

דצמבר 2025

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

Levosimendan MBI 2.5mg/ml

חברת MBI Pharma מבקשת להודיע על עדכונים בעלון לרופא של התכשיר שבנדון.

התווית התכשיר:

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.

Levosimendan 2.5mg/ml מרכיב פעיל:

Concentrate for solution for infusion: צורת המתן של התכשיר:

העדכונים המהותיים בעלון מפורטים למטה. תוספות בקו תחתי, מחיקות בקו חוצה, החמרות מסומנות בצבע צהוב. בעלון נעשו גם שינויים עריכתיים קלים שאינם מפורטים כאן.

עדכונים בעלון לרופא נעשו בסעיפים הבאים:

4.5 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 it can therefore not be excluded that~~ 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 can increase the exposure of concomitantly administered drugs that are primarily metabolized/metabolised by CYP2C8 has not been conducted. However, Therefore,~~ 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 should be avoided when possible.~~

[...]

4.8 Undesirable effects

Body System	Frequency	Preferred Term
Immune system disorders	Not known	Hypersensitivity

5.2 Pharmacokinetic properties

[...]

Biotransformation

[...]

In vitro studies have shown that levosimendan, OR-1855 and OR-1896 do not inhibit CYP1A2, CYP2A6, CYP2B6, CYP2C19, CYP2D6, CYP2E1, or CYP3A4 at concentrations achieved by the recommended dosing. In addition levosimendan does not inhibit CYP1A1 and neither OR-1855 nor OR-1896 inhibit ~~CYP2C9, CYP2C8 or CYP2C9~~. Levosimendan has

shown to be an inhibitor of CYP2C8 in vitro (see section 4.5.). The results of drug interaction studies in humans with warfarin, felodipine, and itraconazole confirmed that levosimendan does not inhibit CYP3A4 or CYP2C9, and metabolism of levosimendan is not affected by CYP3A inhibitors.

העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות, בכתובת
<https://israeldrugs.health.gov.il/#!/byDrug>
וניתן לקבלו מודפס על ידי פניה לבעל הרישום, חברת אמ.בי.איי פארמה, ת.ד. 5061 קדימה, או
בטלפון 09-7719003

בברכה,
חברת אמ.בי.איי פארמה בע"מ