

# NEW ZEALAND CONSUMER MEDICINE INFORMATION

## ARATAC

*Amiodarone hydrochloride 100 mg and 200 mg Tablets*



### 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 risks and benefits. Your doctor has weighed the risks of you taking ARATAC against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

### What ARATAC is used for

ARATAC contains the active ingredient amiodarone. It belongs to a group of medicines called anti-arrhythmics.

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.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

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

### Before you take ARATAC

#### **When you must not take it:**

**Do not take ARATAC if you have an allergy to:**

- any medicine containing amiodarone
- iodine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take ARATAC if you have:**

- thyroid problems
- a heart condition such as slow heart rate, sino-atrial heart block, sick sinus syndrome or a conduction disorder.

Ask your doctor if you are unsure whether you have any of these conditions.

**Do not take ARATAC if you are taking the following medicines:**

- disopyramide
- procainamide
- quinidine
- mexiletine
- sotalol
- bepridil
- vincamine
- cisapride
- erythromycin injections
- pentamidine injections.

**Do not take this medicine if you are pregnant.**

It may affect 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 breastfeed if you are taking this medicine.**

The active ingredient in ARATAC passes into breast milk and there is a possibility that your baby may be affected.

**Do not give this medicine to children.**

Safety and effectiveness in children have not been established.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**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 before starting ARATAC.**

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 have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- any heart conditions
- severe heart failure
- low blood pressure
- a pacemaker or implantable defibrillator inserted
- asthma, respiratory or breathing problems

- nerve damage
- eye problems
- liver problems
- kidney problems.

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

**If you have not told your doctor about any of the above, tell him or her before you start taking ARATAC.**

## ***Taking other medicines***

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

Some medicines and ARATAC may interfere with each other. These include:

- antibiotic medicines used to treat infections such as ciprofloxacin, levofloxacin and moxifloxacin (quinolone antibiotics), erythromycin injections or pentamidine injections
- medicines used to treat arrhythmias such as disopyramide, quinidine, procainamide, mexiletine, sotalol, bepridil
- vincamine
- cisapride
- medicines for the heart including digoxin, flecainide, beta-blockers (such as metoprolol and carvedilol) and calcium channel blocker medicines (such as diltiazem and verapamil)
- monoamine oxidase inhibitor (MAOI) medicines for depression
- medicines that remove excess fluid (diuretics)
- stimulant laxatives
- steroid medicines like prednisone, dexamethasone or tetracosactrin
- amphotericin B injection
- phenytoin for epilepsy
- warfarin and dabigatran, medicines used to thin the blood
- cyclosporin and tacrolimus, immunosuppressant medicines
- fentanyl for severe pain

- statin medicines for lowering cholesterol
- midazolam and triazolam for anxiety or sleeplessness
- sildenafil for erection problems
- colchicine for gout
- medicines used to treat hepatitis C virus such as sofosbuvir, daclatasvir, simeprevir and ledipasvir
- dihydroergotamine or ergotamine medicines used to treat migraines.

These medicines may be affected by ARATAC or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

### **Grapefruit juice and grapefruit products may interfere with ARATAC.**

Avoid grapefruit juice and grapefruit products while you are taking ARATAC.

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

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## **How to take ARATAC**

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### **Follow carefully all directions given to you by your doctor or pharmacist.**

They may differ from the information contained in this leaflet.

### **If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

### ***How much to take***

The dose may vary from patient to patient.

A "loading" regime is usually used at the start of ARATAC treatment, to build up the amount of ARATAC in the body. Following the "loading" regime, a maintenance dose is used.

The loading regime is usually 200 mg (milligrams) three times daily for one week, then 200 mg twice daily for one week.

After this loading regime, the dosage is usually reduced to 200 mg once daily. This dosage may differ between patients.

Ask your doctor or pharmacist if you have any questions about how many ARATAC tablets to take.

