

# ARATAC

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## **Consumer Medicine Information (CMI) summary**

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

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### **1. Why am I taking ARATAC?**

ARATAC contains the active ingredient amiodarone hydrochloride. ARATAC is used to control a fast or irregular heartbeat.

For more information, see Section [1. Why am I taking ARATAC?](#) in the full CMI.

### **2. What should I know before I take ARATAC?**

Do not take if you have ever had an allergic reaction to amiodarone hydrochloride, iodine or any of the ingredients listed at the end of the CMI. Do not take ARATAC if you have or have had any thyroid problems, heart problems that may cause you to faint, low blood pressure, severe problems breathing, heart disease or failure, shock, are pregnant, intend to become pregnant or are breastfeeding.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take ARATAC?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with ARATAC and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I take ARATAC?**

- Your doctor will tell you how many ARATAC tablets you should take. Swallow ARATAC tablets with a glass of water.
- More instructions can be found in Section [4. How do I take ARATAC?](#) in the full CMI.

### **5. What should I know while taking ARATAC?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking ARATAC.</li></ul>
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	<ul style="list-style-type: none"> <li>• Attend your doctor appointments so that your progress can be checked.</li> <li>• Tell your doctor straight away if you become pregnant or intend to become pregnant.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop taking ARATAC suddenly without checking with your doctor.</li> <li>• Do not take ARATAC to treat any other complaints unless your doctor says it is safe.</li> <li>• Do not give ARATAC to anyone else, even if they have the same condition as you.</li> </ul>
<b>Things to be careful of</b>	<ul style="list-style-type: none"> <li>• Always use a sunscreen and wear a hat and protective clothing when you are outdoors. Do not use a sunlamp.</li> <li>• Avoid drinking large quantities of grapefruit juice.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any</li> </ul>

	machines or tools until you know how ARATAC affects you.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep it in a cool, dry place where the temperature stays below 25°C.</li> </ul>

For more information, see Section [5. What should I know while taking ARATAC?](#) in the full CMI.

## 6. Are there any side effects?

Treatment with amiodarone may cause serious lung, liver and eye damage and may worsen heart problems. Serious side effects may include changes to heartbeat such as pounding, rapid or very slow heartbeat; allergic reaction; blurring or deterioration of vision, sensitisation of eyes to light; severe blisters and bleeding in the lips, eyes, mouth, nose and genitals; yellow skin or eyes, faintness, light-headedness; nausea, vomiting, stomach pain, unusual tiredness, passing dark-coloured urine; clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements/speech; chest pain, cough or spitting up blood. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ARATAC

**Active ingredient(s):** *amiodarone hydrochloride*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using ARATAC. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ARATAC.**

**Where to find information in this leaflet:**

- [1. Why am I taking ARATAC?](#)
- [2. What should I know before I take ARATAC?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take ARATAC?](#)
- [5. What should I know while taking ARATAC?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking ARATAC?

**ARATAC contains the active ingredient amiodarone hydrochloride.** ARATAC is a Class III antiarrhythmic agent.

**ARATAC is used to control a fast or irregular heartbeat.**

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.

Your doctor may have prescribed ARATAC for another reason.

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

There is no evidence that ARATAC is addictive.

## **2. What should I know before I take ARATAC?**

### **Warnings**

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

- are allergic to amiodarone hydrochloride, iodine, or any of the ingredients listed at the end of this leaflet. 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

Always check the ingredients to make sure you can use this medicine.

- have or have had any thyroid problems
- have heart problems that may cause you to faint

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

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

### **Check with your doctor if you:**

- have any other medical conditions, especially the following:
  - other heart conditions
  - blood pressure problems
  - liver problems
  - thyroid problems

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

- are allergic to any other medicines, foods, dyes or preservatives
- take any medicines for any other condition
- are not sure whether you should start taking this medicine.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

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

ARATAC is best avoided in the 3 months before pregnancy and throughout the duration of pregnancy. This is because it can stay in the body for several months even after you stop taking it.

