

CORDARONE[®]

Amiodarone Hydrochloride 200mg

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What Cordarone is used for

Cordarone is indicated only for the treatment of severe heart rhythm disorders, not responding to other therapy or when other treatments cannot be used:

- Treat uneven heartbeats
- Treat other types of fast or uneven heartbeats known as 'atrial flutter' or 'atrial fibrillation.
- Treat fast heartbeats which may happen suddenly and may be uneven.
- Treat an illness called Wolff-Parkinson-White Syndrome. This is where your heart beats unusually fast.

How Cordarone works

Cordarone 200mg Tablets contain a medicine called Amiodarone Hydrochloride. This belongs to a group of medicines called anti-arrhythmics. It works by controlling the uneven beating of your heart (called 'arrhythmias'). Taking the tablets helps your heartbeat to return to normal.

Before you use Cordarone

When you must not use it

Do not take Cordarone if:

- You are allergic (hypersensitive) to iodine, amiodarone, or any of the other ingredients of Cordarone (listed in Section 8 below).
- Signs of an allergic reaction include: a rash, swallowing or breathing

problems, swelling of your lips, face, throat or tongue.

- You have a slower than usual heartbeat (called 'sinus bradycardia') or an illness called 'sino-atrial' heart block.
- You have any other problems with your heartbeat and do not have a pacemaker fitted.
- You have ever had thyroid problems. Your doctor should test your thyroid before giving you this medicine.
- You are pregnant or breast-feeding.
- You are taking any other medicines that may induce heart rhythm disturbances.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Cordarone.

Before you start to use it

Take special care with Cordarone and check with your doctor before taking your medicine if:

- You have heart problems.
- You have liver disorders.
- You have neuromuscular disorders.
- You have any problems with your thyroid.
- You have any problems with your lungs or have asthma.
- You have any problems with your eyesight. This includes an illness called 'optic neuritis'.
- You are about to have an operation.
- You are elderly (over 65 years of age).
- You have a pacemaker or implantable cardioverter defibrillator (ICD).
- You have lactose intolerance.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Cordarone.

Taking other medicines

Do not take this medicine and tell your doctor, if you are taking:

- Other medicines for an uneven heartbeat (such as sotalol, quinidine, hydroquinidine, disopyramide dofetilide or ibutilide)
- Other medicinal products (such as arsenic compounds, bepridil, cisapride, diphemanil, dolasetron, erythromycin, mizolastine, vincamine, moxifloxacin, spiramycin, toremifene).

Tell your doctor if you are taking any of the following medicines:

- Medicines used to help prevent rejection of transplants or suppress body's defense system (such as ciclosporin)
- Medicines for antiparasitics (such as halofantrine, lumefantrine or pentamidine)
- Medicines for schizophrenia (such as amisulpride, chlorpromazine, cyamemazine, droperidol, fluphenazine, haloperidol, levomepromazine, pimozide, pipamperone, pipotiazine, sertindole, sulpiride, sultopride, tiapride or zuclopenthixol)
- Medicines for chest pain (angina) or high blood pressure called calcium channel blockers (such as injectable diltiazem or injectable verapamil)
- Medicines used in opioid addiction and pain killer such as methadone.

Cordarone may increase the chance of you getting side effects or increase the effect of the following medicines:

- Oral anticoagulant and dabigatran-used to treat thrombosis or atrial fibrillation
- Bisoprolol, carvedilol, metoprolol, and nebivolol - used to treat heart failure
- Esmolol - used to treat heart rhythm disorders
- Azithromycin, clarithromycin and roxithromycin - used as antibiotics to treat infection.
- Oral diltiazem and oral verapamil - used to treat chest pain or high blood pressure

- Digoxin- used to treat various heart conditions
- Water tablets (diuretics)
- Lidocaine – used as an anaesthetic
- Orlistat- used to treat obesity
- Phenytoin- used as an antiepileptic
- Tacrolimus- used to help prevent rejection of transplants
- Simvastatin – used to treat high cholesterol.

