דצמבר 2019

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 הכוללים עדכונים בצורת המתן, משטר המינון והחמרות.
בהודעה זו מצוינים רק עיקרי השינויים שבוצעו.

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:

1.1 Administration Precautions

...
Administration - Kyprolis can be administered in a 50 mL or 100 mL intravenous bag of **5% Dextrose Injection, USP.** Infuse over 10 or 30 minutes depending on the Kyprolis dose regimen *[see Dosage and Administration (2.2)]*
...

1.2 Recommended Dosing

Kyprolis in Combination with Dexamethasone

For the combination regimen with dexamethasone alone, administer Kyprolis intravenously once weekly or twice weekly as a 30-minute infusion as described in Table 1 & 2 below.

Once weekly 20/70 mg/m^2 regimen by 30-minute infusion

Kyprolis is administered intravenously as a 30-minute infusion once weekly for three weeks followed by a 13-day rest period as shown in Table 1. Each 28-day period is considered one treatment cycle. Administer Kyprolis at a starting dose of 20 mg/m2 in Cycle 1 on Day 1. If tolerated, escalate the dose to 70 mg/m2 on Day 8 of Cycle 1.

Dexamethasone 40 mg is taken by mouth or intravenously on Days 1, 8, and 15 of all cycles and on Day 22 of Cycles 1 to 9. Administer dexamethasone 30 minutes to 4 hours before Kyprolis.

...

6.2 Postmarketing Experience

The following additional adverse reactions were reported in the postmarketing experience with 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), 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*

בברכה,

סיגל בן דור

רוקחת ממונה