הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 3102.50)

תאריך: 29 ספטמבר 2015

שם תכשיר באנגלית ומספר הרישום: Hepatect CP 127-04-30518

שם בעל הרישום: Kamada Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
תוספת: Each vial of 100 ml contains: 5000 IU		**Qualitative and quantitative composition**
הוספת כותרת: Transmissible agents		**Special warnings and precautions for use**
4.6 Fertility, Pregnancy and Lactation Pregnancy The safety of this medicinal product for use in human pregnancy has not been established in controlled clinical trials and therefore should only be given with caution to pregnant women and breast-feeding mothers. Intravenous immunoglobulin G have been shown to cross the placenta, increasingly in the third trimester. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected. Breast-feeding Immunoglobulins are excreted into the milk and may contribute to protecting the neonate from pathogens which have a mucosal portal of entry. Fertility Clinical experience with immunoglobulins suggests that no harmful effects on fertility are to be expected.	**4.6 Pregnancy and lactation** The safety of this medicinal product for use in human pregnancy has not been established in controlled clinical trials. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected.	**Fertility, Pregnancy and Lactation**
The ability to drive and operate machines may be impaired by some adverse reactions associated with intravenous immunoglobulins. Patients who experience adverse reactions during treatment should wait for these to resolve before driving or operating machines.	No effects on ability to drive and use machines have been observed.	**Effects on ability to drive and use machines**

Undesirable effects		תוספת: Reporting of suspected adverse reactions Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form (http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.health.gov.il) or by email (adr@MOH.HEALTH.GOV.IL). Additionally, you should also report to Kamada LTD.
Nature and contents of container		תוספת: Vial with 5000 IU in 100 ml solution

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.
שינויים שאינם בגדר החמרות סומנו (בעלון) **בטקסט מודגש באפור.** יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

העלון הועבר בדואר אלקטרוני בתאריך: 29-09-2015

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