ISOPRENALINE MACURE 1 mg/5 mL

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ISOPRENALINE MACURE?

ISOPRENALINE MACURE contains the active ingredient isoprenaline hydrochloride. ISOPRENALINE MACURE is primarily used to treat heart block and cardiac arrest. It may also be used to help you breathe when your airways spasm and contract; or in combination with other medicines when your body is not getting enough blood flow (shock). For more information, see Section 1. Why am I using Isoprenaline Macure? in the full CMI.

2. What should I know before I use ISOPRENALINE MACURE?

Do not use if you have ever had an allergic reaction to isoprenaline or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Isoprenaline Macure? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Isoprenaline Macure and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use ISOPRENALINE MACURE?

- Your doctor will decide what dose you will receive. The dosage will depend on your condition.
- A doctor or nurse will usually prepare and administer the injection.
- Follow all instructions given to you by your doctor or pharmacist.

More instructions can be found in Section 4. How is Isoprenaline Macure given? in the full CMI.

5. What should I know while using ISOPRENALINE MACURE?

Things you should do	 Call your doctor straight away if you are pregnant while being given this medicine Remind any doctor, nurse or pharmacist you visit that you have been given Isoprenaline Macure Getting out of bed or standing up. If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs will help your body get used to the change in position and blood pressure. 	
Driving or using machines	Be careful before you drive or use any machines or tools until you know how Isoprenaline Macure affects you. Isoprenaline Macure may cause dizziness and light-headedness in some people.	
Drinking alcohol	Tell your doctor if you drink alcohol. Alcohol may worsen dizziness or light-headedness.	
Looking after your medicine	• Store refrigerated (between 2 – 8 °C). This medicine will be stored in the pharmacy or on the ward of a hospital.	

For more information, see Section 5. What should I know while using Isoprenaline Macure? in the full CMI.

6. Are there any side effects?

Some unwanted effects may occur when being treated with Isoprenaline Macure. These include nervousness, headache, dizziness or light-headedness, restlessness, palpitations, sweating, mild tremors, weakness, hot flushes, flushing of the skin, fast heart-beat, ringing in the ears, nausea and vomiting.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

ISOPRENALINE MACURE 1 mg/5 mL

Active ingredient: isoprenaline hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Isoprenaline Macure. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Isoprenaline Macure.

Where to find information in this leaflet:

- 1. Why am I using Isoprenaline Macure?
- 2. What should I know before I use Isoprenaline Macure?
- 3. What if I am taking other medicines?
- 4. How is Isoprenaline Macure given?
- 5. What should I know while using Isoprenaline Macure?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Isoprenaline Macure?

Isoprenaline Macure contains the active ingredient isoprenaline hydrochloride. Isoprenaline Macure belongs to a group of medicines called synthetic sympathomimetic amines. Isoprenaline Macure helps improve the efficiency with which your heart pumps blood around your body. It works by strengthening your heart muscles and increasing the heartbeat rate. Isoprenaline Macure also helps your airway muscles relax.

Isoprenaline Macure is primarily used to treat heart block and cardiac arrest. It may also be used to help you breathe when your airways spasm and contract; or in combination with other medicines when your body is not getting enough blood flow (shock). Isoprenaline Macure is intended to be used in hospitals only.

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 available only with a doctor's prescription.

2. What should I know before I use Isoprenaline Macure?

Warnings

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

 isoprenaline, or any of the ingredients listed at the end of this leaflet. • Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include

- · Shortness of breath
- Wheezing 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 Isoprenaline Macure if you have any of the following:

- Faster than usual heart rate
- Fast, slow or irregular heart beat caused by too much of a type of medicine called cardiac glycoside such as digoxin (digitalis), a medicine used to treat irregular heart beats and heart failure
- Medicines used to treat unusual heart beat, such as inotropic therapy (e.g. adrenaline)
- · Recently suffered a heart attack
- A feeling of tightness, pressure or heaviness in the chest.

Check with your doctor if you:

- Have or have had any other medical conditions:
 - Asthma
 - Diabetes
 - Hyperthyroidism
 - Convulsive disorders
 - Other heart conditions.
- Have ever had a reaction to a medicine affecting the heart and circulation (belonging to the sympathomimetic amine group).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with Isoprenaline Macure and affect how it works.

Medicines that have a similar effect to Isoprenaline Macure on the heart and other parts of the body can have unwanted additive effects when taken at the same time as Isoprenaline Macure.

