הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך **31.05.2016**

שם תכשיר באנגלית ומספר הרישום

Zostavax (zoster vaccine live) 148-70-33584

שם בעל הרישום **Merck Sharp & Dohme (Israel-1996) Company Ltd.**

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
ZOSTAVAX is a live, attenuated varicella-zoster vaccine and administration may result in disseminated disease in individuals who are immunosuppressed or immunodeficient. Patients who previously received immune suppressive therapy should be carefully evaluated for the reconstitution of the immune system prior to receiving Zostavax (see section 4.3).		**4.4 Special warnings and precautions for use**
ZOSTAVAX and 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). Therefore, administration of the two vaccines should be considered to be separated by at least 4 weeks.	ZOSTAVAX and 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).	**4.5 Interaction with other medicinal products and other forms of interaction**
Table 1: Adverse Reactions from Clinical Trial Experience and Post-Marketing Surveillance MedDRA System Organ Class / Adverse reactions / Frequency Infections and infestations / Varicella, Herpes zoster (vaccine strain) / Very rare		**4.8 Undesirable effects** b. Tabulated summary of adverse events

Eye Disorders	Necrotizing retinitis (patients on immunosuppressive therapy)	Very rare		
Of the 295 ZOSTAVAX recipients, one case of serious vaccine related maculo-papular rash was reported on Day 4 following Dose 1 of ZOSTAVAX (see section 4.3).				**4.8 Undesirable effects** c. Description of selected adverse reactions
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.				**5. PHARMACOLOGICAL PROPERTIES** **5.1 Pharmacodynamic properties**