Tell your doctor if you are pregnant or intend to become pregnant.

**Do not take ARATAC if you are breastfeeding.**

ARATAC can be found in breast milk.

If you are breastfeeding and must be taking ARATAC, alternative feeding arrangements such as bottle feeding should be made for your baby.

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

Talk to your doctor about the risks and benefits of taking ARATAC during pregnancy and breastfeeding.

## **Children**

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



### 3. What if I am taking other medicines?

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

**Some medicines may interfere with ARATAC and affect how it works. These include:**

- medicines for your heart
- medicines for your blood pressure
- medicines which reduce the activity of your immune system, such as ciclosporin, cortisone or tacrolimus
- diuretics (water tablets)
- antibiotics, including intravenous erythromycin and pentamidine
- stimulant laxatives e.g., bisacodyl, castor oil, senna
- MAO (monoamine oxidase) inhibitors (a type of medicine used to treat depression)
- antipsychotics (medicines used to treat certain mental and emotional conditions)
- phenytoin (a medicine used to treat epilepsy)
- warfarin and other medicines which thin the blood
- simvastatin and other statins (medicines used to lower cholesterol)
- colchicine (a medicine used to treat gout)
- digoxin (a medicine used to treat heart conditions)
- flecainide and sotalol (medicines used to treat a fast or irregular heartbeat)

- fentanyl (a medicine used to treat pain)
- sildenafil
- triazolam (a medicine used to treat insomnia)
- ergotamine (a medicine used to treat migraine)
- general anaesthesia
- lidocaine (a topical anaesthetic)
- amphotericin B (a medicine used to treat fungal infections)
- antiviral medication e.g., sofosbuvir, daclatasvir, simeprevir, ledipasvir.

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

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

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ARATAC.**

## **4. How do I take ARATAC?**

### **How much to take**

- The usual starting dose is 200 mg three times a day for 1 week.
- Therapy is then reduced and continued with 200 mg two times a day for a further week.
- The dose may then be reduced to 200 mg once per day.
- The dose varies from person to person.

- Follow the instructions provided by your doctor and take ARATAC until your doctor tells you to stop.
- Your doctor or pharmacist will tell you how many ARATAC tablets 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 directions given to you by your doctor or pharmacist may be different from the information in this leaflet.
- If you do not understand the instructions on the pack, ask your doctor or pharmacist.

## **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**

ARATAC tablets should be taken regularly at the same time each day. If you miss your dose at the usual time, 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 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**

If you think that you or anyone else has taken too much ARATAC, urgent medical attention maybe needed.

**You should immediately:**

- phone the Poisons Information Centre **(telephone 13 11 26)** for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while taking ARATAC?

### Things you should do

- Before starting any new medicine, tell your doctor or pharmacist that you are taking ARATAC.
- **Be sure to attend all of your doctor appointments so that your progress can be checked.**  
To help prevent unwanted side effects, your doctor may need to perform the following tests, depending on the length of treatment with ARATAC:
  - ECG
  - eye tests
  - chest X-rays
  - liver function tests
  - thyroid tests.
- **Take ARATAC exactly as your doctor has prescribed.**
- **Tell your doctor if you become or intend to become pregnant while using ARATAC.**
- Remind any doctor, dentist or pharmacist you visit that you are taking ARATAC.

### Things you should not do

- Do not stop taking ARATAC suddenly without checking with your doctor.

- Do not take 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 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.**

Taking ARATAC may cause your skin 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 including dental surgery, tell the anaesthetist that you are taking 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 taking 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.**

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how ARATAC affects you.**

There is no evidence that amiodarone impairs the ability to drive a vehicle or operate machinery.

## **Looking after your medicine**

- Keep your tablets in the blister pack until it is time to take them.
- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

## **Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn, shows signs of tampering or the tablets do not look quite right.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Treatment with amiodarone may cause serious lung, liver and eye damage and may worsen heart problems.**

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.