Medicines that may increase the effect of Isoprenaline Macure include:

- Adrenaline (epinephrine) or digitalis, medicines used to stimulate the heart
- Anaesthetics that are inhaled such as halothane and cyclopropane
- Medicines used to treat certain mental conditions such as chlorpromazine or monoamine oxidase inhibitors
- Doxapram, a class of medicine used in intensive care to increase respiratory rate
- A group of medicines called methyl xanthines (aminophylline, theophylline) or corticosteroids given via the vein (intravenously) in combination with a slow injection of isoprenaline
- Other medicines that stimulate the nervous system such as sympathomimetics or thyroid hormone products
- Medicines combined with sulphates (such as salicylamide) when given at the same time as isoprenaline
- Entacapone, a class of medicine used for Parkinson's disease.

Medicines that may be affected by Isoprenaline Macure include:

- Medicines used to treat certain mental conditions such as tricyclic antidepressants
- Ergotamine, a class of medicines used to treat acute migraines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Isoprenaline Macure.

4. How is Isoprenaline Macure given?

How much is given

Your doctor will decide what dose you will receive.
 The dosage will depend on your condition.

How it is given

- Isoprenaline Macure will normally be given to you as an injection into the vein.
- Isoprenaline Macure may also be given to you as an injection under the skin, muscle or heart.
- The doctor will carefully monitor your heart rate while you are being given Isoprenaline Macure.

If you are given too much Isoprenaline Macure

As Isoprenaline Macure is given to you under the supervision of a doctor, it is very unlikely that you will receive too much. However, if you experience any severe

side effects after being given Isoprenaline Macure, you may need urgent medical attention.

You should immediately:

- contact your doctor or nurse, or
- go to the Emergency Department at your nearest hospital.

In case of overdose, immediately phone the Poisons Information Centre (by calling 13 11 26).

Symptoms of Isoprenaline Macure overdose can include faster or extra heart beats, changes in blood pressure and chest pain. Symptoms of overdose can also include the side effects listed below in the 'Side effects' section, but are usually more severe in nature.

5. What should I know while using Isoprenaline Macure?

Things you should do

Call your doctor straight away if you:

• Are pregnant while being given this medicine.

Remind your doctor, nurse or pharmacist that you have been given Isoprenaline Macure if you:

- Are about to be started on any new medicine
- Are going into surgery. It may affect other medicines used during surgery.
- Are about to have any blood tests. It may interfere with the results of some tests.

Remind any doctor, dentist or pharmacist who treat you that you have been given Isoprenaline Macure.

Keep all of your doctor's appointments so that your progress can be checked.

Getting out of bed or standing up

- If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.
- Standing up slowly, especially when you get up from bed or chairs will help your body get used to the change in position and blood pressure.
- If this problem continues or gets worse, talk to your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Isoprenaline Macure affects you.

Isoprenaline Macure may cause dizziness and lightheadedness in some people.

If you have any of these symptoms, do not drive, use any machines or tools, or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may worsen dizziness or light-headedness.

Looking after your medicine

• Store refrigerated (between 2 − 8 °C).

Each ampoule of Isoprenaline Macure is intended for single use in one patient only. Discard any residue.

Your doctor or pharmacist is responsible for storing Isoprenaline Macure.

They are also responsible for disposing of any unused Isoprenaline Macure properly.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Some unwanted effects may occur when being treated with Isoprenaline Macure. These include:

- Nervousness
- Headache, dizziness or light-headedness
- Restlessness
- Palpitations, sweating
- Mild tremors, weakness
- Hot flushes, flushing of the skin
- Fast heart beat
- Ringing in the ears (tinnitus)
- Nausea and vomiting.

Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.

What Isoprenaline Macure contains

Active ingredient	Isoprenaline hydrochloride
(main ingredient)	
Other ingredients	Disodium edetate
(inactive ingredients)	Sodium citrate dihydrate
	Citric acid monohydrate
	Sodium chloride
	Water for injections

Hydrochloric acid or sodium
hydroxide used to adjust pH

Do not take this medicine if you are allergic to any of these ingredients.

What Isoprenaline Macure looks like

Isoprenaline Macure is a clear, colourless or pale yellow solution for injection. It is available as 5 mL amber glass ampoules in packs of 5 (AUST R 370377).

Who distributes Isoprenaline Macure

Juno Pharmaceuticals Pty Ltd

42 Kelso Street,

Cremorne

VIC - 3121

Australia

www.junopharm.com.au

This leaflet was prepared in April 2022