

PACKAGE LEAFLET : INFORMATION FOR THE USER

Cordarone® 200 mg

sanofi

scored tablets

Amiodarone hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cordarone is and what it is used for
2. What you need to know before you take Cordarone
3. How to take Cordarone
4. Possible side effects
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1. WHAT CORDARONE IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: CLASS III ANTIARRHYTHMICS

This medicine is used to prevent and treat certain serious heartbeat problems.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CORDARONE

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

Contraindications:

Do not take Cordarone:

- If you are allergic (hypersensitive) to amiodarone or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to iodine.
- If you have hyperthyroidism (disease of the thyroid gland).
- If you have certain problems with your heartbeat or problems with the system that sends the signals that cause your heart to contract.
- If your heartbeat is too slow.
- If you are more than 3 months pregnant.
- If you are breast-feeding.
- If you are taking other medicines, make sure that combined use with Cordarone is not contraindicated (see "Other medicines and Cordarone").

Warnings and precautions

Talk to your doctor or pharmacist before taking Cordarone.

Never stop your treatment without talking to your doctor first.

Children

The efficacy and safety of this medicine are not known in children.

Other medicines and Cordarone

Do not use this medicine if you are using one of the following medicines:

- Medicines used to treat heartbeat problems, such as quinidine, hydroquinidine, disopyramide, dofetilide, ibutilide, sotalol;
- Other medicines such as:
 - o arsenic compounds,
 - o bepridil,
 - o cisapride,
 - o citalopram,
 - o diphenamil,
 - o intravenous dolasetron,
 - o domperidone,
 - o dronedarone,
 - o escitalopram,
 - o intravenous erythromycin,
 - o levofloxacin,
 - o mequitazine,
 - o mizolastine,
 - o moxifloxacin,
 - o prucalopride,
 - o intravenous spiramycin,
 - o toremifene,
 - o intravenous vincamine,
 - o sofosbuvir, used to treat hepatitis C

These medicines may cause torsades de pointes (serious heartbeat problems):

- telaprevir,
- cobicistat.

Unless otherwise instructed by your doctor, you must not use this medicine if you are taking any of the following medicines:

- diltiazem or verapamil injection,
- certain antiparasitic medicines (halofantrine, lumefantrine, pentamidine),
- certain neuroleptic medicines (amisulpride, chlorpromazine, cyamemazine, droperidol, flupentixol, fluphenazine, haloperidol, levomepromazine, pimozide, pipamperone, pipotiazine, sertindole, sulpiride, sultopride, tiapride, zuclopenthixol),
- methadone,
- certain antibiotics belonging to a group of medicines called fluoroquinolones (other than levofloxacin and moxifloxacin),
- fidaxomicin,
- stimulant laxatives,
- fingolimod.

Cordarone may enhance the effects of the following medicines: ciclosporin, tacrolimus and sirolimus, used to help prevent transplant rejection.

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

- You are currently taking, or have taken in the past few months, a medicine containing sofosbuvir for the treatment of hepatitis C, as it could be life-threatening by causing your heart to slow down. Your doctor may consider alternative treatment if you are taking this medicine. If treatment with Cordarone and sofosbuvir is needed, you may need additional heart monitoring.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including over the counter medicines.

If you have a pacemaker or implantable cardioverter defibrillator (ICD):

You must ask your doctor to check that your device is working properly before you start and several times during treatment, or if your dose is changed.

If you are on a waiting list for a heart transplant, your doctor may change your treatment. Using amiodarone before a heart transplant has shown to increase the risk of life-threatening complications (primary graft dysfunction) in which the transplanted heart stops working properly within 24 hours after surgery.

During treatment:

Tell your doctor:

- If your heartbeat becomes too fast again, or abnormally slow,
- If you feel abnormally breathless,
- If you have difficulty breathing,
- If you have a dry cough and your health worsens, or you have a dry cough with no other symptoms,
- If you have a temperature or if you have been tired for no apparent reason or for a long time,
- If you have diarrhoea,
- If you have lost weight,
- If you have muscle pain,
- If you have reduced vision,
- If you are going to have surgery, you should tell your anaesthetist that you are using this medicine,
- If you experience severe skin reactions such as a blistering rash with peeling of the skin which can rapidly spread to the whole body and be life-threatening, immediately stop your treatment.
- Protect your skin from sunlight to avoid a sunburn-like reaction.
- Your doctor might prescribe blood tests to check how your thyroid and liver are working.

Tell your doctor immediately if you are currently taking, or have taken in the past few months, any medicine containing sofosbuvir for the treatment of hepatitis C, and if you experience during treatment:

- slow or irregular heartbeat, or heart rhythm problems;
- shortness of breath or worsening of existing shortness of breath;
- chest pain;
- dizziness;
- palpitations;
- near fainting or fainting.

Pregnancy and breast-feeding

Pregnancy

Do not take this medicine if you are more than 3 months pregnant, i.e. from the second trimester of pregnancy.

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Do not breast-feed if you are taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Cordarone contains lactose.

This medicine contains a type of sugar (lactose) that is broken down into galactose and glucose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose/galactose malabsorption should not take this medicine.

3. HOW TO TAKE CORDARONE

Dosage and duration of treatment

The dose should be adjusted on an individual basis.

The recommended dose is:

- At the start of treatment (loading dose), 3 tablets per day, for 8 to 10 days.
- then, the following days (maintenance treatment), 1/2 to 2 tablets per day.

