosphate, sodium hydroxide (NaOH) (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 powder is a white to off-white compact crystalline plug. The solvent is a clear and colourless liquid.
One pack of ZOSTAVAX contains a vial and a pre-filled syringe without needle or with one or 2 separate needles.
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 in Great Britain: Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London EC2M 6UR, United Kingdom

Marketing Authorisation Holder in UK (Northern Ireland): MSD VACCINS, 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:

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This leaflet was last revised in March 2021.

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

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The following information is intended for healthcare professionals only:
Before mixing with the solvent, the powder vaccine is a white to off-white compact crystalline plug. The solvent is a clear colourless liquid. When reconstituted, ZOSTAVAX is a semi-hazy to translucent, off-white to pale yellow liquid.

Avoid contact with disinfectants as they may inactivate the vaccine virus.

To reconstitute the vaccine, use the solvent provided.

It is important to use a separate sterile syringe and needle for each patient to prevent transmission of infectious agents from one individual to another.

One needle should be used for reconstitution and a separate, new needle for injection.

Reconstitution instructions
To attach the needle, it should be firmly placed on the tip of the syringe and secured by rotating a quarter of a turn (90°).

Inject the entire content of the solvent syringe into the vial containing the powder. Gently agitate to dissolve completely.

The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance prior to administration. In the event of either being observed, discard the vaccine.

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

Do not freeze the reconstituted vaccine.

Withdraw the entire content of the reconstituted vaccine from the vial into a syringe, change the needle, and inject the entire volume by subcutaneous or intramuscular route.

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

See also section 3. How to use ZOSTAVAX.

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