ינואר 2022

רוקח/ת נכבד/ה,

**הנדון: ZOSTAVAX® (ZOSTER VACCINE LIVE)**
**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) ועלון לצרכן חדש.**

**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.

### 4.5 Interaction with other medicinal products and other forms of interaction

…
The concomitant use of ZOSTAVAX and a 23-valent pneumococcal polysaccharide vaccine ~~should not be given concomitantly because concomitant use in a clinical trial~~ resulted in reduced immunogenicity of ZOSTAVAX ~~(see section 5.1)~~in a small clinical trial. ~~Therefore, administration of the two vaccines should be considered to be separated by at least 4 weeks.~~ However, data collected in a large observational study did not indicate increased risk for developing herpes zoster after concomitant administration of the two vaccines.
…

### 5.1 Pharmacodynamic properties

**…**
*Concomitant administration*
…
In a double-blind, controlled clinical trial, 473 adults, 60 years of age or older, were randomised to receive a single dose of ZOSTAVAX either concomitantly (N=237), or nonconcomitantly (N=236) with 23-valent pneumococcal polysaccharide vaccine. At four weeks postvaccination, the VZV-specific immune responses following concomitant use were not similar to the VZV-specific immune responses following nonconcomitant administration. ~~Therefore consider administration of the two vaccines separated by at least 4 weeks.~~ However in a US effectiveness cohort study of 35,025 adults ≥ 60 years old, no increased risk of herpes zoster was observed in individuals who received ZOSTAVAX and 23-valent pneumococcal polysaccharide vaccine concomitantly (n=16,532) as compared to individuals receiving ZOSTAVAX one month to one year after 23-valent pneumococcal polysaccharide vaccine (n=18,493) in routine practice. The adjusted hazard ratio comparing the incidence rate of HZ in the two groups was 1.04 (95 % CI, 0.92, 1.16) over a median follow-up of 4.7 years. The data do not indicate that concomitant administration alters the effectiveness of ZOSTAVAX.

**עלון לצרכן**
לתכשיר קיים כעת עלון לצרכן שיצורף בעתיד לאריזתו, במקום העלון לרופא.

העלונים מפורסמים במאגר התרופות שבאתר האינטרנט של משרד הבריאות. ניתן לקבלם מודפסים על ידי פניה לבעל הרישום, חברת MSD, בטלפון 09-9533333.

**ZOSTAVAX®** מופץ ע"י חברת נובולוג בע"מ.

בברכה,
מיכל סרפר
רוקחת ממונה
MSD ישראל

Ref: Israeli SPC revised 12/2021
New Israeli PIL 12/2021