

April 2022

רופא/ה נכבד/ה

רוקח/ת נכבד/ה,

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא של התכשיר:

SIMDAX 2.5mg/ml; Levosimendan 2.5mg

המאושר להתוויה הבאה:

Short-term treatment of acutely decompensated severe chronic heart failure (Simdax should only be used as add-on therapy in situations where conventional therapy with e.g., diuretics, ACE-inhibitors and digitalis is not sufficient and where there is a need for inotropic support).

צורת מתן של התכשיר: Concentrate for solution for infusion

בהודעה זו כלולים העדכונים המהותיים בלבד. החמרות מסומנות **בצהוב**, תוספת טקסט מסומנת בקו תחתון, מחיקת טקסט מסומנת ~~בקו חוצה~~.

השינויים המהותיים בעלון לרופא מופיעים בסעיפים הבאים:

4 CLINICAL PARTICULARS

[...]

4.1 Special warnings and special precautions for use

[...]

This medicine ~~at product~~ contains 3925 mg of alcohol (98 vol % anhydrous ethanol) (alcohol), i.e. up to 3925 mg per in each 5 ml vial, which is equivalent to appr 98 vol%. The amount in one 5 ml vial of this medicine is equivalent to 99.2 ml beer, or 41.3 ml wine per 5ml vial.

Harmful for those suffering from alcoholism.

To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy. The amount of alcohol in this medicinal product may alter the effects of other medicines.

Because this medicine is usually given slowly over 24 hours, the effects of alcohol may be reduced.

4.2 Interaction with other medicinal products and other forms of interaction

[...]

Levosimendan has shown to be an inhibitor of CYP2C8 in vitro, and inhibition of metabolism of sensitive CYP2C8 substrates at the highest levosimendan infusion level (0.2 µg/min/kg), as well as with the higher loading-dose (12 µg/kg) cannot be excluded. Clinical drug-drug interaction study involving levosimendan and a representative substrate primarily metabolized by CYP2C8 has not been conducted. However, co-administration of levosimendan at highest recommended dose with sensitive CYP2C8 substrates should be avoided when possible. Co-administration of levosimendan may increase the plasma concentrations of concomitant CYP2C8 substrates such as loperamide, pioglitazone, repaglinide and enzalutamide. With the lower infusion rate of 0.1 µg/min/kg the drug drug interaction are unlikely.

העלון לרופא מפורסם במלואו למאגר התרופות שבאתר משרד הבריאות.
<https://data.health.gov.il/drugs/index.html#!/byDrug>
ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת ביומד-יר בע"מ, רחוב היסמין 28 תל-מונד,
טל. 09-7746004.

בברכה,
גלי קיסר
רוקחת ממונה