

**הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 3102.50)**

תאריך: 14/5/15

שם תכשיר באנגלית ומספר הרישום: Eylea (151-12-33800)

שם בעל הרישום: Bayer Israel Ltd.

טופס זה מיועד לפרוט החמרות בלבד !

(סימון צהוב = תוספת טקסט בגדר החמרות)

החמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
		Indication
		contraindications
If visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment, Eylea should be discontinued.	If there is no improvement in visual and anatomic outcomes over the course of the first three injections, continued treatment is not recommended.	Posology, dosage & administration
Intravitreal injection-related reactions Intravitreal injections, including those with Eylea, have been associated with endophthalmitis, intraocular inflammation, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract	Endophthalmitis Intravitreal injections, including those with aflibercept, have been associated with endophthalmitis	Special WARNINGS AND PRECAUTIONS
		Interaction with Other Medicaments and Other Forms of Interaction
		pregnancy Fertility, and Lactation
Eye disorders: Rare: Cataract traumatic		Adverse Reaction