

RITHMIK

amiodarone hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about RITHMIK.

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 risk of you taking RITHMIK against the benefits it is expected to 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 want to read it again.

What RITHMIK is used for

RITHMIK is used to treat certain heart rhythm or control a fast or irregular heart beat.

RITHMIK belongs to a group of medicines called antiarrhythmics.

It works by lengthening the gap between one heart beat and the next, thus helping to bring the heart rate to a slower and more regular pace.

Your doctor may have prescribed RITHMIK for another reason.

Ask your doctor if you have any questions about why RITHMIK was prescribed for you.

RITHMIK is available only with a doctor's prescription.

RITHMIK is not addictive.

Before you take RITHMIK

When you must not take it

Do not take RITHMIK if you are allergic to medicines containing amiodarone hydrochloride or iodine or 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 RITHMIK if you have:

- thyroid problems
- heart problems that may cause you to faint. If you have a pacemaker, your doctor may allow the use of it.
- severe breathing problems
- low blood pressure
- heart disease or failure
- shock
- other heart conditions.

Do not take RITHMIK if you are taking MAO inhibitors (a type of medicine used to treat depression).

Do not take RITHMIK if you are pregnant or are thinking of getting pregnant.

RITHMIK 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 RITHMIK as it can be found in breast milk.

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

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

Do not take RITHMIK if the expiry date (Exp.) printed on the pack has passed.

Do not take RITHMIK if the packaging is torn or shows signs of tampering.

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

RITHMIK is not recommended for children.

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

Before you start to take it

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.

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

- thyroid problems
- other heart conditions
- blood pressure problems
- liver problems
- breathing problems.

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 RITHMIK, or may affect how well it works. These include:

- any medicines for your heart
- any 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 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 heart conditions)
- digoxin (a medicine used to treat heart condition)
- medicines used to treat a fast or irregular heart beat (such as flecainide and sotalol)

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

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 RITHMIK.

How to take RITHMIK

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

They may differ from the information contained in this leaflet.

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

How much to take

The usual dose is 200 mg three times a day for one week. The tablets should be taken consistently, at the same time with regards to food.

Therapy is then continued with 200 mg, two times a day for a further week.

The dose may then be reduced to 200 mg a day (or less if your doctor says so).

Follow all directions given to you by your doctor and pharmacist carefully.

Do not stop taking it unless your doctor tell you to, even if you feel better.

How to take RITHMIK

Swallow the tablets with a glass of water.

If you need to break RITHMIK, hold tablet with both hands and snap along break line.

If you forget to take RITHMIK

If you miss a dose, take it as soon as you remember, and continue to take it as you would normally.

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.

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 take too much RITHMIK (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much RITHMIK. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking RITHMIK

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking RITHMIK.

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

If you become pregnant while taking RITHMIK, tell your doctor.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking RITHMIK.

Your doctor may do following tests from time to time to make sure the medicine is working and to prevent unwanted side effects:

- ECG
- Eye tests
- Chest X-rays
- Liver function tests
- Thyroid tests.

Things you must not do

Do not stop taking RITHMIK, or lower the dose, without checking with your doctor.

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

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

Things to be careful of

Always use a 30+ sunscreen and wear a hat and protective clothing when you are outdoors.

Do not use a sunlamp.

Using RITHMIK may make 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, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Avoid drinking large quantities of grapefruit juice as it may affect the absorption of amiodarone.

Side effects

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

Like all other medicines, RITHMIK 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.

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:

- symptoms of an overactive thyroid such as increase in appetite, weight loss, restlessness, heat intolerance, increased sweating, tremors, swelling of the neck and a rapid heart rate
- symptoms of an underactive thyroid such as 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

- allergic condition which causes joint pain, skin rashes, fever and kidney problems
- slow heart beat
- intense sunburn or increased skin sensitivity to sunlight – always wear a sunscreen while taking RITHMIK
- bluish skin discolouration
- rash or hives
- nausea
- metallic taste
- constipation
- loss of appetite
- tremor, insomnia or other sleep disorders, vivid dreams or nightmares
- a feeling of "pins and needles" or numbness in the hands, legs or feet
- muscle weakness, uncontrolled movements or poor coordination
- small deposits on the eyeball. These usually go away after you stop the drug and rarely affect your sight.

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

- yellowing of the skin or eyes (called jaundice, a symptom of liver changes)
- shortness of breath, difficulty in breathing
- clumsiness and lack of coordination affecting balance, limb or eye movements and/or speech, difficulty walking
- blurred or decreased vision
- chest pain, cough or spitting up of blood
- nausea or vomiting, stomach pain, yellow skin, unusual tiredness or passing dark-coloured urine
- faintness or light headedness
- blurring or deterioration of vision, sensitisation of eyes to light
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

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:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- breathlessness or any difficulty breathing
- any disturbance in heart beat, such as pounding heart, very rapid or very slow heart beat.

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

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

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

Some of these side effects can only be found when your doctor does tests from time to time to check your progress. 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 RITHMIK for and what dose you are on.

After using RITHMIK

Storage

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

Do not store RITHMIK or any other medicine in the bathroom or near a sink.

Do not leave RITHMIK in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep RITHMIK 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 RITHMIK, 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

RITHMIK comes in one strength of tablets:

- RITHMIK 200 mg tablets - white, round tablets, biconvex with one-sided score notch.

Each pack contains 30 tablets.

Ingredients

The active ingredient in RITHMIK is amiodarone hydrochloride:

- each RITHMIK 200 mg tablet contains 200 mg of amiodarone hydrochloride.

The tablets also contain:

- maize starch
- lactose monohydrate
- povidone
- magnesium stearate
- anhydrous colloidal silica.

Supplier

Arrow Pharma Pty Ltd
Cremorne, VIC 3121
Australia

This leaflet was revised in August 2019.

Australian Register Number

200 mg tablets: AUST R 98655