

amiodarone

Scored tablet

SANOFI 

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions or are unsure of anything, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Cordarone 200 mg scored tablets are and what they are used for
2. Before you take Cordarone 200 mg scored tablets
3. How to take Cordarone 200 mg scored tablets
4. Possible side effects
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1. WHAT CORDARONE 200 mg scored tablets ARE AND WHAT THEY ARE USED FOR

ANTIARRHYTHMICS, CLASS III

This medicine is used to prevent and treat certain heart rhythm disorders.

2. BEFORE YOU TAKE CORDARONE 200 mg scored tablets

If your doctor has told you that you are intolerant to some sugars, contact him or her before taking this medicine.

This medicine MUST NOT BE USED in the following situations:

- known allergy to iodine, amiodarone or any of the other ingredients of the medicine,
- hyperthyroidism,
- certain heart rhythm and/or conduction disorders,
- excessively slow heart rate,
- from the second trimester of pregnancy,
- breast-feeding,
- in combination with medicines that may induce torsades de pointe (serious heart rhythm disorders):
 - class Ia antiarrhythmics (quinidine, hydroquinidine, disopyramide),
 - class III antiarrhythmics (sotalol, dofetilide, ibutilide),
 - other medicines (arsenious trioxide, bepridil, cisapride, diphemanil, dolasetron IV, erythromycin IV, mizolastine, moxifloxacin, spiramycin IV, toremifene, vincamine IV) (see "Taking or using other medicines").

Take special care with Cordarone 200 mg scored tablets

Special warnings

Inform your treating physician if you experience unusual breathlessness, difficulty breathing or dry cough either alone or with long-term or unexplained deterioration of general health, tiredness or fever, or if you experience diarrhea, weight loss, muscle pain, reduced vision or if your heart rate starts to accelerate.

You should not take this medicine if you have galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption syndrome (rare hereditary diseases).

It is not recommended to use amiodarone concomitantly with ciclosporin, diltiazem (injection) and verapamil (injection), some antiparasitic agents (halofantrine, lumefantrine, pentamidine), certain neuroleptics (amisulpride, chlorpromazine, cyamemazine, droperidol, fluphenazine, haloperidol, levomepromazine, pimozide, pipamperone, pipotiazine, sertindole, sulpiride, sultopride, tiapride, zuclopenthixol) and methadone (see "Taking or using other medicines").

Precautions for use

Protect yourself from the sun throughout treatment, to avoid a "sunburn" type of reaction.

During treatment, you may be asked to have blood tests to monitor your thyroid or liver.

If you have a pacemaker or an implantable cardioverter defibrillator, you are advised to ask your physician to check that it is working correctly before and several times after starting amiodarone treatment as well as any time that the dose is adjusted.

Before surgery, tell your anesthesiologist that you are receiving amiodarone treatment.

The safety and efficacy of amiodarone are unknown for children.

Taking or using other medicines

This medicine MUST NOT BE USED in combination with medicines likely to induce torsades de pointe (serious heart rhythm disorders) such as some antiarrhythmics (quinidine, hydroquinidine, disopyramide, dofetilide, ibutilide, sotalol) and other medicines (such as arsenious trioxide, bepridil, cisapride, diphemanil, dolasetron IV, erythromycin IV, mizolastine, moxifloxacin, spiramycin IV, toremifene, vincamine IV).

This medicine MUST BE AVOIDED in combination with ciclosporin, injectable diltiazem, injectable verapamil, some antiparasitics (halofantrine, lumefantrine, pentamidine), some neuroleptics (amisulpride, chlorpromazine, cyamemazine, droperidol, fluphenazine, haloperidol, levomepromazine, pimozide, pipamperone, pipotiazine, sertindole, sulpiride, sultopride, tiapride, zuclopenthixol) and with methadone (see "Special warnings").

TO AVOID ANY INTERACTIONS BETWEEN DIFFERENT MEDICINES, YOU MUST INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER TREATMENT YOU MAY BE TAKING.

