

ARATAC

Amiodarone 100mg, 200mg Tablets

What is in this leaflet

This leaflet answers some common questions about ARATAC. It does not contain all the information available on this medicine. 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 using ARATAC against the benefits expected it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may want to read it again.

What ARATAC is used for

ARATAC is used to treat certain heart conditions called arrhythmias, where the heart beat or rhythm is irregular. It works by lengthening the gap between one heart beat and the next, helping to bring the heart rate to a slower and more regular pace.

ARATAC belongs to a group of medicines called anti-arrhythmics. These medicines help the heart beat regularly.

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

ARATAC is not recommended for use in children, as its safety and effectiveness have 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
- 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:

- thyroid problems
- low blood pressure
- severe respiratory (breathing) problems.

Do not take ARATAC if you are pregnant or if you are thinking of becoming pregnant.

ARATAC may harm your developing baby if you take it during pregnancy. ARATAC is best avoided in the 3 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.

ARATAC passes into breast milk and may harm your baby.

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.

Tell your doctor if you plan to become pregnant or breastfeed.

You should not take ARATAC for three months before becoming pregnant. This is because ARATAC can stay in the body for some time, even after you have stopped taking it.

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

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

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 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:

- any medicines for heart problems or high blood pressure
- monoamine oxidase inhibitors, medicines to treat depression such as Arima
- phenytoin (e.g. Dilantin), a medicine used to treat epilepsy
- medicines to prevent blood clots such as warfarin (e.g. Coumadin)
- certain types of laxatives such as lactulose (e.g. Actilax)
- corticosteroids such as cortisone (e.g. Cortate), prednisone (e.g. Sone, Panafcort)
- cyclosporin (e.g. Neoral), a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system
- erythromycin (e.g. E-Mycin) and pentamidine, antibiotics used to treat some infections.

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 patient to patient.

The usual starting dose is 200 mg three times a day for one week. This dose will gradually be reduced to 200 mg once a day.

How to take ARATAC

Swallow the tablets with a glass of water.

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.

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, anaesthetists, 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 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.

Like all other medicines, ARATAC 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:

- headaches
- dizziness, tiredness
- anxiety
- tremor
- difficulty sleeping, vivid dreams
- nausea, vomiting
- decreased appetite
- constipation
- salty or metallic taste in the mouth

- skin rash, redness, itching
- bluish discolouration of the skin
- hair loss
- weight gain
- increased sensitivity to the sun - always wear a sunscreen while taking ARATAC.

These are the more common, mild side effects of ARATAC.

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

- disturbances in your vision
- yellowing of the eyes or skin (jaundice)
- dark urine
- 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

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 heartbeat (fast, slow or irregular beat)
- breathlessness, wheezing or other breathing problems.

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.

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

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.

In case of overdose

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any ARATAC by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of ARATAC with you if you can.

Keep telephone numbers for these places handy.

Product description

What it looks like:

ARATAC comes in 2 strengths of tablets:

- ARATAC 100 - round, white, scored tablet marked AM/100 on one side and a Greek alpha symbol on the other
- ARATAC 200 - round, white, scored tablet marked AM/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.

The tablets also contain:

- lactose
- microcrystalline cellulose
- povidone
- colloidal anhydrous silica
- purified talc
- magnesium stearate.

The tablets are gluten free.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
P O Box 11183,

Ellerslie,
Auckland.

Telephone (09) 579 2792

Date of information

19 February 2010