

ברצוננו להביא לידיעתכם את העדכון בעלון לרופא של התכשיר בפברואר 2022:

Bortezomib Taro 3.5 mg

הרכב וחוזק

bortezomib 3.5 mg

התוויה כפי שאושרה בתעודת הרישום:

Bortezomib is indicated for the treatment of patients with multiple myeloma.

Bortezomib is indicated for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy.

Bortezomib 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.

השינויים העיקריים שחלו בעלון לרופא:

7.2 Embryo-Fetal Toxicity

...

~~Women of reproductive potential should avoid becoming pregnant while being treated with bortezomib.~~

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

...

10.3 Females and Males of Reproductive Potential

Contraception

Females

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

העלון נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות www.health.gov.il

וניתן לקבלו מודפס על ידי פנייה לבעל הרישום:

תרו אינטרנשיונל בע"מ, רחוב הקיטור 14, ת.ד. 10347 מפרץ חיפה 2624761 ובטלפון 1-800-464664.

תרו אינטרנשיונל בע"מ

הקיטור 14,

ת.ד. 10347, מפרץ חיפה 2624761

טל: 04-8475700

פקס: 04-8727165