Package leaflet: Information for the user

Levosimendan Bioglan 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 or nurse.
- 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 Levosimendan Bioglan is and what it is used for

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

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

Levosimendan Bioglan 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.

Levosimendan Bioglan is used in adults.

2. What you need to know before you use Levosimendan Bioglan

Do not use Levosimendan Bioglan

- if you are allergic to levosimendan or to any of the other ingredients of this medicine (listed in section 6).
- 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
Talk to your doctor or nurse before using Levosimendan Bioglan

- if you have low blood pressure,
- if you are in a state of decreased blood volume (hypovolaemia),
- if you have any kidney or liver disease
- if you also have low blood counts (anaemia) 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 Levosimendan Bioglan very carefully.

Children and adolescents
Levosimendan Bioglan should not be given to children and adolescents under 18 years of age.

Other medicines and Levosimendan Bioglan
Tell your doctor if you are taking, have recently taken or might take 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 Levosimendan Bioglan.

Tell your doctor if you are taking isosorbide mononitrate, because use of Levosimendan Bioglan can increase fall in blood pressure when standing up.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before this medicine is given to you. It is not known if Levosimendan Bioglan affects your baby. Your doctor will have to decide if the benefit to you outweight the possible risk to your baby.

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

Levosimendan Bioglan 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 breastfeeding, 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 Levosimendan Bioglan

Levosimendan Bioglan will be given to you as an infusion (drip) into your veins. This is why you should only be given Levosimendan Bioglan in a hospital where the doctor can monitor you. Your doctor will decide how much Levosimendan Bioglan you should be given. Your doctor will measure how you respond to Levosimendan Bioglan (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 Levosimendan Bioglan 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 Levosimendan Bioglan 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 Levosimendan Bioglan is too strong or too weak.

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

Your doctor will continue your Levosimendan Bioglan 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 Levosimendan Bioglan infusion is stopped. The effect may continue for 7-10 days after the infusion is stopped.

Renal impairment
Levosimendan Bioglan must be used with caution in patients with mild to moderate renal impairment. Levosimendan Bioglan should not be used in patients with severe renal impairment (see section 2).

Hepatic impairment
Levosimendan Bioglan must be used with caution in patients with mild to moderate hepatic impairment, although no dose adjustment appears necessary for these patients. Levosimendan Bioglan should not be used in patients with severe hepatic impairment (see section 2).

If you get more Levosimendan Bioglan than you should
If you are given too much Levosimendan Bioglan, 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, this medicine 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 Levosimendan Bioglan.

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

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 Levosimendan Bioglan

Keep this medicine out of the sight and reach of children.

Store in a refrigerator (2ºC – 8ºC).
Do not freeze.
Do not use this medicine after the expiry date which is stated on the label and box after "EXP". The expiry date refers to the last day of that month.

The colour of the concentrate may turn to orange during storage, but there is no loss of potency and the product may be used until the indicated expiry date if storage instructions have been followed.

After dilution
Chemical and physical in-use stability has been demonstrated for 24 hours at 25ºC.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8ºC, unless dilution has taken place in controlled and validated aseptic conditions. Storage and in-use time after dilution should never exceed 24 hours.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Levosimendan Bioglan contains
- The active substance is levosimendan.
  Each ml of concentrate contains 2.5 mg of levosimendan.
  One 5 ml vial contains 12.5 mg of levosimendan.
- The other ingredients are: povidone, citric acid (for pH-adjustment) and ethanol, anhydrous.

What Levosimendan Bioglan looks like and contents of the pack
The concentrate for solution for infusion is a clear yellow or orange solution for dilution prior to administration.

Pack sizes
- 1, 4, 10 vials (glass vials with chlorobutyl rubber closure and aluminium cap and seal) of 5 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:
[To be completed nationally]

This leaflet was last reviewed in 2025-09-03

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

Levosimendan Bioglan 2.5 mg/ml concentrate for solution for infusion

Instructions for use and handling
Levosimendan Bioglan 2.5 mg/ml concentrate for solution for infusion is intended for single use only.

Levosimendan Bioglan 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 Levosimendan Bioglan 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 Levosimendan Bioglan 2.5 mg/ml concentrate for solution for infusion with 500 ml of 5% glucose solution.

Posology & Method of Administration
Levosimendan Bioglan 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.

Levosimendan Bioglan 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.