

AMIODARONE SANDOZ®

amiodarone hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Amiodarone Sandoz.

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 risk of you taking Amiodarone Sandoz against the benefits it is expected to 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 Sandoz is used for

Amiodarone Sandoz is used to control a fast or irregular heart beat.

It contains the active ingredient amiodarone hydrochloride.

Amiodarone hydrochloride belongs to a group of medicines called antiarrhythmics.

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

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

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

Amiodarone Sandoz is not recommended for children.

There is no evidence that this medicine is addictive.

Before you take Amiodarone Sandoz

When you must not take it

Do not take Amiodarone Sandoz if you have an allergy to:

- amiodarone hydrochloride, the active ingredient, or iodine, or any of the inactive ingredients mentioned at the end of this leaflet under Product Description
- any other similar medicines.

Symptoms of an allergic reaction include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you have or have had any of the following medical conditions:

- thyroid problems
- heart problems that may cause you to faint. If you have a pacemaker, your doctor may allow the use of it.
- severe breathing problems
- low blood pressure
- heart disease or failure
- shock
- other heart conditions.

Do not take this medicine if you are taking MAO inhibitors (a

type of medicine used to treat depression).

Do not take this medicine if you are pregnant or are thinking of getting pregnant.

Amiodarone Sandoz 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.

Do not breastfeed if you are taking 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 Amiodarone Sandoz during pregnancy and breastfeeding.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take Amiodarone Sandoz

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have had any of the following medical conditions:

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

- breathing problems.

If you have not told your doctor about any of the above, tell him/her before you start taking Amiodarone Sandoz.

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 and Amiodarone Sandoz may interfere with each other. These include:

- 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 heart conditions)
- digoxin (a medicine used to treat heart conditions)
- medicines used 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)
- amphotericin B (a medicine used to treat fungal infections)
- antiviral medication eg sofosbuvir, daclatasvir, simeprevir, ledipasvir.

These medicines may be affected by Amiodarone Sandoz or may affect how well it works. You may need to use different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Amiodarone Sandoz

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

The usual dose is 200 mg three times a day for one 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 a day (or less if your doctor says so).

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Amiodarone Sandoz may not work as well and your problem may not improve.

How to take it

Swallow tablets whole with a little water or other liquid.

If you need to break Amiodarone Sandoz, hold tablet with both hands and snap along break line.

When to take Amiodarone Sandoz

The tablets should be taken consistently, at the same time with regards to food.

How long to take Amiodarone Sandoz

Continue taking your medicine for as long as the doctor tells you.

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

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

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 you missed.

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

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at

your nearest hospital, if you think you or anyone else may have taken too much Amiodarone Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Amiodarone Sandoz

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Amiodarone Sandoz.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

Your doctor may do following tests from time to time to make sure the medicine is working and to prevent unwanted side effects:

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

Things you must not do

Do not take Amiodarone Sandoz to treat any other complaint unless your doctor tells you to.

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

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

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 Sandoz 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 surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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

Side effects

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

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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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 such as increase in appetite, weight loss, restlessness, heat intolerance, increased sweating, tremors, swelling of the neck (goitre) and a rapid heart rate
- symptoms of an underactive thyroid such as 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
- slow heart beat
- intense sunburn or increased skin sensitivity to sunlight - always wear a sunscreen while taking Amiodarone Sandoz
- bluish skin discolouration
- rash or hives
- nausea
- metallic taste
- constipation
- loss of appetite
- tremor, insomnia or other sleep disorders, vivid dreams or nightmares
- 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 rarely affect your sight.

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, difficulty in breathing
- clumsiness and lack of coordination affecting balance, limb or eye movements and/or speech, difficulty walking
- blurred or decreased vision
- chest pain, cough or spitting up of blood
- nausea or vomiting, stomach pain, yellow skin, unusual tiredness or passing dark-coloured urine
- 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.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- breathlessness or any difficulty breathing
- any disturbance in heart beat, such as pounding heart, very rapid or very slow heart beat.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

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

Some of these side effects can only be found when your doctor does tests from time to time to check your progress. 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 Sandoz for and what dose you are on.

After taking Amiodarone Sandoz

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Amiodarone Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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 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 Sandoz comes in two types of tablets:

Amiodarone Sandoz 100 mg tablets - white, round tablets, scored on one side and convex on the other.

Amiodarone Sandoz 200 mg tablets - white, round tablets, biconvex with score on one side.

Available in blister packs of 30 tablets.

Note: 100 mg tablet is not marketed

Ingredients

Active ingredient:

Amiodarone Sandoz 100 mg tablet - 100 mg amiodarone hydrochloride

Amiodarone Sandoz 200 mg tablet - 200 mg amiodarone hydrochloride

Inactive ingredients:

- maize starch
- lactose monohydrate
- povidone
- magnesium stearate

- anhydrous colloidal silica.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
 ABN 60 075 449 553
 54 Waterloo Road
 Macquarie Park, NSW 2113
 Australia
 Tel: 1800 726 369

Novartis New Zealand Ltd
 Private Bag 65904 Mairangi Bay
 Auckland 0754
 New Zealand
 Tel: 0800 354 335

This leaflet was revised in August 2019.

Australian Register Numbers

Amiodarone Sandoz 100 mg tablets: AUST R 77738

Amiodarone Sandoz 200 mg tablets: AUST R 77739