

Aratac

contains the active ingredient amiodarone hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Aratac.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Aratac against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Aratac is used for

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

Aratac belongs to a group of medicines called antiarrhythmics. It works by lengthening the gap between one heartbeat and the next, helping to bring the heart rate to a slower and more regular pace.

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

Your doctor may have prescribed Aratac for another reason.

Aratac is not recommended for use in children, as its safety and effectiveness in children has not been established.

Aratac is available only with a doctor's prescription.

There is no evidence that Aratac is addictive.

Before you take Aratac

When you must not take it

Do not take Aratac if you are allergic to:

- amiodarone hydrochloride (eg. Cordarone X)
- iodine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, coughing, an asthma attack or hayfever.

Do not take Aratac if you have or have had any thyroid problems.

Do not take Aratac if you have heart problems that may cause you to faint.

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

Do not take Aratac if you have any of the following:

- low blood pressure
- heart disease or failure.
- severe problems in breathing respiratory failure
- shock

Do not take Aratac if you are pregnant or plan to become pregnant.

Aratac is best avoided in the three 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 take Aratac if you are breastfeeding as it passes into 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 Aratac during pregnancy and breastfeeding.

Do not take Aratac if the expiry date (EXP) printed on the pack has passed.

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

Do not take Aratac if the packaging is torn, shows signs of tampering or the tablets do not look quite right.

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

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 are pregnant or intend to become pregnant.

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

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

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

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor about any of the above, tell them before you start taking Aratac.

Taking other medicines

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

Some medicines may be affected by Aratac, 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
- monoamine oxidase inhibitors, a type of medicine used to treat depression
- stimulant laxatives e.g. bisacodyl, castor oil, senna
- medicines which reduce the activity of your immune system such as cortisone, ciclosporin and tacrolimus
- diuretics (water tablets)
- antibiotics, including intravenous erythromycin and pentamidine
- digoxin (a medicine used to treat heart conditions)

- flecainide and sotalol, medicines used to treat a fast or irregular heart beat
- phenytoin (Dilantin), a medicine used to treat epilepsy
- warfarin and other medicines which thin the blood
- simvastatin and other statins (medicines used to lower cholesterol levels).
- fentanyl (a medicine used to treat pain)
- antipsychotics (medicines used to treat certain mental and emotional conditions)
- 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)
- colchicine (a medicine used to treat gout)
- antiviral medications eg sofosbuvir, daclatasvir, simeprevir, ledipasvir

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

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

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

How to take Aratac

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

This may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

The dose varies from person to person.

Your doctor will tell you how much Aratac you should take. This depends on your condition, age, how well you respond to Aratac and whether or not you are taking any other medicines.

The usual dose is outlined below:

- 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 once per day.

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

How to take Aratac

Swallow the tablets with a glass of water.

Aratac tablets can be divided in half along the breakline, if advised by your doctor or pharmacist.

How long to take Aratac for

To properly control your condition, Aratac must be taken every day.

Keep taking Aratac for as long as your doctor recommends.

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

If you forget to take Aratac

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 Aratac (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Aratac.

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

You may need urgent medical attention.

While you are taking Aratac

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Aratac.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Aratac.

Visit your doctor regularly so they can check your progress. To help prevent unwanted side effects, you may need to perform the following tests, depending on the length of treatment with Aratac:

- ECG
- Eye tests
- liver function tests
- thyroid tests
- chest X-rays

Take Aratac exactly as your doctor has prescribed.

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

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

Things you must not do

Do not suddenly stop taking Aratac without checking with your doctor.

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

Do not give Aratac 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. If your skin does appear to be burning, tell your doctor immediately.

Aratac may cause your skin to be 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 Aratac.

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 Aratac 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 Aratac.

Side effects

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

Aratac helps most people, but it may have unwanted side effects in some people.

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.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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
- 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 sunscreen
- bluish skin discolouration
- rash or hives
- 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:

- nausea or vomiting, stomach pain, yellow skin, unusual tiredness or passing dark-coloured urine
- yellowing of the eyes or skin (called jaundice, a symptom of liver changes)
- blurring or deterioration of vision, sensitisation of eyes to light
- clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/or speech
- faintness or lightheadedness
- changes to your heart beat such as pounding heart, very rapid or very slow heartbeat
- chest pain, cough or spitting up of blood
- swelling of the face, lips, mouth, tongue or throat
- wheezing, shortness of breath or other difficulty in breathing
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

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

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

This is not a complete list of side effects. Other side effects not listed above may also occur in some people.

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 Aratac for and what dose you are on.

After taking Aratac

Storage

Keep Aratac 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.

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

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

Do not leave Aratac in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Aratac, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Aratac tablets are available in two strengths:

- Aratac 100 - round, white, scored tablet marked "AM" over breakline over "100" on one side and a "G" on the other
- Aratac 200 - round, white, scored tablet marked "AM" over breakline over "200" on one side and a "G" on the other.

Each pack contains 30 tablets.

Ingredients

The active ingredient in Aratac is amiodarone hydrochloride.

Each Aratac 100 tablet contains 100 mg of amiodarone hydrochloride

Each Aratac 200 tablet contains 200 mg of amiodarone hydrochloride.

Aratac tablets also contain the following inactive ingredients:

- Lactose monohydrate
- microcrystalline cellulose
- povidone
- crospovidone
- colloidal anhydrous silica
- purified talc
- magnesium stearate.

The tablets are gluten free.

Manufacturer

Aratac is made in Australia by:

Alphapharm Pty Limited

Level 1, 30 The Bond,

30-34 Hickson Road,

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

Aratac 100 - AUST R 32519

Aratac 200 - AUST R 32514

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