### Less serious side effects

Less serious side effects	What to do
<b>Alertness and sleep-related:</b> <ul style="list-style-type: none"><li>tremor, insomnia or other sleep disorders, vivid dreams or nightmares</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>



Less serious side effects	What to do
<p><b>Allergy-related:</b></p> <ul style="list-style-type: none"> <li>• allergic condition which causes joint pain, skin rashes, fever and kidney problems</li> <li>• rash or hives</li> </ul> <p><b>Sight, hearing, smell, taste or touch- related:</b></p> <ul style="list-style-type: none"> <li>• small cloudy spots forming on the eyeball. These usually go away after you stop the drug and they rarely affect your sight</li> <li>• metallic taste</li> <li>• a feeling of "pins and needles" or numbness in the hands, legs or feet</li> </ul> <p><b>Heart-related:</b></p> <ul style="list-style-type: none"> <li>• slow heartbeat</li> </ul> <p><b>Hormone-related:</b></p> <ul style="list-style-type: none"> <li>• symptoms of an overactive thyroid including increase in appetite, weight loss, restlessness, heat intolerance, increased sweating, tremors,</li> </ul>	

Less serious side effects	What to do
<p>swelling of your neck (goitre) and a rapid heart rate</p> <ul style="list-style-type: none"> <li>• 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</li> </ul> <p><b>Skin and muscle-related:</b></p> <ul style="list-style-type: none"> <li>• muscle weakness, uncontrolled movements or poor coordination</li> <li>• increased skin sensitivity to sunlight - always wear a sunscreen</li> <li>• bluish skin discolouration</li> </ul> <p><b>Stomach and gut-related:</b></p> <ul style="list-style-type: none"> <li>• constipation</li> <li>• loss of appetite</li> </ul>	

## Serious side effects

Serious side effects	What to do
<p><b>Alertness and sleep-related:</b></p> <ul style="list-style-type: none"> <li>• faintness or light-headedness</li> </ul> <p><b>Allergy-related:</b></p> <ul style="list-style-type: none"> <li>• signs of an allergic reaction, such as shortness of breath, wheezing or other difficulty in breathing, swelling of the face, lips, mouth, tongue or throat; rash, itching or hives on the skin</li> </ul> <p><b>Heart and chest-related:</b></p> <ul style="list-style-type: none"> <li>• changes to your heartbeat such as a pounding heart, very rapid or very slow heartbeat</li> <li>• chest pain, cough or spitting up of blood</li> </ul> <p><b>Sight-related:</b></p>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> <p>These may be serious side effects of ARATAC. If any of these symptoms occurs or you suspect any other drug reaction, please consult your doctor immediately.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• blurring or deterioration of vision, sensitisation of eyes to light</li> </ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>• severe blisters and bleeding in the lips, eyes, mouth, nose and genitals</li> <li>• yellowing of the skin or eyes (jaundice, a symptom of liver changes)</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>• nausea or vomiting, stomach pain, yellow skin, unusual tiredness or passing dark-coloured urine</li> <li>• clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/or speech</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What ARATAC contains

<b>Active ingredient (main ingredient)</b>	Amiodarone hydrochloride  (100 mg or 200 mg per tablet)
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• lactose monohydrate</li><li>• microcrystalline cellulose</li><li>• povidone</li><li>• crospovidone</li></ul>

	<ul style="list-style-type: none"> <li>• colloidal anhydrous silica</li> <li>• purified talc</li> <li>• magnesium stearate</li> </ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"> <li>• sulfites</li> <li>• sugars as lactose</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What ARATAC looks like**

- **ARATAC 100** - White, marked "AM" breakline "100" on one side and a "G" on other. (AUST R 32519)
- **ARATAC 200** - White, marked "AM" breakline "200" on one side and a "G" on other. (AUST R 32514)

Each pack contains 30 tablets.

## **Who distributes ARATAC**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

This leaflet was prepared in June 2025.

ARATAC is a Viatris company trade mark.

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