

Simdax

levosimendan

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SIMDAX.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SIMDAX against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What SIMDAX is used for

This medicine is used to treat 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.

This medicine belongs to a class of medicines called calcium sensitisers.

SIMDAX both enhances the pumping force of the heart and allows blood vessels to relax. Improvement of the cardiac function by SIMDAX will reduce the congestion in your lungs and enhance the delivery of blood and oxygen to the organs. Treatment with SIMDAX will help to relieve the shortness of breath from severe heart failure.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you are given SIMDAX

When you must not be given it

You must not be given SIMDAX if you have an allergy to:

- Any medicine containing *levosimendan*
- Any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- Shortness of breath, wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin.

You must not be given Simdax if you have any of the following medical conditions:

- severe liver and kidney disease
- very low blood pressure and abnormally fast heart beat
- 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 heart beat called Torsades de Pointes

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

If you are not sure whether you should be given SIMDAX, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney or liver disease.
- chest pain (ischaemia)
- if you have a very low blood pressure before taking SIMDAX or are at risk of having your blood pressure drop, your doctor should give you a lower dose of SIMDAX. Your doctor should also adjust how long you are given SIMDAX based on how you respond to it.
- if you are dehydrated before using SIMDAX, your doctor should make sure you receive additional liquids before giving you SIMDAX. If your blood pressure or heartbeat change too much, your dose of SIMDAX should be decreased or the infusion should be stopped.
- if you have low blood counts or 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 if you are pregnant or intend to become pregnant.

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.

Tell your doctor if you are breastfeeding or plan to breastfeed

If you are a woman who has had a baby, talk to your doctor about the best way to feed your baby. It is not known if SIMDAX passes into human breast milk. Ask your doctor or pharmacist for advice before taking any medicine.

If you have not told your doctor about any of the above, tell him/her before you start being given SIMDAX.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and SIMDAX may interfere with each other.

These include:

- loperamide, a medicine used to decrease the frequency of diarrhoea
- pioglitazone and repaglinide, medicines used to treat type 2 diabetes
- enzalutamide, a medicine used to treat prostate cancer
- isosorbide mononitrate, a medicine used to prevent chest pain (angina).

Your doctor and pharmacist have more information on medicines to be careful with or avoid after being given this medicine.

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

How SIMDAX is given

How much is given

Your doctor will decide what dose of SIMDAX you will receive. This depends on your condition and other factors, such as your weight.

How it is given

SIMDAX will be given to you as an infusion into your veins, mixed in a liquid called 5% glucose. 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 3-5 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. The doctor should use lower doses if you are taking other heart medicines through your veins, such as medicines to make your blood vessels relax or medicines to make your heartbeat more strongly. If the doctor feels you need a stronger response, he may want you to have a bigger dose of SIMDAX, however you may then have more side effects.

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 7-9 days after the infusion is stopped.

It isn't known whether you should receive SIMDAX several times. Lower doses are recommended if you were using other medicines to help your heart before you took SIMDAX. SIMDAX should not be given into the same vein as other medicines except frusemide, digoxin or glyceryl trinitrate.

Overdosage

As SIMDAX is given to you under the supervision of your doctor, it is unlikely that you will receive too much. However, if you experience any side effects after being given SIMDAX, tell your doctor or nurse immediately.

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.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are being given SIMDAX.

SIMDAX helps most people with heart failure, but it may have unwanted side effects in a few people. All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

The most common side effects are:

- headache
- a fall in blood pressure (hypotension)
- an unusually rapid heart rate

Other common side effects are:

- nausea
- vomiting
- dizziness
- low amount of potassium in your blood
- insomnia
- 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
- constipation
- diarrhoea
- low blood counts

Other side effects not listed above may occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice anything that is making you feel unwell. Your doctor is trained to manage these unwanted effects if they occur.

contains 2.5mg/mL levosimendan.

Other ingredients are:

- povidone,
- citric acid and
- ethanol

Storage:

SIMDAX should be stored in the pharmacy or on the ward. The injection is kept at 2 to 8 °C in a refrigerator but not frozen.

The colour of SIMDAX may turn to orange during storage, but the medicine does not become weaker if this happens. The product may be used until the indicated expiration date if storage instructions have been followed.

After Dilution:

SIMDAX should be used within 24 hours once the solution has been mixed with fluid.

Sponsor

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Product description

What it looks like

SIMDAX is a clear, yellow or orange solution for dilution prior to administration.

SIMDAX is available in 5mL and 10mL vials.

Ingredients:

The active ingredient in SIMDAX is levosimendan. Each vial of SIMDAX