הודעה על החמרה (מידע בטיחות)

(מעודכן 05.2013)

תאריך ___28-05-2015_____

שם תכשיר באנגלית EMEND 80 MG CAPSULES & EMEND 125 MG CAPSULES:

מספר הרישום 135 08 31206, 135 09 3120

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

טופס זה מיועד לפרוט ההחמרות בלבד !

בעלון לצרכן

ההחמרות המבוקשות		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
נטילת תרופות אחרות		במיוחד יידע את הרופא או הרוקח שלך אם אתה נוטל: • אירינוטקאן, אטופוסיד, וינורלבין, איפוספאמיד (תרופות המשמשות לטיפול בסרטן),

בעלון לרופא

ההחמרות המבוקשות		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
4.2 Posology and method of administration		*Highly Emetogenic Chemotherapy Regimen* EMEND: Day 1: 125 mg orally; Day 2: 80 mg orally; Day 3: 80 mg orally; Day 4: none Dexamethasone: Day 1: 12 mg orally; Day 2: 8 mg orally; Day 3: 8 mg orally; Day 4: 8 mg orally 5-HT_3 antagonists: Day 1: Standard dose of 5-HT_3 antagonists. See the product information for the selected 5-HT_3 antagonist for appropriate dosing information; Day 2: none; Day 3: none; Day 4: none *Moderately Emetogenic Chemotherapy Regimen* EMEND: Day 1: 125 mg orally; Day 2: 80 mg orally; Day 3: 80 mg orally Dexamethasone: Day 1: 12 mg orally; Day 2: none; Day 3: none 5-HT_3 antagonists: Day 1: Standard dose of 5-HT_3 antagonists. See the product information for the selected 5-HT_3 antagonist for appropriate dosing information; Day 2: none; Day 3: none

Chemotherapeutic medicinal products Post-marketing events of neurotoxicity, a potential adverse reaction of ifosfamide, have been reported after aprepitant and ifosfamide coadministration.		**4.5 Interaction with Other Medicaments and Other Forms of Interaction**
EMEND may have minor influence on the ability to drive and use machines. Dizziness and fatigue may occur following administration of EMEND (see section 4.8).		**4.7 Effects on ability to drive and use machines**
Skin and subcutaneous tissue disorders – rare - skin lesion		**4.8 Undesirable effects**
<u>3-day regimen of aprepitant</u> In 2 randomised, double-blind studies encompassing a total of 1,094 patients receiving chemotherapy that included cisplatin ≥70 mg/m^2, aprepitant in combination with an ondansetron/dexamethasone regimen (see section 4.2) was compared with a standard regimen (placebo plus ondansetron 32 mg intravenously administered on Day 1 plus dexamethasone 20 mg orally on Day 1 and 8 mg orally twice daily on Days 2 to 4). Although a 32 mg intravenous dose of ondansetron was used in clinical trials, this is no longer the recommended dose. See the product information for the selected 5-HT$_3$ antagonist for appropriate dosing information.		**5.1 Pharmacodynamic properties**