

AMIODARONE JUNO

Amiodarone hydrochloride solution for injection

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Amiodarone Juno injection.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT AMIODARONE JUNO INJECTION IS USED FOR

This medicine is used to control a fast or irregular heart beat.

It works by lengthening the gap between the one heart beat and the next, helping to bring the heart rate to a slower and more regular pace.

Amiodarone Juno injection is not recommended for use in children.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

BEFORE YOU USE AMIODARONE JUNO INJECTION

When you must not use Amiodarone Juno injection

1. **Do not use Amiodarone Juno injection if you are allergic to amiodarone or iodine or any of the ingredients listed at the end of this leaflet.**

The symptoms of an allergic reaction may include a rash, itching, swelling, coughing, an asthma attack or hayfever.

2. **Do not use this medicine if you are pregnant or intending to get pregnant.**

This medicine is best avoided in the 3 months before getting pregnant and during pregnancy.

This is because it can stay in the body for several months even after you stop taking it.

3. **Do not breastfeed if you are using this medicine as it can be found in breast milk.**

If you are breastfeeding, alternative feeding arrangements such as bottle feeding should be made for your baby.

Talk to your doctor about the risks and benefits of taking this medicine during pregnancy and breastfeeding.

4. **Do not use this medicine if you have or have had any thyroid problems.**

5. **Do not use this medicine if you have heart problems that may cause you to faint.**

If you have a pacemaker, your doctor may allow the use of it.

6. **Do not use this medicine if you have any of the following:**

- Low blood pressure
- Severe problems in breathing
- Heart disease or failure
- Shock

7. **Do not use this medicine in neonates (children less than one month of age) or premature neonates.**

Talk to your doctor if you are unsure whether you have any of the conditions listed above.

Do not use this medicine after the expiry (EXP) printed on the pack.

If you use the medicine after the expiry date has passed, it may not work as well.

Do not use this medicine if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaint unless your doctor says it is safe. Do not give this medicine to anyone else.

Before you start to use Amiodarone Juno injection

Tell your doctor if you are pregnant or intend to become pregnant.

Tell your doctor if you are breastfeeding or planning to breastfeed.

Tell your doctor if you have or have had any medical conditions, especially the following:

- other heart conditions;
- blood pressure problems;
- liver problems;
- thyroid problems.

If you have not told your doctor about any of the above, tell

him/her before you use this medicine.

Taking other medicines

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

Some medicines may be affected by Amiodarone Juno injection or may affect how well it works.

You need to tell your doctor if you are using any other medicines including:

- any medicines for your heart;
- any medicines for your blood pressure;
- medicines which reduce the activity of your immune system such as cyclosporin, cortisone or tacrolimus;
- diuretics (water tablets);
- antibiotics, including intravenous erythromycin and pentamidine;
- stimulant laxatives, eg. Bisacodyl, castor oil, senna;
- MAO inhibitors (a type of medicine used to treat depression);
- antipsychotics (medicines used to treat certain mental and emotional conditions);
- phenytoin (a medicine used to treat epilepsy);
- warfarin and other medicines which thin the blood;
- simvastatin and other statins (medicines used to lower cholesterol);
- digoxin (a medicine used to treat heart conditions);
- medicines to treat a fast or irregular heart beat such as flecainide and sotalol;
- fentanyl (a medicine used to treat pain);
- sildenafil (Viagra);
- triazolam (a medicine used to treat insomnia);

- ergotamine (a medicine used to treat migraine);
- general anaesthesia;
- lignocaine (a topical anaesthetic); or
- amphotericin B (a medicine used to treat fungal infections).

If you are unsure whether you are taking one of the above drugs, ask your doctor or pharmacist.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell them before you take this medicine.

HOW TO USE AMIODARONE JUNO INJECTION

How to give it

The injectable dose will only be given in hospitals.

How much to give

The usual dose is:

- 5 mg/kg given slowly over a period of 20 minutes to 2 hours.

Further doses may also be given based upon your response to the treatment. An overlap of up to 2 days with the tablets may occur.

