

PATIENT INFORMATION LEAFLET

CADRONAX (AMIODARONE 100mg, 200mg Tablets BP)

Please read this leaflet carefully before you start to take your medicine. It contains important information.

Keep the leaflet in a safe place because you may want to read it again.

If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be 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 CADRONAX is and what it is used for.
2. Before you take CADRONAX.
3. How to take CADRONAX.
4. Possible side effects.
5. How to store CADRONAX.
6. Further information.

1. WHAT CADRONAX ARE AND WHAT THEY ARE USED FOR

CADRONAX belong to a group of medicines called anti-arrhythmics. They are used when the heartbeat is very irregular or very fast.

They are only used for serious conditions which do not respond to other treatments or when other treatments cannot be used. Treatment with amiodarone is normally under hospital or specialist supervision.

2. BEFORE YOU TAKE CADRONAX

- If you are allergic (hypersensitive) to amiodarone or any of the other ingredients of CADRONAX.
- if you have heart block - which may cause a very slow, very fast or irregular pulse or dizziness
- if you are allergic to iodine
- if you have thyroid problems or have not yet had your thyroid function tested
- If you are taking certain medicines (see "Taking other medicines")
- if you are pregnant or breast feeding

Take special care with CADRONAX

Tell your doctor before taking these tablets if any of the following apply to you:

if you are elderly

- if you are exposed to sunlight for long periods (see section 4, Possible Side Effects)
- if you are going to have an operation
- if you have heart failure
- if you have a pacemaker or implantable cardioverter defibrillator
- if you take high doses of amiodarone or are elderly and suffer from a very slow heart rate
- if you have been taking amiodarone for long periods, as your doctor may need to monitor you to avoid delayed side effects
- if you suffer from blurred or decreased vision
- if you have liver problems
- if you suffer from nerve or muscular disorders
- if you have sudden shortness of breath or a dry cough.

Your doctor may want to arrange tests such as blood tests, chest x-rays and eye examinations before and during treatment with these tablets.

Taking other medicines

The effects of amiodarone can be altered by other medicines and the effects of the other medicines can be changed by amiodarone. Please check with your doctor if you are taking any of the following medicines: certain antibiotics called fluoroquinolones (e.g. moxifloxacin)

- medicines used to thin the blood (particularly warfarin)
- phenytoin (for epilepsy)
- tolbutamide (for diabetes)
- aspirin
- fentanyl (a strong painkiller)
- diuretics (water tablets)
- digoxin (used for heart problems).
- Beta blockers (used to treat high blood pressure, angina or an irregular heart beat) e.g. atenolol and propranolol - you must NOT take amiodarone if you are taking sotalol
- certain medicines to treat high blood pressure and angina (chest pain) e.g. verapamil and diltiazem
- medicines used to treat irregular heartbeats (e.g. quinidine, disopyramide, procainamide, and bretylium)
- medicines used to treat psychiatric problems (e.g. chlorpromazine, thioridazine, fluphenazine, amisulpiride, pimozide and haloperidol)
- lithium and tricyclic antidepressants (e.g. doxepin, maprotiline and amitriptyline)
- some antihistamines (used to treat allergies and hayfever) e.g. terfenadine and astemizole
- intravenous erythromycin, co-trimoxazole, amphotericin or pentamidine (used to treat infections)
- anti malarials (used to treat or prevent malaria) e.g. chloroquine, halofantrine, mefloquine and quinine
- ciclosporine and tacrolimus (used after transplant operations)

- oral steroids, e.g. prednisolone
- stimulant laxatives (e.g. dantron or bisacodyl) which may cause low levels of potassium in the blood
- flecainide (used to regulate the rate and rhythm of the heart).
- cholesterol reducing drugs (statins)
- lidocaine (a local anaesthetic)
- sildenafil (also known as Viagra)
- midazolam (a sedative)
- ergotamine

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking CADRONAX with food and drink

You should AVOID drinking grapefruit juice whilst on treatment with CADRONAX.

Grapefruit juice contains some substances that can change the way these tablets work.

You should limit the amount of alcohol you drink whilst taking these tablets.

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant, likely to become pregnant, or are breast feeding.

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

Driving and using machines

Amiodarone can cause eye disorders and blurred vision. If you are affected do not drive or operate machinery.

