

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 certain heart rhythm conditions such as a fast or irregular heart beat or rhythm.

Aratac belongs to a group of medicines called antiarrhythmics. These medicines help the heart to beat slower and at a more regular pace.

Ask your doctor 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; wheezing or shortness of breath.

Do not take Aratac if you have or have had:

- * thyroid problems
- * low blood pressure
- * certain heart conditions, such as slow or irregular heart rate, heart muscle disorder or heart failure.
- * severe lung respiratory failure

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

Aratac is not recommended for use during pregnancy as it may harm your developing baby if you take it during pregnancy.

Aratac is also best avoided in the first three months before getting pregnant, as it can stay in the body for some time even after you have stopped taking it.

Do not take Aratac if you are breastfeeding.

Aratac passes into breast milk and may harm your baby.

Do not take Aratac if you are taking or using any of the following medicines:

- * disopyramide (Rythmodan)
- * quinidine (Kinidin Durules)
- * mexiletine (Mexitil)
- * sotalol (eg. Sotacor, Cardol)
- * procainamide (Pronestyl Injection)
- * erythromycin injection
- * pentamidine injection.

Ask your doctor or pharmacist if you are not sure if you are taking one of these medicines.

Taking Aratac with the medicines listed above may cause a serious condition called "Torsade de Pointes", which is characterised by a very fast and irregular heart beat.

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

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

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

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

Before you start to take it

You may need to have some tests.

Your doctor may want to perform an electrocardiogram (ECG) and check that your thyroid function and blood potassium levels are normal before prescribing Aratac.

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

Aratac may cause serious lung, liver and eye damage and may worsen heart problems. Therefore, tell your doctor if you have any medical conditions, especially the following:

- * asthma or other respiratory (breathing) problems
- * liver problems
- * kidney problems
- * heart conditions or problems

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

Tell your doctor if you plan to have surgery.

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

Taking other medicines

Do not take Aratac if you are taking or using any of the following medicines:

- * disopyramide (Rythmodan)
- * quinidine (Kinidin Durules)
- * mexiletine (Mexitil)
- * sotalol (eg. Sotacor, Cardol)
- * procainamide (Pronestyl Injection)
- * erythromycin injection
- * pentamidine injection.

Taking Aratac with the medicines listed above may cause a serious condition called "Torsade de Pointes", which is characterised by a very fast and irregular heart beat.

Tell your doctor if you are taking any other medicines, including any that you buy 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. These include:

- * certain medicines used for the heart or high blood pressure such as beta-blockers and calcium antagonists
- * monoamine oxidase inhibitors, medicines to treat depression and symptoms of Parkinson's disease
- * certain types of laxatives
- * corticosteroids such as cortisone (Cortate), prednisone (Sone, Panafcort)
- * cyclosporin (Neoral), a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system
- * digoxin (eg. Lanoxin), a medicine used to treat heart failure and fast irregular heart beats
- * flecainide (Tambocor, Flecatag), a medicine used to treat an irregular heart beat
- * phenytoin (Dilantin), a medicine used to treat epilepsy
- * medicines used to prevent blood clots such as warfarin (Coumadin, Marevan)
- * certain medicines used to lower high cholesterol levels such as simvastatin (eg. Lipex).

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.

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 starting dose is 200 mg three times a day for one week. Your doctor will then gradually reduce your dose to 200 mg once a day.

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.

If you forget to take Aratac

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

If you are not sure what to do, 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.

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

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

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.

Your doctor may want you to have some tests while you are taking Aratac and for several months after you stop taking Aratac.

These tests may include checking your eyes, liver, heart and thyroid gland. You may also need to have chest X-rays. These tests help to prevent or detect unwanted side effects.

Things you must not do

Do not use Aratac to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

Protect your skin when you are in the sun, especially between 10 am and 3 pm. If outdoors, wear protective clothing and use a SPF 30+ sunscreen. If your skin does appear to be burning, tell your doctor immediately.

Aratac may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight may cause skin rash, itching, redness or severe sunburn.

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.

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

If you are over 65 years of age, you may have an increased chance of getting 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.

Tell your doctor if you notice any of the following and they worry you:

- * headache
- * anxiety
- * tremor
- * difficulty sleeping, vivid dreams
- * decreased appetite
- * constipation
- * salty or metallic taste in the mouth.

These are the more common and mild side effects of Aratac.

Aratac may cause serious lung, liver and eye damage and may worsen heart problems. Some of the symptoms are listed below.

Tell your doctor immediately if you notice any of the following:

- * shortness of breath, wheezing or other difficulty in breathing
- * nausea or vomiting, stomach pain, yellowing of the eyes or skin (jaundice), unusual tiredness or passing dark-coloured urine.
- * blurring or deterioration of vision, increased eye sensitivity to light
- * muscle weakness or difficulty walking
- * tingling or numbness of the hands or feet
- * weight loss and restlessness
- * weight gain together with reduced activity and constipation
- * increased skin sensitivity to the sun.

These are serious side effects of taking Aratac. You may need medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- * disturbances in your heart beat, such as pounding heart, very rapid or very slow heartbeat, faintness or light headedness
- * chest pain, cough or spitting up of blood

- * symptoms of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

These are very serious but uncommon side effects. You may need urgent medical attention or hospitalisation.

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.

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 30 degrees 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 "Greek Alpha symbol" on the other
- * Aratac 200 - round, white, scored tablet marked "AM" over breakline over "200" on one side and a "Greek Alpha symbol" 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
- * 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

(ABN 93 002 359 739)
Chase Building 2
Wentworth Park Road
Glebe NSW 2037
Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Aratac 100 - AUST R 32519

Aratac 200 - AUST R 32514

This leaflet was prepared on 5 September 2005.