J-C Health Care Ltd.

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יולי 2022

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

הנדון: ***Velcade 3.5mg ולקייד 3.5 מ"ג***

חברת יאנסן ישראל בע"מ (J-C Health Care Ltd.) מבקשת להודיעכם כי העלון לרופא של התכשיר שבנדון התעדכן ב-06/2022.

פרטי העדכון העיקריים מופיעים בהמשך (טקסט שנוסף מסומן באדום, טקסט שהושמט מסומן בטקסט ~~בחול עם קו חוצה~~, טקסט המהווה החמרה מודגש ברקע צהוב), אך קיימים עדכונים נוספים.

ההתוויות המאושרות לתכשיר בישראל:

Velcade (bortezomib) for injection is indicated for the treatment of patients with multiple myeloma.
Velcade (bortezomib) for injection is indicated for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy.
Velcade in combination with rituximab, cyclophosphamide, doxorubicin and prednisone is indicated for the treatment of adult patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation.

מרכיב פעיל:
Bortezomib 3.5mg

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות: https://israeldrugs.health.gov.il/#!/byDrug.

כמו כן, מצורף לפרסום זה וניתן לקבל העתק מודפס של באמצעות פנייה לבעל הרישום: יאנסן ישראל בע"מ , קיבוץ שפיים, 6099000, טל': 09-9591111.

בברכה,
דנית ראובני

רוקחת ממונה
יאנסן ישראל בע"מ

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העדכון בעלון לרופא הינו:

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13 CLINICAL PHARMACOLOGY

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Drug Interaction Studies

Clinical Studies

No clinically significant differences in bortezomib pharmacokinetics were observed when coadministered with dexamethasone (weak
CYP3A4 inducer), omeprazole (strong CYP2C19 inhibitor), or melphalan in combination with prednisone.
In vitro studies indicate that bortezomib is a weak inhibitor of the cytochrome P450 (CYP) isozymes 1A2, 2C9, 2C19, 2D6 and 3A4. Based on the limited contribution (7%) of CYP2D6 to the metabolism of bortezomib, the CYP2D6 poor metaboliser phenotype is not expected to affect the overall disposition of bortezomib.
A drug-drug interaction study assessing the effect of ketoconazole, a potent CYP3A4 inhibitor, on the pharmacokinetics of bortezomib (injected intravenously), showed a mean bortezomib AUC increase of 35% ($CI_{90\%}$ [1.032 to 1.772]) based on data from 12 patients. Therefore, patients should be closely monitored when given bortezomib in combination with potent CYP3A4 inhibitors (e.g. ketoconazole, ritonavir).
In a drug-drug interaction study assessing the effect of omeprazole, a potent CYP2C19 inhibitor, on the pharmacokinetics of bortezomib (injected intravenously), there was no significant effect on the pharmacokinetics of bortezomib based on data from 17 patients.
A drug-drug interaction study assessing the effect of rifampicin, a potent CYP3A4 inducer, on the pharmacokinetics of bortezomib (injected intravenously), showed a mean bortezomib AUC reduction of 45% based on data from 6 patients. Therefore, the concomitant use of bortezomib with strong CYP3A4 inducers (e.g., rifampicin, carbamazepine, phenytoin, phenobarbital and St. John's Wort) is not recommended, as efficacy may be reduced.
In the same drug-drug interaction study assessing the effect of dexamethasone, a weaker CYP3A4 inducer, on the pharmacokinetics of bortezomib (injected intravenously), there was no significant effect on the pharmacokinetics of bortezomib based on data from 7 patients.

Strong CYP3A4 Inhibitor
Coadministration with ketoconazole (strong CYP3A4 inhibitor) increased bortezomib exposure by 35%.
Strong CYP3A4 Inducer
Coadministration with rifampin (strong CYP3A4 inducer) decreased bortezomib exposure by approximately 45%.

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