

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Amdarone tablets.

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. In deciding to give you Amdarone, your doctor has weighed the risks of you taking Amdarone against the benefits it will have for you.

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

**Keep this leaflet with this medicine.**

You may need to read it again.

### What Amdarone is used for

Amdarone is used to control a fast or irregular heart beat.

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

Amdarone is not recommended for use in children.

Your doctor may have prescribed this medicine for another reason.

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

### Before you take it

#### *When you must not use Amdarone*

1. **Do not use Amdarone 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 Amdarone if you are pregnant or intending to get pregnant.**

Amdarone 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 Amdarone 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 Amdarone during pregnancy and breastfeeding.**

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

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

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

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

**Make sure your doctor is aware of all medications you are taking as some**

**medications may affect how Amdarone works.**

**Do not use Amdarone 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 Amdarone 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 Amdarone*

**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 them before you use this medicine.**

*Taking other medicines*

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

Some medicines may be affected by Amdarone, or may affect how well Amdarone 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 ciclosporin, cortisone or tacrolimus
- diuretics (water tablets)
- antibiotics, including intravenous erythromycin and pentamidine
- stimulant laxatives e.g. 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)
- colchicine (a medicine used to treat gout)
- 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
- lidocaine (lignocaine) (a topical anaesthetic)
- amphotericin B (amphotericin) (a medicine used to treat fungal infections)
- antiviral medication e.g. sofosbuvir, daclatasvir, simeprevir, ledipasvir

**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 Amdarone.**

### How to use Amdarone

#### *How to take it (tablets)*

Therapy will be started as soon as possible once your heart beat is controlled.

Swallow Amdarone tablets whole, with water or another liquid such as tea or milk.

#### *How much to take*

The usual dose is outlined below:

- 200 mg, three times a day for 1 week.
- Therapy is then continued with 200 mg two times a day for a further week.
- The dose may then be reduced to 200 mg once per day.

Your doctor or pharmacist will tell you how many Amdarone tablets you should take.

The directions given to you by your doctor or pharmacist may be different from the information in this leaflet.

**Talk to your doctor or pharmacist if you are unsure what dose to take.**

**Do not stop taking it unless your doctor tells you to, even if you feel better.**

*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.**

**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 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Amdarone. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

### While you are using Amdarone

#### *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 Amdarone:

- ECG
- Eye tests
- Chest X-rays
- Liver function tests
- Thyroid tests

**Take Amdarone exactly as your doctor has prescribed.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are using Amdarone.**

**Tell your doctor if you become or intend to become pregnant while using Amdarone.**

*Things you must not do*

**Do not suddenly stop taking Amdarone without checking with your doctor.**

**Do not use Amdarone to treat any other complaints unless your doctor says it is safe.**

**Do not give this 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 Amdarone 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 Amdarone.**

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 Amdarone before you are given any medical procedure or any new medicines.**

**Avoid drinking large quantities of grapefruit juice as it may affect the absorption of Amdarone.**

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## Side Effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while using Amdarone.**

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

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

**Tell your doctor 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

- allergic condition which causes joint pain, skin rashes, fever and kidney problems
- a feeling of "pins and needles" or numbness in the hands, legs or feet
- muscle weakness, uncontrolled movements or poor coordination
- small cloudy spots forming on the eyeball. These usually go away after you stop 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 coordination, 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 heartbeat
- 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 Amdarone. 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 patients. Tell your doctor 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 Amdarone for and what dose you are on.

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## After using Amdarone

### Storage

**Keep your tablets in the blister pack until it is time to take them.**

If you take the tablets out of the box or blister pack they may not keep well.

**Keep it in a cool, dry place where the temperature stays below 30°C.**

**Do not store it or any other medicine in the bathroom or near a sink.**

**Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

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

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## Product description

### What it looks like

Amdarone is available as 200mg tablets - white to off-white circular tablets, scored on one side with logo on reverse side marked with 200.

Each box contains 30 tablets.

### Ingredients

#### Active Ingredient

Each tablet contains amiodarone hydrochloride 200mg.

#### Other Ingredients

The tablets also contain lactose monohydrate, maize starch, povidone, anhydrous colloidal silica and magnesium stearate.

### Sponsor

sanofi-aventis australia Pty Ltd  
12-24 Talavera Road  
Macquarie Park NSW 2113

### Distributor

Arrotex Pharmaceuticals Pty Ltd  
15-17 Chapel Street  
Cremorne VIC 3121

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