

Zepzelca

הרכב:

LURBINECTEDIN 4 MG/VIAL

ההתוויה הרשומה לתכשיר בישראל:

ZEPZELCA is indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

בהודעה זו כלולים השינויים המהותיים בלבד. בעלונים ישנם שינויים נוספים.
טקסט חדש מסומן עם קו תחתון, טקסט המהווה חמרה **מודגש בצהוב**.

להלן העדכונים העיקריים בעלון לרופא:

8. Adverse Reactions

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Myelosuppression
Advise patients to immediately contact their healthcare provider for fever, other signs of infection, **unusual bruising, bleeding, tiredness or pallor** [see *Warnings and Precautions (7.1)*]
- Hepatotoxicity
Advise patients to contact their healthcare provider immediately for signs and symptoms suggestive of *hepatotoxicity* [see *Warnings and Precautions (7.2)*]
- Extravasation Resulting in Tissue Necrosis
Advise patients to contact their healthcare provider immediately for signs and symptoms of extravasation. The time to onset of necrosis after extravasation may vary [see *Warnings and Precautions (7.3)*]
- Rhabdomyolysis
Advise patients to contact their healthcare provider immediately for signs and symptoms of *rhabdomyolysis* [see *Warnings and Precautions (7.4)*]

9. DRUG INTERACTIONS

9.1 Effect of Other Drugs on ZEPZELCA

[...]

Avoid grapefruit and seville oranges during ZEPZELCA treatment, as these contain strong or moderate inhibitors of CYP3A.

[...]

12.3 Pharmacokinetics

Drug Interactions Studies

Clinical Studies

Effects of CYP3A Inhibitors on Lurbinectedin: Coadministration of itraconazole (a strong CYP3A inhibitor) increased systemic exposure (AUC) of total lurbinectedin by 2.7-fold and unbound lurbinectedin by 2.4-fold.

Effects of CYP3A Inducers on Lurbinectedin: Coadministration of bosentan (a moderate CYP3A inducer) decreased systemic exposure (AUC) of total lurbinectedin by 20% and unbound lurbinectedin by 19%. These changes are not considered clinically relevant.

העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בברכה,
דיויד וגנר
רוקח ממונה
מגאפארם בע"מ