תאריך: 08.2026

רופא /ה, רוקח/ת נכבד/ה

חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר

Trabectedin Teva 0.25, 1 mg

Powder for Concentrate for Solution for I.V. Infusion

טרבקטדין טבע 0.25, 1 מ"ג

אבקה להכנת תמיסה מרוכזת למתן תוך ורידי (I.V.) בעירוי

Contains: *Trabectedin 0.25, 1 mg*

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Trabectedin Teva is indicated for the treatment of patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients.

ברצוננו להודיע שהעלון לרופא עודכן. בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):

4.2 Posology and method of administration

Dose adjustments during treatment

[…]

- Neutropenia < 500/mm^3 lasting for more than 5 days or associated with fever or infection
- Thrombocytopenia < 25,000/mm^3
- Increase of bilirubin > ULN and/or alkaline phosphatase>2.5 x ULN
- Alkaline phosphatase of non-osseous origin > 2.5 x ULN
- Increase of aminotransferases (AST or ALT) > 2.5 x ULN which has not recovered by day 21
- Any other grade 3 or 4 adverse reactions (such as nausea, vomiting, fatigue)

[…]

Table 1: Dose modification table for Trabectedin Teva as single agent for soft tissue sarcoma (STS)

[…]

4.4 Special warnings and precautions for use

[…]

Others

The concomitant use of trabectedin with alcohol must be avoided (see section 4.5).

Women of childbearing potential must use highly effective contraception during treatment and 8 months thereafter and immediately inform the treating physician if a pregnancy occurs (see section 5.3).

Men in fertile age must use highly effective contraception during treatment and 5 months after treatment (see section 4.6).

[…]

4.6 Pregnancy and lactation

[…]

Women of childbearing potential
Women of childbearing potential must use highly effective contraception during treatment and 8 months thereafter, and immediately inform the treating physician if a pregnancy occurs (see section 5.3).
If pregnancy occurs during treatment the possibility of genetic counselling should be considered.

Fertility
Men in fertile age must use highly effective contraception during treatment and 5 months after treatment (see section 4.4).

[…]

4.8 Undesirable effects

[…]

Tabulated summary of adverse reactions

[…]

Adverse reactions are listed by System Organ Class and frequency.

The frequencies are classified as very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100) and rare (≥1/10,000 to <1/1,000).

5.2 Pharmacokinetic properties

[…]

Hepatic impairment
The effect of hepatic impairment on the pharmacokinetics of trabectedin was assessed in 15 cancer patients at doses ranging from 0.58 to 1.3 mg/m^2 administered as 3-hour infusion. The geometric mean dose normalized trabectedin exposure (AUC) increased by 97% (90% CI: 20%, 222%) in 6 patients with moderate hepatic impairment (increased serum bilirubin levels from 1.5 to 3 x ULN and increase of aminotransferases (AST or ALT) <8 x ULN) following administration of a single trabectedin dose of 0.58 mg/m^2 (n=3) or 0.9 mg/m^2 (n=3) compared to 9 patients with normal liver function following administration of a single trabectedin dose of 1.3 mg/m^2 (see sections 4.2 and 4.4).

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

ניתן לקבלו מודפס ע"י פניה לחברת טבע., https://israeldrugs.health.gov.il