יוני 2025

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 הרחבת התוויה של התכשיר קיפרוליס.
בנוסף, כלולים בהודעה זו עיקר עדכונים הנובעים משינויי זה ובוצעו בעלון התכשיר.

ההתוויות המאושרות:

Kyprolis (carfilzomib) is indicated:

- for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy in combination with:
  - Lenalidomide and dexamethasone; or
  - Dexamethasone; or
  - Daratumumab (I.V. or S.C.) and dexamethasone.

• 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.

8.1 Pregnancy

Risk Summary

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~~The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes.~~

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%–4% and 15%–20%, respectively.

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8.4 Pediatric Use

The safety and effectiveness of Kyprolis in pediatric patients have not been established.

The safety and effectiveness of Kyprolis in combination with chemotherapy was evaluated, but not established in an open label trial (Study 20140106; NCT02303821) in 124 patients aged 1 to younger than 17 years with relapsed or refractory B-cell acute lymphoblastic leukemia (ALL) who have received prior targeted B-cell immune therapy or relapsed or refractory T-cell ALL.

No new safety signals were observed in these pediatric patients. The systemic exposure of carfilzomib in these pediatric patients was within range of that observed in adults given the same dose based on body surface area.

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,
אמג'ן יורופ B.V