### ***How to take it***

**Swallow the tablets whole with a full glass of water.**

### ***When to take it***

**Take your medicine at about the same time(s) each day.**

Taking it at the same time(s) each day will have the best effect. It will also help you remember when to take it.

### ***How long to take it***

**Continue taking your medicine as prescribed by your doctor, for as long as your doctor tells you.**

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

### ***If you forget to take it***

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

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

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

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

### ***If you take too much (overdose)***

**Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at**

the nearest hospital, if you think that 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. Take the pack of ARATAC with you if possible.

Symptoms of an overdose may include slow heart rate, irregular heart beats and excessive sweating.

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## While you are using ARATAC

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### *Things you must do*

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ARATAC.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

**Keep all of your doctor's appointments so that your progress can be checked.** Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects. These tests may include checking your eyes, liver, heart and thyroid glands. You may also need to have chest X-rays.

### *Things you must not do*

**Do not take ARATAC to treat any other complaints unless your doctor tells you to.**

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

**Do not stop taking your medicine or change the dosage without checking with your doctor.**

If you stop taking it, your condition may worsen.

### *Things to be careful of*

**Be careful driving or operating machinery until you know how ARATAC affects you.**

This medicine may cause dizziness and vertigo in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

**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.**

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 as soon as possible.

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## Side effects

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

All medicines can have side effects and some people taking ARATAC may have unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical attention 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 the following lists of side effects. You may not experience any of them.**

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

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

- nausea or vomiting
- constipation
- loss of appetite
- headaches
- dizziness or vertigo
- taste disturbance or loss of taste
- smell disturbance
- tremor
- sleeplessness (insomnia) or other sleep disorders
- vivid dreams or nightmares
- anxiety
- fatigue
- hair loss
- small cloudy spots forming on the eyeball. These usually go away after you stop the medicine and they rarely affect your sight
- skin rashes or skin redness
- bluish or grey discolouration of the skin
- increased sensitivity of the skin to sunlight – always wear protective clothing and sunscreen when in the sun.

The above list includes some of the more common side effects of your medicine.

**Tell your doctor as soon as possible if you notice any of the following:**

- changes in weight, intolerance to cold temperatures, reduced activity, restlessness. These may be symptoms of thyroid problems.
- swollen feet or ankles
- muscle weakness
- clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/or speech
- tingling or numbness in the hands or feet
- changes in your vision, blurred or decreased vision
- itching, burning or "gritty" feeling in the eyes.

The above list includes serious side effects that may require medical attention.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- changes in your heart beat (fast, slow or irregular heart beat)
- chest pain or angina
- breathlessness, wheezing or difficulty breathing
- yellowing of the eyes or skin (jaundice), dark urine, light coloured stools. These may be symptoms of liver problems.
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

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

Some side effects (for example, changes in thyroid function, liver and kidney function, heart rhythm) can only be found when your doctor does tests from time to time to check your progress.

ARATAC can stay in the body for several months after you stop taking it, so side effects could still occur after stopping ARATAC therapy.

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## After using ARATAC

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### Storage

**Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the pack they may not keep well.

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

**Heat and dampness can destroy some medicines.**

Do not store ARATAC or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

**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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product description

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ARATAC tablets come in two strengths, ARATAC 100 mg and ARATAC 200 mg tablets.

ARATAC tablets are supplied in blister packs of 30 tablets.

### What it looks like

ARATAC 100 mg tablets are round, white tablets, 8.5mm diameter, imprinted "AM" | "100" on one side and "G" on the other.

ARATAC 200 mg tablets are round, white tablets, 10.0mm diameter, imprinted "AM" | "200" on one side and "G" on the other.

### Ingredients

ARATAC 100 mg tablets contain 100 mg of amiodarone as the active ingredient.

ARATAC 200 mg tablets contain 200 mg of amiodarone as the active ingredient.

ARATAC tablets also contain:

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

ARATAC tablets do not contain gluten.

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## If you want to know more

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

## Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland.

Telephone: (09) 579 2792

## Date of Information

8 May 2019  
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