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

תאריך: 26/11/2014

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

שם בעל הרישום: Bayer Israel Ltd.

טופס זה מיועד לפרוט ההחמרות בלבד !

(סימון צהוב= תוספת טקסט בגדר החמרות)

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
		Indication
		contraindications
Diabetic Macular Oedema The recommended dose for Eylea is 2 mg aflibercept equivalent to 50 microlitres. Eylea treatment is initiated with one injection per month for five consecutive doses, followed by one injection every two months. There is no requirement for monitoring between injections. After the first 12 months of treatment with Eylea, the treatment interval may be extended based on visual and anatomic outcomes. The schedule for monitoring should be determined by the treating physician. If visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment, Eylea should be discontinued.		**Posology, dosage & administration**
Systemic effects Systemic adverse events including non-ocular haemorrhages and arterial thromboembolic events have been reported following intravitreal injection of VEGF inhibitors and there is a theoretical risk that these may relate to VEGF inhibition. There are limited data on safety in the treatment of patients with CRVO or DME with a history of stroke or transient ischaemic attacks or myocardial infarction within the last 6 months. Caution should be exercised when treating such patients. Other As with other intravitreal anti-VEGF treatments for AMD, CRVO and DME the following also applies:	Systemic effects Systemic adverse events including non-ocular haemorrhages and arterial thromboembolic events have been reported following intravitreal injection of VEGF inhibitors, and there is a theoretical risk that these may relate to VEGF inhibition. Other As with other intravitreal anti-VEGF treatments for AMD and CRVO the following also applies: • The safety and efficacy of	**Special WARNINGS AND PRECAUTIONS**

• The safety and efficacy of Eylea therapy administered to both eyes concurrently have not been systematically studied (see section 5.1). If bilateral treatment is performed at the same time this could lead to an increased systemic exposure, which could increase the risk of systemic adverse events.	Eylea therapy administered to both eyes concurrently have not been systematically studied.	
		Interaction with Other Medicaments and Other Forms of Interaction
		pregnancy Fertility, and Lactation
Very common: Visual acuity reduced, **Common:** Cataract cortical, Punctate keratitis, **Uncommon:** Blindness, Uveitis,	**Uncommon :** Cataract cortical **Rare:** Uveitis	**Adverse Reaction**