What to expect?

Cardiac output (index)

Pulmonary capillary wedge pressure

Haemodynamic and neurohormonal effects

Stroke volume

Pulmonary vascular resistance

No impairment of diastolic function

Anti-ischemic effect

Other clinical effects

Detailed infusion rates for loading dose and continuous infusion of a 0.5 mg/ml SIMDAX solution for infusion:

<table>
<thead>
<tr>
<th>Patient weight</th>
<th>Loading dose (µg/kg)</th>
<th>Continuous infusion rate (µg/kg/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 60 kg</td>
<td>10</td>
<td>0.25</td>
</tr>
<tr>
<td>30-60 kg</td>
<td>7.5</td>
<td>0.20</td>
</tr>
<tr>
<td>20-30 kg</td>
<td>5</td>
<td>0.15</td>
</tr>
</tbody>
</table>

Therapeutic indications

Simdax is indicated for intravenous use in patients with an acute decompensated severe chronic heart failure (ACSH) symptoms who are in shock or in hypotensive septic shock, with or without diabetes mellitus, requiring inotropic support. It may also be administered to a patient suffering from chronic heart failure, in the event of an acute decompensation, who requires inotropic support on top of conventional therapy.

Design and administration

The recommended loading dose is 2.5 mg/kg, administered over a 10-minute period, followed by an initial continuous infusion rate of 0.25 µg/kg/min. Increments of 0.05 µg/kg/min may be added, if necessary, until a satisfactory pulmonary wedge pressure is achieved. The continuous infusion rate is generally kept at 0.25 µg/kg/min, however, a range of 0.15-0.3 µg/kg/min may be used.

Further readings

More detailed recommendations are available in literature on the use of SIMDAX in acute heart failure,“advanced heart failure,” and peripartum settings.

PRODUCT INFORMATION: SIMDAX 2.5 mg/ml concentrate for solution for infusion. Therapeutic indications: SIMDAX is indicated for intravenous use in patients with an acute decompensated severe chronic heart failure (ACSH) symptoms who are in shock or in hypotensive septic shock, with or without diabetes mellitus, requiring inotropic support. It may also be administered to a patient suffering from chronic heart failure, in the event of an acute decompensation, who requires inotropic support on top of conventional therapy. Design and administration: The recommended loading dose is 2.5 mg/kg, administered over a 10-minute period, followed by an initial continuous infusion rate of 0.25 µg/kg/min. Increments of 0.05 µg/kg/min may be added, if necessary, until a satisfactory pulmonary wedge pressure is achieved. The continuous infusion rate is generally kept at 0.25 µg/kg/min, however, a range of 0.15-0.3 µg/kg/min may be used. Further readings: More detailed recommendations are available in literature on the use of SIMDAX in acute heart failure, “advanced heart failure,” and peripartum settings.
SIMDAX is a cardioprotective inodilator with a unique triple mechanism of action. It improves hemodynamics without significant increase in oxygen consumption, reduces symptoms of acute heart failure, and has a sustained effect.

What is SIMDAX (levosimendan i.v.)?
- Is a cardioprotective inodilator with a unique triple mechanism of action.
- Improves hemodynamics without significant increase in oxygen consumption.
- Reduces symptoms of acute heart failure.
- Has a sustained effect.

Introduction to SIMDAX

In clinical practice

SIMDAX is indicated for the short-term treatment of acutely decompensated severe chronic heart failure in situations where conventional therapy is not sufficient, and in cases where inotropic support is considered appropriate.

SIMDAX improves myocardial contractility without increasing oxygen requirements and induces peripheral and coronary vasodilation with a potential anti-stunning and anti-ischaemic effect. Clinical trial data from heart failure patients showed that SIMDAX offers:
- Improved hemodynamic without a significant increase in oxygen consumption.
- Reduced symptoms of acute heart failure.
- Beneficial effect on neurohormone levels.
- Sustained efficacy due to formation of an active metabolite.
- Additional benefit in patients under beta-blockade.
- A good and predictable safety profile.
- No impairment of diastolic function.
- No development of tolerance.

Overall characteristics of patients

Your first SIMDAX patients will have an existing chronic heart failure with a left ventricular ejection fraction below 40%, assessed within 12 months before the dosing of SIMDAX. In this document, we describe examples of both patients who fall in the category of acutely decompensated heart failure (cardiology setting) and patients who undergo coronary artery bypass grafting (cardiac surgery settings).

Exclusion criteria

- Severe hypotension and/or tachycardia
- Severe renal impairment
- Severe hepatic impairment
- History of Torsades de Pointes

Acute decompensated heart failure

Coronary Artery Bypass Grafting

Dosing

Dosing of levosimendan will be according to the SPC. However, the bolus dose should only be given if immediate effects are needed and the baseline blood pressure is ≥ 120 mmHg. In most cases:
- SIMDAX-infusion will be started with an infusion rate of 0.1 mcg/kg/min.
- The rate can be increased to 0.2 mcg/kg/min if further effect is warranted or decreased to 0.05 mcg/kg/min if adverse effects (e.g. hypotension) occur.
- The maximum duration of the infusion should not exceed 24 hours.

Timing of the infusion

SIMDAX infusion should be started as soon as the treating physician finds a clinical need for it, in case of cardiac surgery, the infusion should preferably be started before the operation (up to 2.4 hours before the planned operation), while, in case of failure to wean from CPB or post-operative low cardiac output syndrome, the infusion is started later.

Measures during the treatment

- Hypovolemia and hypotension should be corrected before the initiation and during the levosimendan infusion, with colloids and/or vasoconstrictors (e.g. norepinephrine).
- The dosing of i.v. diuretics should be temporarily interrupted or their dose reduced.
- Potassium levels should be followed regularly and supplemented as needed, serum potassium should preferably be kept ≥ 4.0 mmol/l.