

PACKAGE LEAFLET: INFORMATION FOR THE USER

Simdax 2.5 mg/ml concentrate for solution for infusion levosimendan

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Simdax is and what it is used for
2. What you need to know before you use Simdax
3. How to use Simdax
4. Possible side effects
5. How to store Simdax
6. Contents of the pack and other information

1. WHAT SIMDAX IS AND WHAT IT IS USED FOR

Simdax is a concentrated form of a medicine, which must be diluted before it is given to you as an infusion into your veins.

Simdax works by increasing the pumping force of the heart and allows blood vessels to relax. Simdax will lessen the congestion in your lungs and make it easier for blood and oxygen to go through your body. Simdax will help to relieve the shortness of breath from severe heart failure.

Simdax is used for treatment of heart failure, in people who still find it hard to breathe, even though they are taking other medicines to get rid of extra water from the body.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SIMDAX

Do not use Simdax:

- if you are allergic (hypersensitive) to levosimendan or to any of the other ingredients in Simdax.
- if you have very low blood pressure or an abnormally fast heartbeat

- if you have severe kidney or liver disease
- if you have a heart disease which makes filling or emptying of the heart harder
- if you have been told by your doctor that you have ever had an abnormal heartbeat called Torsades de Pointes

Warnings and precautions

- if you have any kidney or liver disease
- if you also have low blood counts and chest pain
- if you have an abnormally fast heartbeat, an abnormal heart rhythm or have been told by your doctor that you have atrial fibrillation or an abnormally low amount of potassium in your blood, your doctor should use Simdax very carefully.

Tell your doctor before starting Simdax if you have one of the above mentioned diseases or symptoms.

Children and adolescents

Simdax should not be given to children and adolescents under 18 years of age.

Other medicines and Simdax

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you have been given other heart medicines through your veins, your blood pressure may drop if you are given Simdax.

Pregnancy and breast-feeding

Ask your doctor for advice before starting Simdax if you are pregnant or think you may be pregnant. It is not known if Simdax affects your baby. Your doctor will have to decide if the benefit to you is worth the possible risk to your baby.

There are indications that Simdax passes into human breast milk. You should not breast-feed while using Simdax in order to avoid potential cardiovascular side-effects in the infant.

Simdax contains alcohol

This medicine contains 3925 mg of alcohol (anhydrous ethanol) 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.

The amount of alcohol in this medicine can affect your ability to drive or use machines. This is because it may affect your judgement and how fast you react.

If you have epilepsy or liver problems, talk to your doctor or pharmacist before taking this medicine.

The amount of alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

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

3. HOW TO USE SIMDAX

Simdax will be given to you as an infusion (drip) into your veins. This is why you should only be given Simdax in a hospital where the doctor can monitor you. Your doctor will decide how much Simdax you should be given. Your doctor will measure how you respond to Simdax (for example by measuring your heart rate, blood pressure, ECG, and how you are feeling). Your doctor may then change your dose if needed. The doctor may want to monitor you for up to 4-5 days after Simdax is stopped.

You may be given a fast infusion over ten minutes, followed by a slower infusion for up to 24 hours.

Your doctor should check to see how you respond to Simdax from time to time. He may decrease your infusion if your blood pressure drops or your heart starts to beat too fast or you do not feel well. Tell your doctor or nurse if you feel your heart racing, if you are light-headed or if you feel that the effect of Simdax is too strong or too weak.

If the doctor feels you need more Simdax and you aren't having side effects, he may increase your infusion.

Your doctor will continue your Simdax infusion for as long as you need it to support your heart. Usually this is for 24 hours.

The effect on your heart will last for at least 24 hours after the Simdax infusion is stopped. The effect may continue for 7-10 days after the infusion is stopped.

If you get more Simdax than you should

If you are given too much Simdax, your blood pressure may drop and your heartbeat may get faster. Your doctor will know how to treat you based on your condition.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Simdax can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people)

Abnormally fast heartbeat
Headache
Drop in blood pressure.

Common (may affect up to 1 in 10 people)

Low amount of potassium in your blood
Insomnia
Dizziness
An abnormal heartbeat called atrial fibrillation (a part of the heart flutters instead of beating properly)
Extra heartbeats
Heart failure
Your heart doesn't get enough oxygen
Nausea
Constipation
Diarrhoea
Vomiting
Low blood counts

Not known (frequency cannot be estimated from the available data)

Hypersensitivity (symptoms may include rash and itching).

Abnormal heartbeat called ventricular fibrillation (a part of the heart flutters instead of beating properly) has been reported in patients who received Simdax.

Please inform your doctor immediately if you experience side effects. Your doctor may reduce the rate of infusion or stop the Simdax infusion.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SIMDAX

Keep out of reach and sight of children.

Store in a refrigerator (2°C – 8°C).

Do not freeze.

Do not use Simdax after the expiry date which is stated on the carton.

Storage and in-use time after dilution should never exceed 24 hours.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Simdax contains

- The active substance is levosimendan 2.5 mg/ml.
- The other ingredients are: povidone, citric acid and ethanol.

What Simdax looks like and contents of the pack

The concentrate is a clear yellow or orange solution for dilution prior to administration.

Pack sizes

- 1, 4, 10 vials (Type I glass) of 5 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

To be completed nationally

Further Information

For any information about this medicinal product, please contact the local representative of the marketing authorisation holder:

[To be completed nationally.]

This leaflet was last approved in 18/08/2025

The following information is intended for medical or healthcare professionals only:

Simdax 2.5 mg/ml concentrate for solution for infusion

Instructions for use and handling

Simdax 2.5 mg/ml concentrate for solution for infusion is intended for single use only. Simdax 2.5 mg/ml concentrate for solution for infusion should not be diluted into a higher concentration than 0.05mg/ml as instructed below, otherwise opalescence and precipitation may occur.

As for all parenteral medicinal products, inspect the diluted solution visually for particulate matter and discolouration prior to administration.

- To prepare the 0.025 mg/ml infusion, mix 5 ml of Simdax 2.5 mg/ml concentrate for solution for infusion with 500 ml of 5 % glucose solution.
- To prepare the 0.05 mg/ml infusion, mix 10 ml of Simdax 2.5 mg/ml concentrate for solution for infusion with 500 ml of 5% glucose solution.

Posology & Method of Administration

Simdax is for in-hospital use only. It should be administered in a hospital setting where adequate monitoring facilities and expertise with the use of inotropic agents are available.

Simdax is to be diluted prior to administration.

The infusion is for intravenous use only and can be administered by the peripheral or central route.

Please refer to the Summary of Product Characteristics for posology information.