If you forget to take it

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the dose you missed, and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, or have trouble remembering when to take your medicine, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Amiodarone Juno Injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE USING AMIODARONE JUNO INJECTION

Things you must do

Be sure to keep all of your doctor appointments so that your progress can be checked.

- To help prevent unwanted side effects, your doctor may need to perform the following tests, depending on the length of treatment with this medicine:
- ECG
- Eye tests
- Chest X-rays
- Liver function tests
- Thyroid tests

Take this medicine exactly as your doctor has prescribed.

Tell all the doctors, dentists and pharmacists who are treating you that you are using this medicine.

Tell your doctor if you become or intend to become pregnant while using this medicine.

Things you must not do

Do not stop taking your medicine without checking with your doctor.

Do not take Amiodarone Juno injection to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Always use a 30+ sunscreen and wear a hat and protective clothing when you are outdoors. Do not use a sunlamp.

Using Amiodarone Juno injection may make your skin more sensitive to the sun or sunlamps. This can range from an increased tendency to tan, to intense redness and swelling of the skin.

If you are going to have surgery, tell the anaesthetist that you are using Amiodarone Juno injection.

This medicine may affect some of the medicines that may be needed, such as general anaesthetics.

Tell your doctor or medical professional that you are using Amiodarone Juno injection before you are given any medical procedure or any new medicines.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Amiodarone Juno injection.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Treatment with amiodarone may cause serious lung, liver and eye damage and may worsen heart problems.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- symptoms of an overactive thyroid including increase in appetite, weight loss, restlessness, heat intolerance, increased sweating, tremors,

swelling of your neck (goiter) and a rapid heart rate;

- symptoms of an underactive thyroid including tiredness, lethargy, muscle weakness, cramps, feeling the cold, a slow heart rate, dry and flaky skin, hair loss, a deep and husky voice and weight gain;
- a feeling of “pins and needles” or numbness in the hands, legs or feet;
- muscle weakness, uncontrolled movements or poor co-ordination;
- small cloudy spots forming on the eyeball. These usually go away after you stop taking the drug and they rarely affect your sight;
- Increased skin sensitivity to sunlight – always wear a sunscreen;
- bluish skin discolouration;
- rash or hives;
- pain or swelling at the site where you were injected;
- tremor, insomnia or other sleep disorders, vivid dreams or nightmares;
- metallic taste;
- constipation;
- loss of appetite;
- slow heart beat.

Tell your doctor immediately if you notice any of the following:

- yellowing of the skin or eyes (called jaundice, a symptom of liver changes);
- shortness of breath, wheezing or other difficulty in breathing;
- swelling of the face, lips, mouth, tongue or throat;
- clumsiness and lack of co-ordination, affecting balance and manner of walking, limb or eye movements and/or speech;
- chest pain, cough or spitting up of blood;
- nausea or vomiting, stomach pain, yellow skin, unusual tiredness or passing dark coloured urine;

- changes to heartbeat such as pounding heart, very rapid or very slow heart beat;
- faintness or light headedness;
- blurring or deterioration of vision, sensitisation of eyes to light;
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

These may be serious side effects of Amiodarone Juno injection. If any of the above symptoms occurs or you suspect any other drug reaction, please consult your doctor immediately.

Other side effects not listed above may also occur in some people.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Your doctor will monitor you very carefully for side effects. This will involve blood tests to check how well your liver and thyroid are functioning. It will also involve regular chest X-rays, ECGs and eye tests.

Your doctor will tell you how often you need to have these tests. This will depend on how long you are on Amiodarone Juno Injection for and what dose you are on.

AFTER USING AMIODARONE JUNO INJECTION

Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

If you need to store it before taking it to the hospital, make sure it is stored below 25°C. Do not freeze. Protect from light.

Amiodarone Juno injection should only be given to you in a hospital.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Amiodarone Juno injection is a clear, slightly yellow solution, filled in a 3mL glass ampoule.

Each box contains 10 ampoules.

Ingredients

Active ingredients:

Each 3 mL ampoule contains amiodarone hydrochloride 150mg.

Inactive ingredients:

The injection also contains benzyl alcohol, polysorbate 80, sodium hydroxide, hydrochloric acid and water for injections.

Sponsor

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