Package leaflet: Information for the patient

Labrycor 0.2 mg/ml concentraat voor oplossing infusie

Labrycor 1mg/5ml concentraat voor oplossing infusie

Isoprenaline hydrochloride

Read all of this leaflet carefully before you start taking 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, pharmacist 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Product name> is and what it is used for

This medicine is used in certain heart rhythm disorders and some cardiac emergencies.

2. What you need to know before you take <Product name>

Do not take <Product name>

- If you are allergic to the active substance or any of the other ingredients of this medicine, mentioned in section 6.
- Certain heart rhythm disorders;
- Certain forms of angina pectoris;
- In case of digitalis intoxication;

This medicine is usually not recommended in case of association with volatile halogenated anaesthetics.

Warnings and precautions

Please talk to your doctor, pharmacist or nurse before taking <product name>.

- In case of hyperthyroidism, caution is recommended.
- In case of angina pectoris, in diabetic or digitalized patient, in case of hyperthyroidism.

Follow the advices of your doctor.

Children and adolescents
No data available

Other medicines and <Product name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

<Product name> with food and drink
No data available

Pregnancy and breast-feeding

It is preferable not to use this medicine during pregnancy.
If you discover that you are pregnant during treatment, consult your doctor as he alone can judge the need to continue it.
Ask your doctor or pharmacist for advice before taking any medicine.

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.

<Product name> contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial that is essentially "sodium-free".

3. How to use <Product name>

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage
Dosage is adapted according to the patient's state.

Mode of administration
Continuous intravenous route or rarely, subcutaneously.

If you have used more <Product name> than you should have:
As this medicine will be administered to you by a healthcare professional, it is extremely unlikely that you will receive too high or too low a dose. However, consult your doctor if you have any queries.

In the event of an overdose, you might experience an increase in the number and/or intensity of side effects. Your doctor will treat these side effects accordingly.

If you forget to use <Product name>:
As this medicine will be administered to you by a healthcare professional, this does not apply to you.

If you stop using <Product name>:
As this medicine will be administered to you by a healthcare professional, this does not apply to you.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Hot flashes, increased heart rate, hypotension, ventricular rhythm disorders, anginal pain, tremor, headache, nausea.

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 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 <Product name>

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

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

Before opening: Do not refrigerate. Keep vials 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist to dispose of the medicines that you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <Product name> contains

The **active** substance is Isoprenaline hydrochloride, 0.2 mg/ml and 1mg/5ml.

The other ingredients are:

Disodium Edetate, Sodium Citrate dihydrate, Citric acid anhydrous, sodium chloride, Hydrochloric acid , Sodium hydroxide, Water for injections.

What <Product name> looks like and content of the pack

<Product name> 0.2 mg/ml solution for injection/infusion is a clear, colourless to slightly yellow coloured solution, free from visible particles. It is available as 1 ml fill in 2 ml

clear type-I glass vial along with 13 mm rubber stopper and 13 mm flip off seal and, is available in pack sizes of 1 vial or 5 vials.

<Product name> 1mg/5ml solution for injection/infusion is a clear, colourless to slightly yellow coloured solution, free from visible particles. It is available as 5 ml fill in 5 ml clear type-I glass vial along with 13 mm rubber stopper and 13 mm flip off seal and, is available in pack sizes of 1 vial or 5 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Macure Healthcare Ltd.
62 Arclight Building
Triq l-Gharbiel
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Manufacturer[1]

MIAS Pharma Limited
Suite 2, Stafford House, Strand Road
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Ireland

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 medicinal product is authorised in the Member States of the EEA under the following names:

France	ISOPRENALINE CHLORHYDRATE TILLOMED 0,2 mg/1 mL, solution injectable/perfusion ISOPRENALINE CHLORHYDRATE TILLOMED 1 mg/5 mL, solution injectable/perfusion
Portugal	Isoprenalina Tillomed

Deze bijsluiter is voor het laatst goedgekeurd in augustus 2024

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