נובמבר 2018

KYPROLIS (Carfilzomib) 60 mg/vial
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 המהווים החמרה בלבד: קו תחתי משמעו תוספת טקסט והדגשה משמעה החמרה.

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.

עדכונים בעלון לרופא:

5. WARNINGS AND PRECAUTIONS

5.1 Cardiac Toxicities

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New onset or worsening of pre-existing cardiac failure (e.g., congestive heart failure, pulmonary edema, decreased ejection fraction), restrictive cardiomyopathy, myocardial ischemia, and myocardial infarction including fatalities have occurred following administration of Kyprolis. Some events occurred in patients with normal baseline ventricular function. In clinical studies with Kyprolis, these events occurred throughout the course of Kyprolis therapy. Death due to cardiac arrest has occurred within one day of Kyprolis administration. In randomized, open-label, multicenter trials for combination therapies, the incidence of cardiac failure events was 8% [*see Adverse Reactions (6.1)*].

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5.16 Embryo-Fetal Toxicity

Based on the mechanism of action and findings in animals, Kyprolis can cause fetal harm when administered to a pregnant woman. Carfilzomib administered intravenously to pregnant rabbits during organogenesis at a dose approximately 40% of the clinical dose of 27 mg/m^2 based on body surface area caused post-implantation loss and a decrease in fetal weight [*see Use in Specific Populations (8.1)*].

Females of reproductive potential should avoid becoming pregnant while being treated with Kyprolis. Advise females of reproductive potential that they must use contraception during treatment with Kyprolis and for 6 months following the final dose. Advise males with female sexual partners of reproductive potential that they must use contraception during treatment with Kyprolis and for 3 months following the final dose. If Kyprolis is used during pregnancy or if the patient becomes pregnant during Kyprolis treatment, the patient should be apprised of the potential risk to the fetus [*see Use in Specific Populations (8.1, 8.3) and Nonclinical Toxicology (13.1)*].

8. USE IN SPECIFIC POPULATIONS

Information for Pregnancy, Lactation, Females and Males of Reproductive Potential, Geriatric Use and Hepatic Impairment was updated

17 PATIENT COUNSELING INFORMATION

Patient counseling information was added.

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות שאתר משרד הבריאות, וניתן לקבלו גם על-ידי פניה למפיץ המקומי של התרופה, חברת מדיסון פארמה.
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בברכה,

סיגל בן דור

רוקחת ממונה