

Package leaflet: Information for the user

Isoprenaline hydrochloride Macure 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

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1. What Isoprenaline hydrochloride Macure is and what it is used for

Isoprenaline hydrochloride Macure 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.

Isoprenaline hydrochloride Macure 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 Isoprenaline hydrochloride Macure

Do not use Isoprenaline hydrochloride Macure

- 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) and irregular heartbeat (ventricular arrhythmia) that requires treatment

Warnings and precautions

Talk to your doctor or nurse before using Isoprenaline hydrochloride Macure:

- 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 an injured or failing heart. This medicine can have a harmful effect on the heart.
- 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) Isoprenaline Hydrochloride Macure 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.

In some patients <[Invented name]> has been reported to worsen the heart block or cause a condition with loss of consciousness caused by a slowing of heart rate (Adams-Stoke syndrome). Your doctor will monitor your heart.

Other medicines and Isoprenaline hydrochloride Macure

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**).

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

Pregnancy and breast-feeding

If you are pregnant, this medicine may only be used if the doctor considers it absolutely necessary. The administration of Isoprenaline hydrochloride Macure during the breast-feeding period is not recommended.

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.

Isoprenaline hydrochloride Macure contains sodium

This medicine contains less than 1 mmol (16 mg) of sodium i.e. it is essentially sodium-free.

3. How to use Isoprenaline hydrochloride Macure

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 Isoprenaline hydrochloride Macure while closely monitoring your heart rate.

Isoprenaline is not meant to be used routinely.

If you use more Isoprenaline hydrochloride Macure than you should

The symptoms of overdose are nausea, headaches, extra heart beats and heart rate acceleration.

If you use more Isoprenaline hydrochloride Macure 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
- nausea
- chest pains
- low blood pressure
- high blood pressure
- headaches
- restlessness
- tremors
- dizziness
- a feeling of weakness and sweating.

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 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 Isoprenaline hydrochloride Macure

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

Store and transport refrigerated (2 °C – 8 °C).

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

6. Contents of the pack and other information

What Isoprenaline hydrochloride Macure contains

- The active substance is isoprenaline hydrochloride. 1 ml contains 0.2 mg isoprenaline hydrochloride equivalent to 0.17 mg isoprenaline.
- The other ingredients are sodium chloride, EDTA, sodium citrate, citric acid monohydrate, water for injections, sodium hydroxide (for pH adjustment) and hydrochloric acid (for pH adjustment)

What Isoprenaline hydrochloride Macure looks like and contents of the pack

Isoprenaline hydrochloride Macure is a clear and colourless or pale yellow concentrate for solution for infusion in an ampoule containing 5 ml.

Packages of 5 ampoules.

Marketing Authorisation Holder

Macure Pharma ApS
Hejrevej 39,
2400 Copenhagen NV
Denmark

Manufacturer

s.a.l.f. Laboratorio Farmacologico S.p.A.
Via Giuseppe Mazzini 9
24069 Cenate Sotto
Italy

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:

Isoprenaline hydrochloride Macure 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 (2 ampoules of 5 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 of infusion.

Isoprenaline hydrochloride Macure 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 Isoprenaline hydrochloride Macure 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 48 h at 25 °C and 2 °C – 8 °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 and would normally not be longer than 24 hours at 2 °C to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.