PACKAGE LEAFLET

Package leaflet: Information for the patient

Labrycor 0.2 mg/ml concentrate for solution for infusion

isoprenaline hydrochloride

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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 Labrycor is and what it is used for
2. What you need to know before you use Labrycor
3. How to use Labrycor
4. Possible side effects
5. How to store Labrycor
6. Contents of the pack and other information

1. What Labrycor is and what it is used for

Labrycor contains the active substance isoprenaline, which has a stimulating effect on a certain part of the nervous system (sympathomimetic). Isoprenaline leads to, among other things, increased heart rate, increased heart contractility and dilatation of blood vessels, which decreases blood pressure.

Labrycor is used for the short-term treatment of:
- slow heart rate in patients awaiting the insertion of a pacemaker or when this is contraindicated.
- sudden fainting with loss of consciousness caused by a slowing of heart rate (called Adams-Stokes syndrome).

2. What you need to know before you use Labrycor

Do not use Labrycor
- if you are allergic to isoprenaline hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you are also taking adrenaline, a medicine used in intensive care to treat cardiac arrest
- If you suffer from a faster-than-usual heart rhythm
- If your heart is stressed (atrial or ventricular hyperexcitability)
- if you have taken too much of a type of medicine called cardiac glycoside, such as digoxin (digitalis), a medicine to treat heart arrhythmia and heart failure
- if you suffer from a heart attack (myocardial infarction);
- If you suffer from chest pain (angina pectoris)
- If you suffer from irregular heartbeat (ventricular arrhythmia) that requires treatment

Warnings and precautions
Talk to your doctor or nurse before using Labrycor.
- if you have heart problems.
- if you suffer from diabetes.
- if you are taking digoxin (digitalis) (another medicine affecting the heart).
- if you have an overactive thyroid gland. This medicine is to be avoided in cases of uncontrolled hyperthyroidism.
- if you suffer from convulsive disorders.

- if you have ever had a reaction to a medicine affecting the heart and circulation (belonging to the sympathomimetic amine group).
- during your treatment with this medicine, you will be monitored by ECG and your dose may be adjusted.
- if you are being treated for decreased blood volume in the body (shock) Labrycor can only be used after your blood volume has been restored.
- be particularly careful in cases of doses high enough to reach a heart rate of above 130 beats/minute.

Other medicines and Labrycor
Tell your doctor if you are using, have recently used or might use any other medicines.
This is particularly important if you are taking any of the following medicines:

- other cardiac or central nervous system stimulants.
- **adrenaline** (a medicine used in intensive care to treat cardiac arrest).
- **digitalis** (another medicine affecting the heart).
- **monoamine oxidase inhibitors** (MAOIs), a class of medicines used to treat depression.
- antidepressants (such as **imipramine**).
- sulphates, such as **salicylamide** (painkiller).
- **entacapone** (a class of medicine used for Parkinson's disease).
- **doxapram** (a class of medicine used in intensive care to increase respiratory rate).
- **ergotamine** (a class of medicines used to treat acute migraine attacks).
- sympathomimetic vasoconstrictors (such as **oxytocin**).

Labrycor may not be administered under chloroform, cyclopropane or halothane **anaesthetics** or any other halogen anaesthetic.

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 taking this medicine.

It is preferable to avoid the use of isoprenaline during pregnancy. The clinical benefits should be weighed against the possible risks to the mother and child.

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from isoprenaline therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Labrycor contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially "sodium-free".

Driving and ability to use machines
As this medicine will be administered to you by a healthcare professional as an emergency medicine, this does not apply to you.

3. How to use Labrycor

This medicine will be administered to you by intravenous infusion by a specialist doctor.

The doctor will decide the best suitable dose for you. The medicine will be diluted in a physiological saline or isotonic glucose solution.

The doctor will carefully increase the dose of Labrycor while closely monitoring your heart rate.

Isoprenaline is not meant to be used routinely.

If you use more Labrycor than you should
The symptoms of overdose are nausea, headaches, extra heart beats and heart rate acceleration.

If you use more Labrycor than you should, contact your doctor or nurse immediately.

If necessary, a plasma or complete blood transfusion may be performed.

