

# **APO-Amiodarone tablets**

Contains the active ingredient amiodarone (as amiodarone hydrochloride)

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## **Consumer Medicine Information**

**For a copy of a large print leaflet, Ph: 1800 195 055**

## **What is in this leaflet**

This leaflet answers some common questions about this medicine. 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 this medicine is used for**

The name of your medicine is APO-Amiodarone tablets. It contains the active ingredient amiodarone hydrochloride.

It is used to treat tachyarrhythmia (an excessively fast heart rate with an irregular rhythm).

Amiodarone belongs to a group of medicines called antiarrhythmics.

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

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

Your doctor may have prescribed amiodarone for another reason.

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

There is no evidence that this medicine is addictive.

## **Use in children**

Amiodarone should not be used in children.

# **Before you take this medicine**

## **When you must not take it**

**Do not take this medicine if you have an allergy to:**

- any medicine containing amiodarone or iodine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may 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 any of the following medical conditions:**

- thyroid problems
- certain heart problems that may cause you to faint (check with your doctor), unless your doctor advises you can use amiodarone in combination with a pacemaker.

**Do not take this medicine if you are pregnant.**

Amiodarone may affect your developing baby if you take it during pregnancy. Amiodarone should be avoided in the 3 months before becoming pregnant and during pregnancy.

**Do not breastfeed if you are taking this medicine.**

Amiodarone passes into human breast milk. Do not take amiodarone if you are 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 it**

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

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

- other heart conditions
- blood pressure problems
- liver problems
- breathing or lung (respiratory) problems
- family history of thyroid disorders.

**Tell your doctor if you have or have a pacemaker or implantable defibrillator.**

**Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.**

Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell them before you start taking 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 and amiodarone may interfere with each other. These include:

- beta-blocking agents or calcium antagonists used for the heart and blood pressure
- digoxin, used to treat heart conditions
- stimulant laxatives used to treat constipation
- diuretics (also known as fluid or water tablets)
- fluoroquinolones, erythromycin and intravenous pentamidine, antibiotics used to treat infections

- medicines which reduce the activity of your immune system, such as cyclosporin, cortisone, tetracosactide or tacrolimus
- intravenous amphotericin B, used for fungus infections
- MAO inhibitors, used to treat depression
- warfarin and other medicines which thin the blood
- flecainide or sotalol, used to treat abnormal heart rhythms
- phenytoin, used to treat epilepsy
- certain types of statins such as simvastatin, atorvastatin or lovastatin, used to lower cholesterol
- fentanyl, a painkiller
- sildenafil, used for erectile dysfunction and hypertension
- triazolam, used to treat insomnia
- dihydroergotamine or ergotamine, used to treat migraine
- anaesthesia and oxygen used during surgery
- midazolam, used for pain relief and in anaesthetics
- lignocaine, a topical anaesthetic
- colchicine, used for gout
- antiviral medicines such as sofosbuvir, daclatasvir, simeprevir, ledipasvir.

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

**The following medicines may cause torsades de pointes (a rare type of excessively fast heart rate). Do not take these medicines at the same time as amiodarone:**

- digoxin
- disopyramide
- procainamide
- quinidine
- mexiletine
- sotalol
- bepridil
- vincamine
- cisapride
- certain antipsychotics (medicines used to treat certain mental and emotional conditions)
- clarithromycin, erythromycin, azithromycin and intravenous pentamidine.

Other medicines not listed above may also interact with amiodarone.

# **How to take this medicine**

**Follow all directions from your doctor carefully.**

They may be different from the information in this leaflet.

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

## **How much to take**

The usual dose is outlined below:

### **Initial Dose**

200 mg three times a day for one week. The dose is then reduced to 200 mg twice a day for a further week.

### **Maintenance Dose**

The dose may then be reduced to 200 mg once a day (or less if your doctor says so).

## **How to take it**

**Swallow the tablets with a glass of water.**

## **When to take it**

**Take it at about the same time each day.**

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

## **How long to take it for**

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

Amiodarone helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

## **If you forget to take it**

**If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

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

This may increase the chance of you experiencing side effects.

**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 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 of**

**this medicine. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

## **While you are taking this medicine**

### **Things you must do**

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

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

**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.

**If you become pregnant or start breastfeeding while taking this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

It may interfere with the results of some tests.

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

Your doctor may do some tests from time to time to make sure amiodarone is working and to prevent unwanted side effects. These include:

- ECG
- eye tests
- chest X-rays
- liver function tests
- thyroid tests.

## **Things you must not do**

**Do not take this medicine 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.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

## **Things to be careful of**

**Be careful when driving or operating machinery until you know how this medicine affects you.**

Amiodarone may cause drowsiness, dizziness or blurred vision in some people, especially after the first dose.

**Be careful when drinking alcohol while you are taking amiodarone.**

The combination may make you feel more sleepy, dizzy or light-headed and less alert than usual.

**Always use a 30+ sunscreen and wear a hat when outdoors. Do not use a sunlamp.**

Taking amiodarone tablets may make your skin more sensitive to the sun. This can range from an increased tendency to tan to intense redness and swelling.

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

## **Side effects**

**Tell your doctor as soon as possible if you do not feel well while taking amiodarone or if you have any concerns.**

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

**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:**

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

increased sweating, tremors, swelling of your neck (goitre) 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
- rash or hives
- a feeling of "pins and needles" or numbness in the hands, legs or feet
- muscle weakness, uncontrolled movements or poor coordination
- small cloudy spots on the eyeball
- increased skin sensitivity to sunlight - always wear sunscreen while taking amiodarone
- grey or bluish skin discolourations on areas exposed to the sun
- unusual taste sensation
- tremor, insomnia or vivid dreams
- constipation
- loss of appetite
- slow heartbeat.

**Tell your doctor immediately if you notice any of the following.**

These may be serious side effects and you may need medical attention:

- fever, a painful, red rash that spreads quickly, which may peel or blister around the eyes, nose, mouth and genitals (rare life-threatening skin reactions)
- yellowing of the skin or eyes (called jaundice, a symptom of liver changes)
- clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/or speech
- chest pain, cough or spitting up blood
- nausea or vomiting, stomach pain, unusual tiredness or passing dark-coloured urine
- changes to heartbeat such as pounding heart, very rapid or very slow heartbeat
- fainting or feeling faint
- blurring or deterioration of vision, sensitisation of eyes to light.
- shortness of breath, wheezing or other difficulty in breathing
- swelling of the face, lips, mouth, tongue or throat

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

Other side effects not listed above may occur in some patients.

## **Storage and disposal**

### **Storage**

**Keep this medicine in its original packaging until it is time to take them.**

If you take the tablets out of their original packaging they may not keep well.

**Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect it from light.**

**Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a windowsill or in the car on hot days.**

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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.**

## **Product description**

### **What APO-Amiodarone tablets looks like**

#### **200 mg tablets:**

White, round tablets, biconvex, scored on one side.

They are available in blister packs of 30 tablets. AUST R 80768.

## **Ingredients**

Each tablet contains 200 mg amiodarone hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- maize starch
- lactose
- povidone
- magnesium stearate
- . colloidal anhydrous silica

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

## **Sponsor**

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

This leaflet was last updated in:

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