Pregnancy and breast-feeding

Pregnancy

This medicine is contraindicated from the 2nd trimester of pregnancy because it contains iodine.

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

Breast-feeding

Breast-feeding is contraindicated in women taking this treatment.

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

List of excipients with specific effects: lactose.

3. HOW TO TAKE Cordarone 200 mg scored tablets

Dosage

The usual dose varies depending on the person, but is usually as follows:

- initial treatment (loading dose): 3 tablets daily for 8 to 10 days,
- maintenance treatment: 1/2 to 2 tablets daily.

You must always follow the prescription strictly and never change the dosage without medical advice. Similarly, you must not interrupt your treatment without medical advice.

Method of administration

Oral use.

Frequency of administration

The tablets can be swallowed before, during or away from meals. The properties of the tablet are not altered if it is crushed.

Duration of treatment

STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

If you take more Cordarone 200 mg scored tablets than you should
If you take too high a dose of this medicine, immediately call your doctor or regional poison information center.

If you forget to take Cordarone 200 mg scored tablets

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

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

4. POSSIBLE SIDE EFFECTS

As with all medicines, Cordarone 200 mg scored tablets can cause side effects in some patients, although not everybody gets them.

Effects should be reported to your doctor who will tell you if you should continue or stop treatment.

Very common:

- vision disorders (feeling of being in the fog or seeing colored halos around objects),
- skin reaction to the sun,
- changes in thyroid hormones without clinical signs of thyroid disease,
- increase in certain liver enzymes in the blood (transaminases),
- benign gastrointestinal disorders (nausea, vomiting, bad taste in the mouth).

Common:

- grey skin color,
- thyroid disease (weight gain, feeling cold and tired, or on the contrary, excessive weight loss and diarrhea),
- breathing difficulties (difficulty breathing, breathlessness, fever, dry cough) which can be very serious,
- tremor,
- difficulty sleeping as well as nightmares,
- difficulties walking (nerve damage in the legs),
- acute liver damage and/or jaundice, which can be very serious,
- slowing of the heart rate.

Less common:

- Cardiac conduction disorders,
- Damaged muscles in the arms and legs.

Very rare:

- blurred or reduced vision,
- skin reactions with redness and itching,
- hair loss,
- breathing difficulties in patients with asthma or during surgery, which can be very serious,
- chronic liver damage,
- pronounced slowing of heart rate,
- decrease in the number of blood platelets,
- kidney damage,
- headache (if you have headache, consult your doctor),
- decrease in blood sodium.

Unknown:

- pulmonary hemorrhage often with breathing difficulties,
 - allergic reaction with swelling of the face and neck.
- If you notice any side effects not listed in this leaflet, or if any of the side effects become serious, please tell your doctor or pharmacist.

5. How to store Cordarone 200 mg scored tablets

Keep out of the reach and sight of children.
Do not use Cordarone 200 mg scored tablets after the expiry date which is stated on the box.
Store at a temperature no higher than +30°C.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist what to do with unused medicines. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Cordarone 200 mg scored tablets contain

The active substance is:
Amiodarone hydrochloride200 mg
for one scored tablet.

The other ingredients are:
Lactose, corn 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.

Marketing Authorization Holder and Operating Company

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1-13, boulevard Romain Rolland
75014 Paris
France

Manufacturer
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This leaflet was last revised in: June 2011.

<p style="text-align: center;">THIS MEDICAMENT</p> <p>Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.</p> <p>Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.</p> <p>The doctor and the pharmacist are the experts in medicines, their benefits and risks.</p> <ul style="list-style-type: none">• Do not by yourself interrupt the period of treatment prescribed.• Do not repeat the same prescription without consulting your doctor.• Keep all medications out of reach of children. <p style="text-align: center;">Council of Arab Health Ministers, Union of Arab Pharmacists.</p>
