

**ZOSTAVAX® (ZOSTER VACCINE LIVE): הנדון:
זוסטאווקס****Dosage Form:** Powder and solvent for suspension for injection**Composition:** After reconstitution, 1 dose (0.65 mL) contains:

Varicella-zoster virus, Oka/Merck strain, (live, attenuated) not less than 19,400 PFU

חברת מרק שארפ ודוהם (ישראל-1996) בע"מ (MSD ישראל), מבקשת ליידע על עדכון העלון לרופא של
Zostavax (Zoster Vaccine Live)

להלן לשון ההתוויה המאושרת לתכשיר:

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

עדכונים מהותיים בעלון לרופא

טקסט שהתווסף מודגש עם קו תחתון. טקסט שנמחק מופיע בקו-חוצה.

4.4 Special warnings and precautions for useTraceabilityIn order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

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SodiumThis medicinal product contains less than 1 mmol sodium (23 milligrams) per dose, that is to say essentially 'sodium-free'.PotassiumThis medicinal product contains less than 1 mmol potassium (39 milligrams) per dose, that is to say essentially 'potassium-free'.**6.6 Special precautions for disposal and other handling**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. ~~When reconstituted, ZOSTAVAX is a semi-hazy to translucent, off-white to pale yellow liquid.~~

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°).

~~If two needles are provided, separate needles should be used for the reconstitution and administration of the vaccine.~~

~~To reconstitute the vaccine, inject the entire content of the solvent syringe into the vial containing the powder, all the solvent in the pre-filled syringe into the vial of lyophilised vaccine and gently agitate to mix thoroughly dissolve completely.~~

~~Withdraw the entire contents of the reconstituted vaccine using the same syringe. Inject the vaccine. One or 2 separate needles may be available in the secondary 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.~~

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 content 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.

בעלון לרופא היו עדכונים נוספים שאינם מהותיים ואינם נכללים בהודעה זו.
העלון נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות. ניתן לקבלו מודפס על ידי פניה לבעל
הרישום, חברת MSD, בטלפון 09-9533333.

ZOSTAVAX® מופץ ע"י חברת נובולוג בע"מ.

בברכה,
אורית בילין
רוקחת ממונה
MSD ישראל