Use in children

There are only limited data on the efficacy and safety of this medicine in children. The doctor will decide how much should be given.

In all cases, you must strictly follow your doctor's prescription and you must not change the dosage without seeking medical advice.

Likewise, you must not stop your treatment without asking your doctor for advice.

Method of administration

You should take the tablets with a small amount of water (oral use). You may swallow them before, during or at any time between meals. Crushing the tablets will have no effect on how well they work.



Cordarone tablets are easy to recognise thanks to the 2 logos engraved on the side.

If your doctor has prescribed a half tablet (once or several times a day), halve the tablet as described below.

The Cordarone tablet has a break-line, so you can easily break it into 2 equal halves.

To halve the tablet, press down on it with your thumb on a flat surface.



SURFACE DURE

If you take more Cordarone than you should:

Talk to your doctor or pharmacist immediately.

If you forget to take Cordarone

You do not run any particular risk if you occasionally forget to take a tablet.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common:

- Micro-deposits in the cornea that can cause vision problems such as cloudy vision or coloured halos,
- Extreme skin reaction to sunlight (photosensitisation),
- Changes in thyroid hormones without any obvious signs of thyroid disease,
- Increased amount of certain liver enzymes (transaminases) in the blood,
- Digestive problems (nausea, vomiting, changes in taste).

Common:

- Grey skin,
- Thyroid disease, with symptoms such as weight gain, sensitivity to cold and feeling tired (hypothyroidism), or on the contrary, excessive weight loss (hyperthyroidism). Serious forms of

hyperthyroidism can be life-threatening.

- Lung damage that can progress to life-threatening pulmonary fibrosis; pleurisy. If you have a dry cough, shortness of breath, fever or feel tired, tell your doctor as soon as possible.
- Extrapyramidal symptoms such as trembling,
- Sleep disorders including nightmares,
- Nerve damage (peripheral neuropathy),
- Acute hepatitis that can be life-threatening,
- Slowed heartbeat.
- Decreased libido.

Uncommon:

- Slowed heartbeat and heart rate problems (although the medicine is used to treat such problems),
- Muscle damage (myopathy) in the arms and legs.

Rare:

- Decrease in the amount of sodium in the blood (hyponatraemia, syndrome of inappropriate antidiuretic hormone secretion, SIADH).

Very rare:

- Blurred vision or impaired eyesight that can progress to blindness (total loss of eyesight),
- Red, sometimes scaly, skin reaction,
- Hair loss,
- Difficulty breathing, particularly after an operation, that can be life-threatening,
- Chronic hepatitis,
- Severely slowed heartbeat (sinus arrest),
- Decrease in the number of platelets in the blood,
- Increase in the amount of creatinine in the blood (kidney problem),
- Difficulty coordinating movements (ataxia),
- Inflammation of the small blood vessels (vasculitis),
- Pain and inflammation near the testicles (epididymitis),
- Headache, increased pressure in the brain that can lead to swelling in the brain (cerebral oedema).

In this case, do not disregard these symptoms and tell your doctor.

Not known:

- Bleeding in your lungs (haemoptysis),
- Angioedema (sudden swelling of the face and neck, which may cause difficulty breathing),
- Hives,
- Irregular heartbeat, which may be life-threatening (torsades de pointes),
- Inflammation of the pancreas (pancreatitis/acute pancreatitis),
- Granuloma, including bone marrow granuloma.
- Skin problems with itching, redness and a burning sensation (eczema),
- Blistering rash with peeling of the skin which can rapidly spread to the whole body and be life-threatening (Toxic Epidermal Necrolysis, Stevens-Johnson syndrome),
- Skin disease with blisters (bullous dermatitis),
- Serious allergic reaction (drug-induced hypersensitivity syndrome), causing a combination of several symptoms, such as fever, skin rash, enlarged lymph nodes, liver damage, kidney damage, abnormal blood test results such as an increased number of certain white blood cells (eosinophils),
- Change in your sense of smell, often smelling bad smells (parosmia),
- Symptoms that resemble Parkinson's disease, such as rigid muscles, slowed movement and tremor,
- Dry mouth,
- Constipation,
- you are at risk of getting more infections than usual. This may be

- due to a decrease in the number of white blood cells (neutropenia),
- severe decrease in the number of white blood cells, which makes infections more likely (agranulocytosis);
- Serious allergic reaction, in particular suddenly feeling faint, a significant drop in blood pressure, accelerated heart rate and difficulty breathing (anaphylactoid reactions and anaphylactic shock),
- Decreased appetite,
- Confusional state, delirium,
- Seeing, hearing or feeling things that are not there (hallucinations).
- Lupus syndrome (a disease in which the immune system attacks various parts of the body causing pain, rigidity and swelling of the joints and skin redness, often in the form of a butterfly wings pattern on the face).
- Potentially fatal complication after heart transplant (primary graft dysfunction) in which the transplanted heart stops working properly (see section 2 "Warnings and precautions")

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CORDARONE

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box. The expiry date refers to the last day of that month.

Store below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cordarone 200 mg scored tablets contain

- The active substance is:
Amiodarone hydrochloride..... 200 mg

For one scored tablet.

- The other ingredients are: lactose, maize starch, povidone, anhydrous colloidal silica, magnesium stearate.

What Cordarone 200 mg scored tablets look like and contents of the pack

This medicine is a scored tablet.

Box of 30, 50 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder

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Manufacturer

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