

ARATAC TABLET

Amiodarone Hydrochloride (100mg, 200mg)

What is in this leaflet

1. What *Aratac* is used for
2. How *Aratac* works
3. Before you use *Aratac*
4. How to use *Aratac*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Aratac*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

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.

How *Aratac* works

Aratac contain Amiodarone that is a Class III antiarrhythmic agent. It works by controlling the uneven beating of your heart (called arrhythmias) hence helps your heartbeat to return to normal.

Before you use *Aratac*

- When you must not use it

Do not use *Aratac* if you are allergic to:

- amiodarone hydrochloride
- 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
- certain heart conditions, such as slow or irregular heart rate, heart muscle disorder or heart failure.

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

Do not take *Aratac* if you are breastfeeding.

- Before you start to use it

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.

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

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

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

- disopyramide (used to treat abnormal heart rhythms)
- quinidine (used to treat heartbeat irregularities)
- mexiletine (used to treat certain types of serious/possibly fatal irregular heartbeat)
- procainamide (used to treat a certain serious, life-threatening irregular heartbeat)

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. These include:

- Beta-Adrenergic blocking medicines and Calcium Antagonists, medicines used for the management of cardiac arrhythmias
- Digoxin, a medicine used to treat heart failure and fast irregular heart beats
- Anti-coagulants, medicine help to reduce blood clot
- Simvastatin, used to inhibit the production of cholesterol by the liver

How to use *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 use

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 may then gradually reduce your dose to 200 mg once a day.

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

- When to use it

Swallow the tablets with a glass of water.

- How long to use it

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

ARATAC TABLET

Amiodarone Hydrochloride (100mg, 200mg)

Keep taking *Aratac* for as long as your doctor recommends.

- *If you forget to use it*

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 use too much (overdose)*

Immediately contact your doctor or go to 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 using it

- *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.

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.

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 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.

If you are going to have surgery, tell the anaesthetist that you are using *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.

Tell your doctor if you notice any of the following:

- Symptoms of an overactive thyroid including increase in appetite, weight loss, restlessness, heat tolerance, 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
- Small cloudy spots forming on the eyeball. These usually go away after you stop the medicine and they rarely affect your sight
- increased skin sensitivity to sunlight - always wear sunscreen
- bluish skin discoloration
- rash or hives
- tremor, insomnia or other sleep disorders, vivid dreams or nightmares
- metallic taste
- constipation
- loss of appetite
- slow heart beat

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:

- 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
- clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/or speech

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

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel:

ARATAC TABLET

Amiodarone Hydrochloride (100mg, 200mg)

03-78835550, or visiting the website portal.bpfk.gov.my (Consumers - Reporting).

Storage and Disposal of Aratac

- Storage

Keep out of the reach and sight of children.

A locked cupboard at least one-and-a-half meters 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 leave *Aratac* in the car or on window sills.

Heat and dampness can destroy some medicines.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Aratac tablets are available in two strengths:

- *Aratac* 100 - white, marked "AM" breakline "100" on one side and a "α" on reverse
- *Aratac* 200 - white, marked "AM" breakline "200" on one side and a "α" on reverse

Each pack contains 30 tablets.

- Ingredients

- Active Ingredient
Amiodarone hydrochloride
- Inactive ingredients
Lactose, Microcrystalline cellulose, Povidone, purified water, crospovidone, colloidal

anhydrous silica, purified talc and magnesium stearate.

- MAL number (s):

ARATAC 100: MAL19970061AZ
ARATAC 200: MAL19970062AZ

Manufacturer

ALPHAPHARM PTY LIMITED
Carole Park, 4300 Brisbane, Australia

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai,
5 ½ Miles off Jalan Meru,
Klang, Selangor, MALAYSIA.

Date of Revision

08/06/2015

Serial Number

BPFK(R4/1)290515/00132