

Package leaflet: Information for the user

Cordarone X® 100 mg tablets
Cordarone X® 200 mg tablets

amiodarone hydrochloride

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, please ask your doctor or pharmacist
- 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 X Tablets are and what they are used for
2. What you need to know before you take Cordarone X Tablets
3. How to take Cordarone X Tablets
4. Possible side effects
5. How to store Cordarone X Tablets
6. Contents of the pack and other information

1. What Cordarone X Tablets are and what they are used for

Cordarone X 100mg or 200mg Tablets (called Cordarone X Tablets in this leaflet) 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.

Cordarone X Tablets can be used to:

- Treat uneven heartbeats where other medicines either have not worked or cannot be used
- Treat an illness called Wolff-Parkinson-White Syndrome. This is where your heart beats unusually fast
- Treat other types of fast or uneven heartbeats known as ‘atrial flutter’ or ‘atrial fibrillation’. Cordarone X Tablets are used only when other medicines cannot be used
- Treat fast heartbeats which may happen suddenly and may be uneven. Cordarone X Tablets are used only when other medicines cannot be used.

2. What you need to know before you take Cordarone X Tablets

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to:
 - iodine
 - amiodarone
 - any of the other ingredients of Cordarone X Tablets (listed in Section 6 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 or sick sinus syndrome
- 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 taking certain other medicines which could affect your heartbeat (see ‘Taking other medicines’ below)
- You are pregnant or breast-feeding (see ‘Pregnancy and breast-feeding’ below)

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

Take special care with Cordarone X Tablets

Check with your doctor or pharmacist before taking your medicine if:

- You have heart failure
- You have liver problems
- You have any problems with your lungs or have asthma
- You have any problems with your eyesight. This includes an illness called ‘optic neuritis’
- The person having the medicine is a child or adolescent
- You are about to have an operation
- You are elderly (over 65 years of age). The doctor will need to monitor you more carefully
- You have a pacemaker or implantable cardioverter defibrillator (ICD). Your doctor will check that your device is working properly shortly after you start taking the tablets or if your dose is changed.
- You currently take a medicine containing sofosbuvir for the treatment of hepatitis C as it may result in a life-threatening slowing of your heart beat. Your doctor may consider alternative treatments. If treatment with amiodarone and sofosbuvir is needed, you may require additional heart monitoring.

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

Warnings and precautions

There have been very rare reports of potentially life-threatening skin rashes (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis) with the use of Cordarone. Symptoms of which may include: flu-like symptoms followed by a painful red or purplish rash that spreads and blisters. If you develop any of the above you must stop taking your medicine and inform your doctor straight away (see Section 4).

Tell your doctor immediately if you are taking a medicine containing sofosbuvir for the treatment of hepatitis C and during treatment you experience:

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

If you are on a heart transplant waiting list, your doctor may change your treatment. This is because taking amiodarone before heart transplantation has shown an increased risk of a life-threatening complication (primary graft dysfunction) in which the transplanted heart stops working properly within the first 24 hours after surgery.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Cordarone X Tablets can affect the way some other medicines work. Also some medicines can affect the way Cordarone X Tablets works.

In particular, do not take this medicine and tell your doctor, if you are taking:

Medicines which may induce torsade de pointes, a heart condition which may be fatal, such as:

- Other medicines for an uneven heartbeat (such as sotalol, quinidine, procainamide, disopyramide, bepridil or bretylium).

- Medicines for infections (such as intra-venous erythromycin, co-trimoxazole, moxifloxacin, pentamidine, vincamine or cisapride)
- Medicines for schizophrenia (such as chlorpromazine, thioridazine, fluphenazine, pimozide, haloperidol, amisulpiride or sertindole)
- Medicines for other mental illnesses (such as lithium, doxepin, maprotiline or amitriptyline)
- Medicines for malaria (such as quinine, mefloquine, chloroquine or halofantrine)
- Medicines used for hay fever, rashes or other allergies called antihistamines (such as terfenadine, astemizole or mizolastine)

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

- Medicines for infection (such as ciprofloxacin, ofloxacin or levofloxacin)
- Medicines for heart problems called beta-blockers (such as propranolol)
- sofosbuvir, used for the treatment of hepatitis C
- Medicines called calcium channel blockers - for chest pain (angina) or high blood pressure (such as diltiazem or verapamil)
- Medicines for constipation (laxatives) such as bisacodyl or senna
- Medicines for high cholesterol (statins) such as simvastatin or pravastatin

The following medicines can increase the chance of you getting side effects, when taken with Cordarone X Tablets:

- Amphotericin (when given directly into a vein) - used for fungal infections
- Medicines for inflammation (corticosteroids) such as hydrocortisone, betamethasone or prednisolone
- Water tablets (diuretics)
- General anaesthetics or high dose oxygen - used during surgery
- Tetracosactide - used to test some hormone problems

Cordarone X Tablets may increase the effect of the following medicines:

- Ciclosporin and tacrolimus - used to help prevent rejection of transplants
- Medicines for impotence such as sildenafil, tadalafil or vardenafil
- Fentanyl - used for pain relief
- Ergotamine - used for migraines
- Midazolam - used to relieve anxiety or to help you relax before surgery
- Flecainide - another medicine used for uneven heartbeats. Your doctor should monitor your treatment and may half your dose of Flecaïnide
- Lidocaine – used as an anaesthetic.
- Warfarin, dabigatran, medicines used to thin the blood
- Phenytoin for prevention of seizures
- Digoxin for heart problems

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

Taking Cordarone X Tablets with food and drink

Do not drink grapefruit juice while taking this medicine. This is because drinking grapefruit juice while taking Cordarone X Tablets can increase your chance of getting side effects.

Limit the amount of alcohol you drink while taking this medicine. This is because drinking alcohol while taking this medicine will increase the chance of you having problems with your liver. Talk to your doctor or pharmacist about the amount of alcohol you can drink.

Protect your skin from sunlight

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.

Pregnancy and breast-feeding

- Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or think you may be pregnant. Cordarone X Tablets are not normally given during pregnancy
- Do not take if you are breast-feeding or plan to breast-feed. This is because small amounts of this medicine may pass into the mothers’ milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Cordarone X Tablets is unlikely to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Cordarone X Tablets

This medicine contains:

- **Lactose (a type of sugar):** If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine
- **Iodine:** Cordarone X Tablets contain 37.5mg of iodine in a 100 mg tablet and 75 mg of iodine in a 200mg tablet. Iodine is present in amiodarone hydrochloride, the medicine your tablets contain. Iodine can cause problems to your thyroid (see ‘Tests’ below)

3. How to take Cordarone X Tablets

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

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets 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 take

Adults

- The usual starting dose is 200 mg (one 200 mg or two 100 mg Cordarone X Tablets) **three times** each day for one week
- The dose will then be lowered to 200 mg **twice** each day for one week
- The dose will then be lowered to 200 mg **once** each day, until you are told otherwise
- In some cases, your doctor may then decide to either increase or lower the amount you take each day. This will depend on how you react to this medicine.

Children and adolescents

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

Elderly

- The doctor may give you a lower dose of Cordarone X Tablets. Also, the doctor should check your blood pressure and thyroid function regularly.

If you take more Cordarone X Tablets than you should

If you take more Cordarone X Tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: feeling dizzy, faint or tired, confusion, slow heartbeat, damage to the liver or being sick.

If you forget to take Cordarone X Tablets

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 taking Cordarone X Tablets

Keep taking Cordarone X Tablets until your doctor tells you to stop. Do not stop taking Cordarone X Tablets just because you feel better. If you stop taking this medicine the uneven heartbeats may come back. This could be dangerous.

Tests

Your doctor may do regular thyroid tests while you are taking this medicine. This is because Cordarone X Tablets contain iodine which can cause problems to your thyroid. Your doctor may also do other regular tests such as blood tests, chest X-rays, ECG (electrical test of your heartbeat) and eye tests both before and while you are taking Cordarone X Tablets. If you have any further questions on the use of this product, ask your doctor or pharmacist

4. Possible side effects

Like all medicines, Cordarone X Tablets can cause side effects, although not everybody gets them. Cordarone X Tablets may stay in your blood for up to a month after stopping treatment. You may still get side effects in this time.

Stop taking Cordarone X Tablets and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swollen eyelids, face, lips, throat or tongue

Common (affects less than 1 in 10 people)

- 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 or damage which can be fatal
- Difficulty breathing or tightness in the chest, coughing which will not go away, wheezing, weight loss and fever. This could be due to inflammation of your lungs which can be fatal

Uncommon (affects less than 1 in 100 people)

- Your heartbeat becomes even more uneven or erratic. This can lead to a heart attack, so you should go to hospital straight away

Very rare (affects less than 1 in 10,000 people)

- You get loss of eyesight in one eye or your eyesight becomes dim and colourless. Your eyes may feel sore or tender and feel painful to move. This could be an illness called 'optic neuropathy or neuritis'
- Your heartbeat becomes very slow or stops beating. If this happens, go to hospital straight away

Not known (frequency cannot be estimated from the available data)

- You experience a life-threatening skin reaction characterised by rash, blisters, peeling skin and pain (toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), bullous dermatitis, Drug reaction with eosinophilia and systemic symptoms (DRESS).
- Severe allergic reaction (anaphylactic reaction, anaphylactic shock)
- Your white blood cell count drops (neutropenia or agranulocytosis)
- Life-threatening complication after heart transplantation (primary graft dysfunction) in which the transplanted heart stops working properly (see section 2, Warnings and precautions)

Stop taking Cordarone X Tablets and see a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

Uncommon (affects less than 1 in 100 people)

- Feeling numb or weak, tingling or burning feelings in any part of your body

Very rare (affects less than 1 in 10,000 people)

- Skin rash caused by narrow or blocked blood vessels (called 'vasculitis')
- Headache (which is usually worse in the morning or happens after coughing or straining), feeling sick (nausea) fits, fainting, eyesight problems or confusion can occur. These could be signs of problems with your brain
- Moving unsteadily or staggering, slurred or slow speech
- Feeling faint, dizzy, unusually tired and short of breath. These could be signs of a very slow heartbeat (especially in people over 65 years old) or other problems with your heart's natural beat.