How to use Cordarone

Always take Cordarone exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Swallow the tablets orally in whole. Do not crush or chew your tablets.
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

How much to use

Adults

- The starting dose is 200 mg three tablets daily for 8 to 10 days.
- The minimum maintenance dose ranges from half a tablet to 2 tablets daily.

When to use it

Take Cordarone at about the same time each day unless your doctor tells you otherwise.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the medicine.

If you are not sure when to use it, ask your doctor or pharmacist.

How long to use it

Continue taking your medicine as long as your doctor tells you.

If you forget to use it

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten tablet.

If you stop using it

Keep taking Cordarone until your doctor tells you to stop. Do not stop taking Cordarone just because you feel better. If you stop taking this medicine

the uneven heartbeats may come back. This could be dangerous.

If you use too much (overdose)

If you take more Cordarone than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. The following effects may happen: slow or rapid heartbeat, damage to the liver.

While you are using it

Things you must do

- If you become pregnant while you are taking this medicine, tell your doctor immediately.
- Keep out of direct sunlight while taking this medicine and for a few months after you have finished taking it. This is because your skin will become much more sensitive to the sun and may burn, tingle or severely blister if you do not take the following precautions:
 - Make sure you use high factor sun cream
 - Always wear a hat and clothes which cover your arms and legs.

Things you must not do

- Do not give this medicine to anyone else, even if they have the same symptoms as you.
- Limit the amount of alcohol you drink while taking this medicine. This is because it will increase the chance of you having liver problems.
- Do not take this medicine if you are pregnant or breast-feeding.

Things to be careful of

Driving and using machines

You may have blurred eyesight after taking Cordarone. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Cordarone

This medicine contains:

- Lactose (a type of sugar): If you are lactose intolerance, talk to your doctor before taking this medicine
- Iodine can cause problems to your thyroid.

Side Effects

All medicines can cause side effects although not everybody gets them.

Do not be alarmed by this list of possible side effects.

Stop taking Cordarone and see a doctor as soon as possible if:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swollen eyelids, face, lips, throat or tongue.
- You get yellowing of the skin or eyes (jaundice) feel tired or sick, loss of appetite, stomach pain or high temperature. These can be signs of liver problems.
 - Difficulty breathing or tightness in the chest, coughing non-stop, wheezing, weight loss and fever. This could be due to inflammation of your lungs.

Tell your doctor as soon as possible if you have any of the following side effects:

- **Very common side effects** (affects more than 1 in 10 people)
 - Blurred eyesight or seeing a coloured halo in dazzling light
 - Feeling sick (nausea) or being sick (vomiting)
 - Changes in the amount of liver enzymes can be seen in blood tests
 - Burning more easily in the sun

Common side effects (affects less than 1 in 10 people)

- Feeling extremely restless or agitated, weight loss, increased sweating and being unable to stand the heat. These could be signs of an illness called 'hyper-thyroidism'.
- Feeling extremely tired, weak or 'run-down', weight gain, being unable to stand the cold, constipation and aching muscles. These could be signs of an illness called 'hypo-thyroidism'.
- Trembling when you move your arms or legs.
- Blue or grey marks on parts of your skin exposed to sunlight, especially the face.
- Slightly slower heart beat
- Nightmares
- Problems sleeping

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. Other side effects

not listed above may 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: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Cordarone

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

- **Keep this medicine in a safe place where children cannot see or reach it.**
- **Do not use Cordarone after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.**
- **Keep the blister strip in the outer carton in order to protect from light.**
- **Do not use Cordarone if you notice your tablets are crumbling, broken or discoloured.**
- **Store below 30°C**

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

The tablets are white, round, scored and engraved with a “heart-shaped” symbol and “200” on one face. The tablets are available in blister-packs of 30 tablets.

Ingredients:

- Each Cordarone 200mg Tablet contains 200mg of the active substance, amiodarone hydrochloride.
- The other ingredients are lactose monohydrate, maize starch, povidone, colloidal anhydrous silica and magnesium stearate.

MAL Numbers:

Cordarone Tablets 200mg
MAL19987968AR

Manufacturer and Product Registration Holder

Manufacturer

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Product Registration Holder

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