PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS (PREPARATIONS) 1986

This medicine is to be marketed upon physician's prescription only

ZOSTAVAX®
(ZOSTER VACCINE LIVE)
POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION

After reconstitution, one dose (0.65 mL) contains:
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

For a list of inactive ingredients see section 6 "FURTHER INFORMATION" and section 2.6 "Important information about some of the ingredients of **ZOSTAVAX**".

Read the entire leaflet carefully before you are vaccinated with ZOSTAVAX.
- This leaflet contains concise information about **ZOSTAVAX**. If you have any further questions, refer to the doctor or the pharmacist.
- This vaccine has been prescribed for you. Do not pass it on to others. It may harm them, even if their medical condition seems similar.

1. WHAT ZOSTAVAX IS INTENDED FOR?

ZOSTAVAX is a live attenuated vaccine indicated for prevention of herpes zoster (shingles) in individuals 50 years of age and older.

Therapeutic group: Vaccines, Viral vaccine.

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.

2. BEFORE USING ZOSTAVAX

2.1 Do not use ZOSTAVAX if:

- you are allergic (hypersensitive) 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). For a list of inactive ingredients, see section 6 "FURTHER INFORMATION".
- you have a blood disorder or any type of cancer that weakens your immune system.
- you have been told by your doctor that you have a weakened immune system as a result of a disease, medicines, or other treatment.
- you have active untreated tuberculosis.
- you are pregnant (in addition, pregnancy should be avoided for 1 month after vaccination, see section 2.4 "**Pregnancy and breast-feeding**").

2.2 Special warnings regarding use of ZOSTAVAX

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. “FURTHER INFORMATION”) before you receive this vaccine.

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

ZOSTAVAX cannot be used to treat existing shingles.

2.3 Interactions with other medicines

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, you should tell the doctor or pharmacist.
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 pharmacist.

2.4 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 you 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.

2.5 Driving and operating machinery

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

2.6 Important information about some of the ingredients of ZOSTAVAX

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 SHOULD YOU USE ZOSTAVAX?

Always use **ZOSTAVAX** as instructed by the doctor.
You should check with the doctor or the pharmacist if you are not sure regarding the dosage and method of treatment.
The dosage and method of treatment will be determined by the doctor only.

ZOSTAVAX is given as a single dose.

Do not exceed the recommended dose.

Method of administration
ZOSTAVAX should be injected under the skin, preferably in the upper arm (deltoid region).

Instructions intended for healthcare professionals are included in the leaflet in a separate section.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.
Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take your medicine. Wear glasses if you need them.

If you have further questions on the use of the medicine, consult with a doctor or a pharmacist.

4. SIDE EFFECTS

As with any medicine and vaccines, **ZOSTAVAX** may cause side effects, in some users.
Do not be alarmed by reading the list of side effects, you may not suffer from any of 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.

If a side effect appears, if any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report " at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link:
https://sideeffects.health.gov.il/

5. HOW TO STORE ZOSTAVAX?

- Avoid Poisoning! This medicine and any other medicine must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use **ZOSTAVAX** after the expiry date (exp. date) that appears on the packaging. The expiry date refers to the last day of the indicated month.
- **Storage conditions**:
  Store and transport refrigerated (2°C - 8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light.
- Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredients **ZOSTAVAX** also contains:
Powder
Sucrose (41.05 mg), Hydrolyzed gelatin (porcine), Urea, Sodium chloride, Monosodium L-glutamate monohydrate, Sodium phosphate dibasic, Potassium phosphate monobasic, Potassium chloride

This vaccine may contain traces of neomycin.

Solvent
Water for Injection

What ZOSTAVAX looks like and the contents of the package
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 colorless liquid. Before mixing with the solvent, the powder is a white to off-white compact crystalline plug.

One pack of **ZOSTAVAX** contains:
Powder in a single dose vial, solvent in a pre-filled syringe without attached needles and two needles.

Marketing authorization holder and address:
Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O.Box 7121, Petah-Tikva 49170.

Manufacturer:
Merck Sharp & Dohme Corp., Whitehouse station, NJ, USA.

Revised in December 2021 according to MoHs guidelines.

Registration number of the medicine listed in the National Drug Registry of the Ministry of Health:
148 70 33584

Preparation and handling Instructions 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 minimize loss of potency. Discard reconstituted vaccine if it is not used within 30 minutes.

Do not freeze the reconstituted vaccine.

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

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

See also section 3-“How to use ZOSTAVAX”.