Some cases of bleeding in the lungs have been reported in patients taking Cordarone X Tablets. You should tell your doctor straight away if you cough up any blood

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

Very common (affects more than 1 in 10 people)

- Blurred eyesight or seeing a coloured halo in dazzling light

Common (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', which can sometimes be fatal
- 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

Uncommon (affects less than 1 in 100 people)

- Muscle cramps, stiffness or spasm

Very rare (affects less than 1 in 10,000 people)

- Swelling of the testicles
- Red, scaly patches of skin, loss of hair or loosening of nails (called 'exfoliative dermatitis')
- Feeling tired, faint, dizzy or having pale skin. These could be signs of anaemia
- You may bleed or bruise more easily than usual. This could be because of a blood disorder (called 'thrombocytopenia')
- Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called 'syndrome of inappropriate anti-diuretic hormone secretion' (SIADH)

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

Very common (affects more than 1 in 10 people).

- Feeling sick (nausea) or being sick (vomiting)
- Change in the way things taste
- Changes in the amount of liver enzymes at the beginning of treatment. This can be seen in blood tests
- Burning more easily in the sun (see 'Protect your skin from sunlight' in Section 2)

Common (affects less than 1 in 10 people)

- Slightly slower heart beat
- Nightmares
- Problems sleeping
- Itchy, red rash (eczema)
- Constipation

Uncommon (affects less than 1 in 100 people)

- Dry mouth

Very rare (affects less than 1 in 10,000 people)

- Headache
- Balance problems, feeling dizzy (vertigo)
- Difficulty in getting or maintaining an erection or in ejaculating
- Hair loss, balding
- Skin rash
- Skin redness during radio-therapy
- Increase in blood creatinine, which will show up in a blood test. This may be a sign of impaired kidney function.

Not known (frequency cannot be estimated from the available data)

- Urticaria
- Granuloma (inflammation of tissue), including bone marrow granuloma
- Pancreatitis/acute pancreatitis (sudden inflammation of the pancreas)
- Decreased appetite
- Parkinsonism (unusual muscle movements, stiffness, shaking and restlessness)
- Parosmia (abnormal sense of smell)
- Confusion (delirium), hallucinations
- Decreased libido

Other side effects reported:

Lupus-Like syndrome (a disease where the immune system attacks various parts of the body and leading to pain, stiffness and swelling in joints and red skin, sometimes in the shape of butterfly wings on the face)

Tests

Your doctor will take regular tests to check how your liver is working. Cordarone X Tablets can affect how your liver works. If this happens, your doctor will decide whether you should keep taking these tablets.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

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

5. How to store Cordarone X Tablets

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 carton and blister foil after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the blister strip in the outer carton in order to protect from light.

Do not use this medicine if you notice your tablets are crumbling, broken or discoloured.

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 X Tablets contain:

- Each Cordarone X 100mg Tablet contains 100mg of the active substance, amiodarone hydrochloride.
- Each Cordarone X 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.

What Cordarone X Tablets looks like and contents of the pack

Cordarone X 100mg Tablets imported from the UK are round, white tablets with a break-line on one side, and '100' and a logo on the other side.

Cordarone X 200mg Tablets imported from The Netherlands, Czech Republic and Hungary are round, white tablets with a break-line, '200' and a logo on one side, plain on the other side.

Cordarone X 200mg Tablets imported from the UK are round, white tablets with a break-line on one side, '200' and a logo on the other side.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Pack size:

Cordarone X 100mg Tablets are available in blister packs of 28 tablets.
Cordarone X 200mg Tablets are available in blister packs of 28, 30 or 60 tablets.
Not all pack sizes may be marketed.

Parallel Product Authorisation (PPA) Number:

Cordarone X 200mg PPA 465/119/1
Cordarone X 100mg PPA 465/119/2

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturers

Sanofi-Synthelabo Limited, Edgefield Avenue, Fawdon, Newcastle-upon-Tyne NE3 3TT, UK or Chinoin Pharmaceutical and Chemical Works Co. Ltd., Hungary or Sanofi Winthrop Industrie, France or Sanofi-Aventis S.A., Riells I Viabrea, Spain or Fawdon Manufacturing Centre, Edgefield Avenue, Fawdon, Newcastle-upon-Tyne, NE3 3TT, UK or S.C. Zentiva S.A., 50, Theodor Pallady Blvd., 032266, Bucharest, Romania.

Cordarone X is a registered trademark of SANOFI.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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