הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 05.2013)

תאריך 10.10.2016

שם תכשיר באנגלית ומספר הרישום Eylea 151-12-33800-00

שם בעל הרישום באייר ישראל בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
wet AMD … After the first 12 months of treatment with Eylea, and based on visual and/or anatomic outcomes, the treatment interval may be extended, such as with a treat-and-extend dosing regimen, where the treatment intervals are gradually increased to maintain stable visual and/or anatomic outcomes: however there are insufficient data to conclude on the length of these intervals. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly. … *Diabetic macular oedema* … After the first 12 months of treatment with Eylea, and based on visual and/or anatomic outcomes, the treatment interval may be extended, such as with a treat-and-extend dosing regimen, where the treatment intervals are gradually increased to maintain stable visual and/or anatomic outcomes: however there are insufficient data to conclude on the length of these intervals. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly. The schedule for monitoring should	wet AMD … After the first 12 months of treatment with Eylea, the treatment interval may be extended based on visual and/or anatomic outcomes. In this case the schedule for monitoring should be determined by the treating physician and may be more frequent than the schedule of injections. … *Diabetic macular oedema* … After the first 12 months of treatment with Eylea, the treatment interval may be extended based on visual and/or anatomic outcomes. The schedule for monitoring should be determined by the treating physician. …	**4.2 Posology and method of administration**

therefore be determined by the treating physician and may be more frequent than the schedule of injections. …		
Table 1 **Immune system disorders** **Uncommon** Hypersensitivity*** *** During the post-marketing period, reports of hypersensitivity included rash, pruritus, urticaria, and isolated cases of severe anaphylactic/anaphylactoid reactions … *Description of selected adverse reactions* Arterial thromboembolic events (ATEs) are adverse events potentially related to systemic VEGF inhibition. There is a theoretical risk of arterial thromboembolic events, including stroke and myocardial infarction, following intravitreal use of VEGF inhibitors.	**Table 1** **Immune system disorders** **Uncommon** Hypersensitivity*** *** including allergic reactions *Description of selected adverse reactions* Arterial thromboembolic events (ATEs) are adverse events potentially related to systemic VEGF inhibition. There is a theoretical risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors.	**4.8 Undesirable effects**