Important Information about some of the ingredients of CADRONAX

This medicine contains lactose. If you have been told that you have an intolerance to some

sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE CADRONAX

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

Swallow the tablets whole with a glass of water. CADRONAX can be taken with or without food.

Adults:

The usual dose is one 200mg tablet taken three times a day for the first week, followed by one 200mg tablet taken twice a day for the next week and then one 200mg taken daily

In some patients this may be reduced to one 100mg tablet taken each day.

Elderly:

Elderly patients may be prescribed lower doses. Your doctor will decide the correct dose for you.

Children and adolescents:

There are only limited data on the efficacy and safety in children. Your doctor will decide on an appropriate dose.

Keep taking your medicine until your doctor tells you to stop. Do not stop taking it because you feel better.

If you take more CADRONAX than you should

If you have taken too many tablets tell your doctor or go to the nearest hospital casualty department IMMEDIATELY. Take this leaflet and any remaining tablets with you so the doctor knows what you have taken.

If you forget to take CADRONAX

If you forget a dose take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

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

You should contact your doctor as soon as possible if you experience any of the following symptoms, as you may have to stop taking the tablets:

jaundice (yellowing of the skin or whites of the eyes)

- extreme restlessness and / or loss of weight
- extreme tiredness and / or weight increase
- persistent cough and / or shortness of breath or fever
- pins and needles, weakness of hands or legs, cramps and loss of balance
- problems with your eyesight
- problems with the rhythm of the heart including palpitations (heart flutter) or chest pain.

Exposure to sunlight: Amiodarone can cause some patients to become sensitive to the sun or may cause a discolouration of the skin or a rash. You should avoid exposure of your skin to direct sunlight or sunlamps. You should take sensible precautions when you are in the sun such as wearing a wide brimmed hat and keeping arms and legs covered. Use a total sun block cream for exposed areas of skin. Occasionally, amiodarone may cause a grey or blue discolouration of skin exposed to light. If you are sensitive to the sun, then this may persist for some time after treatment stops.

The following side effects have also been reported. Tell your doctor or pharmacist if you get any troublesome symptoms which you think might be side effects.

Very common side effects (probably affecting more than 1 in 10 people):

blurred vision

- feeling sick
- vomiting
- a metallic taste
- sensitivity

Common side effects (probably affecting fewer than 1 in 10 people)

- slow pulse
- liver problems (enlarged liver, jaundice, liver failure)
- disturbed sleep patterns
- shortness of breath
- thyroid problems
- coughing,
- shakiness.

Uncommon side effects (probably affecting fewer than 1 in 100 people)

difficulty balancing and walking

- muscle pain and weakness
- irregular pulse / dizziness.

Very rare side effects (probably affecting fewer than 1 in 10,000 people)

- anaemia
- very slow pulse
- chronic liver disease
- progressive blindness
- impotence
- headache
- painful swelling of the testicles
- vertigo (dizziness)
- skin rashes
- hair loss
- scaly and flaking skin
- inflammation of the veins and problems with the blood (you may notice bruising or nose bleeds).

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

5. HOW TO STORE RAFOMAX

Keep out of the reach and sight of children.

Do not use CADRONAX after the expiry date which is stated on the carton after EXP;. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

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.

6. FURTHER INFORMATION

What CADRONAX contain

- The active substance is amiodarone hydrochloride.

The tablets are available in two strengths containing 100mg and 200mg amiodarone.

- The other ingredients are lactose monohydrate, maize starch, povidone K90, silica, colloidal anhydrous, pregelatinised starch and magnesium stearate.

What CADRONAX look like and contents of the pack

Amiodarone 100mg Tablets are round, white, flat with a central division line on one face and embossed on the reverse.

Amiodarone 200mg Tablets are round, white, flat with a central division line on one face and embossed on the reverse.

Amiodarone 100mg and 200mg Tablets are supplied in cartons of 28 tablets.



Manufactured By:

TAJ PHARMACEUTICALS Ltd.
Mumbai, INDIA

Marketed By:

TAJ PHARMA INDIA LTD.
CRESCENT, SAHAR AIRPORT ROAD,
MUMBAI, MAHARASHTRA 400059
INDIA

This leaflet was last revised in August 2015