

יוני 2020

KYPROLIS (Carfilzomib) 2 mg/ml
Powder for solution for injection

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

אמג'ן אירופה בי.וי, בעלת הרישום, מבקשת להודיעך על עדכונים בעלון לרופא לתכשיר קיפרוליס. בהודעה זו מצוינים השינויים העיקריים בלבד.

ההתוויות המאושרות:

Kyprolis (carfilzomib) is indicated:

- in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.
- as a single agent for the treatment of patients with multiple myeloma who have received at least two prior therapies including bortezomib and an immunomodulatory agent and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

החמרות בעלון לרופא:

5. WARNINGS AND PRECAUTIONS

5.15 Progressive Multifocal Leukoencephalopathy

Progressive multifocal leukoencephalopathy (PML), which can be fatal, has occurred with Kyprolis. In addition to Kyprolis, other possible contributory factors include prior or concurrent immunosuppressive therapy that may cause immunosuppression. Consider PML in any patient with new onset of or changes in pre-existing neurological signs or symptoms. If PML is suspected, discontinue Kyprolis and initiate evaluation for PML including neurology consultation.


6 ADVERSE REACTIONS

- Progressive Multifocal Leukoencephalopathy [see Warnings and Precautions (5.15)]

6.2 Postmarketing Experience

The following adverse reactions have been identified during post approval use of Kyprolis. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: hemolytic uremic syndrome (HUS), hepatitis B virus reactivation, gastrointestinal perforation, pericarditis, and cytomegalovirus infection including chorioretinitis, pneumonitis, enterocolitis, and viremia.

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות שאתר משרד הבריאות, וניתן לקבלו גם על-ידי פניה למפיץ המקומי של התרופה, חברת מדיסון פארמה. שרות לקוחות: Medison-CS@medison.co.il טלפון: *5634



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