

APO-Amiodarone tablets

Contains the active ingredient amiodarone (as amiodarone hydrochloride)

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about amiodarone.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with the medicine.

You may want 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).

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

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

How it works

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.

There is no evidence that this medicine is addictive.

Use in children

This medicine 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 or have had any of the following:**
 - 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.
- **You are taking any medicines that may cause torsades de pointes (a rare type of excessively fast heart rate), such as: disopyramide, procainamide, quinidine, mexiletine, sotalol, bepridil, vincamine, some antipsychotic medications, cisapride, erythromycin, clarithromycin, azithromycin or intravenous pentamidine.**
- **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.
- **You are breastfeeding.** Amiodarone passes into human breast milk. Do not take amiodarone if you are breastfeeding.

- **You are hypersensitive to, or have had an allergic reaction to, amiodarone, iodine or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines, especially other medicines used for heart problems
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - other heart conditions
 - blood pressure problems
 - liver problems
 - breathing or lung (respiratory) problems
 - family history of thyroid disorders.
3. You have a pacemaker or implantable defibrillator.
4. You are planning to have surgery or an anaesthetic.
5. You are currently receiving or are planning to receive dental treatment.

6. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with amiodarone. These include:

- fluoroquinolones, a type of antibiotic
- medicines used for the heart and blood pressure such as, betablocking agents, calcium antagonists
- digoxin, a medicine use to treat heart conditions
- stimulant laxatives used to treat constipation
- diuretics
- 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, a class of medicines used to treat depression
- warfarin and other medicines which thin the blood
- flecainide, used to treat abnormal heart rhythms
- phenytoin (a medicine used to treat epileptic fits)
- certain types of statins such as simvastatin, atorvastatin or lovastatin (medicines used to lower cholesterol).
- fentanyl (a painkiller)
- sildenafil (used for erectile dysfunction and hypertension)
- triazolam (a medicine used to treat insomnia)
- dihydroergotamine or ergotamine (a medicine 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 e.g. sofosbuvir, daclatasvir, simeprevir, ledipasvir.

If you are taking any of these you may need a different dose 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
- 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.

How much to take

Your doctor will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

Your doctor may do some tests before starting you with this medicine.

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.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the one 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)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up.

Your doctor may do tests to make sure the medicine is working and to prevent side effects. These may include:

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

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first 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.

Possible side effects

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

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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 (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 coordination
- small cloudy spots on the eyeball
- increased skin sensitivity to sunlight - always wear sunscreen while taking amiodarone
- grey or bluish skin colouring 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 lifethreatening 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.

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

Allergic reactions

If you think you are having an allergic reaction to amiodarone, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

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.

- magnesium stearate
- anhydrous colloidal silica.

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

Australian Registration Numbers

APO-Amiodarone 200 mg tablet (blister pack): AUST R 80768.

Sponsor

Apotex Pty Ltd
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This leaflet was last updated in: May 2017.

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.

Ingredients

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

It also contains the following inactive ingredients:

- maize starch
- lactose
- povidone