4. Possible side effects

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

Not known (may affect an unknown number of people):

- heart rate acceleration
- cardiac rhythm disorders
- chest pains
- low blood pressure
- high blood pressure
- nervousness
- shakiness
- dizziness
- headache
- nausea
- a feeling of weakness and sweating

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance
Website: www.hpra.ie.
mailto: By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Labrycor

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

Do not use this medicine after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month.

Before opening: Do not refrigerate. Keep the vial in the outer carton in order to protect from light.
After opening: The product must be used immediately.
After dilution:

Chemical and physical in-use stability of the solution diluted in 5% glucose or 0.9% sodium chloride has been demonstrated for 24 hours at 25°C.

From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not use this medicine if you notice any visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. 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 Labrycor contains
The **active** substance is isoprenaline hydrochloride. Each ml contains 0.2 mg isoprenaline hydrochloride.

The other ingredients are:
disodium edetate, sodium citrate dihydrate, citric acid, sodium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections.

What Labrycor looks like and content of the pack
Labrycor 0.2 mg/ml concentrate for solution for infusion is a clear, colourless to slightly yellow coloured solution, free from visible particles.
1 ml - Each pack contains 1 or 5 glass vials each containing 1 ml concentrate for solution for infusion.

5 ml - Each pack contains 1 or 5 glass vials each containing 5 ml concentrate for solution for infusion.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Macure Healthcare Limited
62 Arclight Building
Triq L-Gharbiel
Is-Swieqi
Malta

Manufacturer[1]
SGS Pharma Magyarorszag Kft.
Derkovits Gyula Utca 53,
Budapest XIX,1193,
Hungary

Tillomed Malta Limited
Malta Life Sciences Park,
LS2.01.06 Industrial Estate,
San Gwann, SGN 3000, Malta

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	Labrycor 0,2 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Belgium	Labrycor 0,2 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Cyprus	Labrycor 0,2 mg/ml Πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Czech Republic	Labrycor
Denmark	Xytrina
Greece	Labrycor
Spain	Labrycor 0,2 mg/ml concentrado para solución para perfusión EFG
Finland	Xytrina 0,2 mg/ml infuusiokonsentraatti, liuosta varten
Ireland	Labrycor 0.2 mg/ ml concentrate for solution for infusion
Netherlands	Labrycor 0,2 mg/ml Concentraat voor oplossing voor infusie
Norway	Xytrina
Sweden	Xytrina 0,2 mg/ml koncentrat till infusionsvätska, lösning

[1] Only actual site will be listed on printed leaflet

This leaflet was last revised in

Detailed information on this medicine is available on the website of HPRA – Health Products Regulatory Authority: https://www.hpra.ie/

The following information is intended for healthcare professionals only:

Labrycor must only be administered by physicians trained in anaesthesia, cardiology or in intensive care, in an appropriately monitored or critical care setting.
Circulatory and respiratory functions should be closely monitored.

Isoprenaline should not be used routinely.

For intravenous use.

Dilute 10 ml of concentrate for solution for infusion (= 2.0 mg) in 500 ml of sodium chloride 9 mg/ml (0.9 %) solution for injection **or** glucose 50 mg/ml (5 %) solution for injection. This gives a concentration of 4 microgram/ml isoprenaline solution for infusion. Labrycor should be carefully titrated under close monitoring to the lowest possible dose that obtains a heart rate of 50-60 beats per minute.

The recommended start dose is 0.01 microgram/kg/minute.

The dose can be increased in increments of 0.01 microgram/kg/minute until a maximal dose of 0.15 microgram/kg/minute.

The rate of infusion should be adjusted based on the heart rate of the patient.

National and international recommendations and guidelines on the appropriate use of isoprenaline should be followed.

Do not inject Labrycor at the same time as adrenaline in any circumstances. However, if the administration of the two medicinal products is necessary, they can be given alternately every 4 hours.

After dilution with sodium chloride 9 mg/ml (0.9 %) solution for injection or glucose 50 mg/ml (5 %) solution for injection, the chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C.

From a microbiological point of view, diluted solutions should be used immediately. If not used immediately, in-use storage times and conditions prior to use of the diluted solution are the responsibility of the user.