

ינואר 2022

רופא/ה נכבד/ה

רוקח/ת נכבד/ה

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא של התכשיר:

Velcade 3.5mg powder for solution for injection 131-60-3139-01/02/03

הרשום להתוויות:

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.

להלן השינויים העיקריים שחלו בעלון לרופא:

[...]

7.2 Embryo-Fatal Toxicity

[...]

~~Females of reproductive potential should avoid becoming pregnant while being treated with VELCADE.~~ Advise females of reproductive potential that they must to use effective contraception during treatment with VELCADE and for seven months following treatment. Advise males with female ~~sexual~~ partners of reproductive potential that they must to use effective contraception during treatment with VELCADE and for four months following treatment. If VELCADE is used during pregnancy or if the patient becomes pregnant during VELCADE treatment, the patient should be apprised of the potential risk to the fetus [see Use in Specific Populations (10.1, 10.3), Nonclinical Toxicology (14.1)].

[...]

10.3 Females and Males of Reproductive Potential

[...]

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Contraception

Females

Advise females of reproductive potential to ~~avoid pregnancy and~~ use effective contraception during treatment with VELCADE and for ~~at least~~ seven months after the last dose.

Males

Males with female ~~sexual~~ partners of reproductive potential should use effective contraception during treatment with VELCADE and for ~~at least~~ four months after the last dose.

מצ"ב הקובץ הנקי לאחר השינויים. על מנת לראות את פירוט השינויים ניתן לפנות למאגר המידע שבאתר משרד הבריאות בכתובת <https://data.health.gov.il/drugs/index.html#!/byDrug>.

העלונים נשלחו לפרסום במלואם למאגר התרופות שבאתר משרד הבריאות. כמו כן, ניתן לקבלם מודפסים בפניה אלינו לטלפון 09-9591111.

בברכה,

צפריר כהן

רוקח ממונה