

PACKAGE LEAFLET: INFORMATION FOR THE USER
Cordarone® X 150mg/3ml, solution for injection
amiodarone hydrochloride



Is this leaflet hard to see or read?
Phone 0800 035 2525 for help

Read all of this leaflet carefully before you start using 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, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Cordarone X is and what it is used for
2. What you need to know before you use Cordarone X
3. How to use Cordarone X
4. Possible side effects
5. How to store Cordarone X
6. Contents of the pack and other information

1. What Cordarone X is and what it is used for



Cordarone X 150mg/3ml, solution for injection (called Cordarone X in this leaflet) contains 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'). Using the injection helps your heartbeat to return to normal.

Cordarone X is normally only given in a hospital when a quick response is needed or when tablets cannot be given. Cordarone X 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 is used only when other medicines cannot be used.
- Treat fast heartbeats which may happen suddenly and may be uneven. Cordarone X is used only when other medicines cannot be used.

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The following information is intended for healthcare professionals only:

Practical information on preparation and administration of Cordarone X 150mg/3ml solution for injection (see also Section 3).

Posology and method of administration

Cordarone X Intravenous should only be used when facilities exist for cardiac monitoring, defibrillation, and cardiac pacing.

Cordarone X Intravenous may be used prior to DC cardioversion.

2. What you need to know before you use Cordarone X

Do not use this medicine and tell your doctor, pharmacist or nurse if:

- You are allergic (hypersensitive) to:
 - iodine
 - amiodarone
 - any of the other ingredients of Cordarone X (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.
- 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 have severe breathing problems.
- You have serious blood circulation problems.
- You have very low blood pressure.
- 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 use this medicine if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before using Cordarone X.

If you are on a heart transplant waiting list, your doctor may change your treatment. This is because taking Cordarone X 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.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using this medicine if:

- You have a weak heart ('cardiomyopathy') or heart failure
- You have low blood pressure
- You have liver problems
- You have any problems with your lungs including asthma
- You have any problems with your eyesight. This includes an illness called 'optic neuropathy' or 'neuritis'



The standard recommended dose is 5mg/kg bodyweight given by intravenous infusion over a period of 20 minutes to 2 hours. This should be administered as a dilute solution in 250ml 5% dextrose. This may be followed by repeat infusion up to 1200mg (approximately 15mg/kg bodyweight) in up to 500ml 5% dextrose per 24 hours, the rate of infusion being adjusted on the basis of clinical response.

In extreme clinical emergency the drug may, at the discretion of the clinician, be given as a slow injection of 150-300mg in 10-20ml 5% dextrose over a minimum of 3 minutes. This should not be repeated for

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- You have a problem with your thyroid gland
- You are taking amiodarone tablets
- You are about to have an operation
- The person using the medicine is an infant or child under 3 years old
- You have blistering or bleeding of the skin, including around your lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome'
- You have a severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body. You may also feel generally unwell, have a fever, chills and aching muscles (Toxic Epidermal Necrolysis)
- You currently take a medicine containing sofosbuvir for the treatment of hepatitis C as it may result in a life-threatening slowing of your heartbeat. Your doctor may consider alternative treatments. If treatment with amiodarone and sofosbuvir is needed, you may require additional heart monitoring

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 not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before using Cordarone X.

Other medicines and Cordarone X

Tell your doctor, pharmacist or nurse 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 can affect the way some other medicines work. Also some medicines can affect the way Cordarone X works.

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

- Other medicines for an uneven heartbeat (such as quinidine, procainamide, disopyramide, sotalol or bretylium)
- Medicines for infections (such as intravenous erythromycin, co-trimoxazole, moxifloxacin or pentamidine injection)
- Medicines for schizophrenia (such as chlorpromazine, thioridazine, fluphenazine, pimozide, haloperidol, amisulpride 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)
- Sofosbuvir, used for the treatment of hepatitis C

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)
- 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 atorvastatin

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

- Amphotericin (when given directly into a vein) used for fungal infections
- Corticosteroids used for inflammation such as hydrocortisone, betamethasone or prednisolone
- Water tablets (diuretics) such as furosemide
- General anaesthetics or high dose oxygen – used during surgery
- Tetracosactide – used to test some hormone problems
- Amiodarone tablets – used to control the uneven beating of the heart called 'arrhythmias'.

Cordarone X may increase the effect of the following medicines:

- Warfarin – used for thinning the blood. Your doctor should reduce your dose of warfarin and monitor your treatment closely.
- Digoxin – used for heart problems. Your doctor should monitor your treatment closely and may halve your dose of digoxin.
- Phenytoin – used to treat fits.
- Flecainide - another medicine used for uneven heartbeats. Your doctor should monitor your treatment closely and may halve your dose of flecainide.
- Ciclosporin, tacrolimus and sirolimus - used to help prevent rejection of transplants.
- Medicines for impotence such as sildenafil, tadalafil or vardenafil.
- Fentanyl – used for pain relief

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at least 15 minutes. Patients treated in this way with Cordarone X Intravenous must be closely monitored, e.g. in an intensive care unit.

Changeover from Intravenous to Oral therapy

As soon as an adequate response has been obtained, oral therapy should be initiated concomitantly at the usual loading dose (i.e. 200mg three times a day). Cordarone X Intravenous should then be phased out gradually.

Paediatric population

The safety and efficacy of amiodarone in children has not been established.

Due to the presence of benzyl alcohol, intravenous amiodarone is contraindicated in neonates, infants and children up to 3 years old.

Elderly

As with all patients it is important that the minimum effective dose is used. Whilst there is no evidence that dosage requirements are different for this group of patients they may be more susceptible to bradycardia and conduction defects if too high a dose is employed. Particular attention should be paid to monitoring thyroid function.

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- Ergotamine – used for migraines
- Midazolam – used to relieve anxiety or to help you relax before surgery
- Lidocaine – used as an anaesthetic

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

Taking Cordarone X with food and drink

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

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

Do not use this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant.
- You are breast-feeding or planning to breast-feed.

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

Cordarone X contains

Iodine: This medicine contains approximately 56 mg of iodine in a 3 ml ampoule. Iodine is present in amiodarone hydrochloride, the medicine your infusion contains. Iodine can cause problems to your thyroid (see 'Tests' below).

Benzyl Alcohol: This medicine contains 60mg benzyl alcohol in each 3ml ampoule which is equivalent to 20mg/ml.

Benzyl alcohol may cause allergic reactions.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. This medicine should not be used in newborn babies (up to 4 weeks old), unless recommended by your doctor.

This medicine should not be used for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

3. How to use Cordarone X

Your doctor or nurse will normally give you Cordarone X. This is because it needs to be given as an infusion into your vein in the hospital where the doctor can monitor your progress.

Using this medicine

- This medicine will be diluted before it is given to you
 - Your doctor will change you over to Cordarone X tablets as soon as possible
 - If you feel the effect of your medicine is too weak or too strong, tell your doctor, nurse or pharmacist
- If you are not sure why you are receiving Cordarone X or have any questions about how much Cordarone X is being given to you, speak to your doctor, pharmacist or nurse.

How much will be given to you

Your doctor will decide how much to give you depending on your illness.

Adults

- The usual dose is 5mg for every kilogram of your weight given over a period of 20 minutes to 2 hours.
- You may be given another infusion of approximately 15mg for every kilogram of your weight every 24 hours depending on your illness.
- In an emergency, your doctor may decide to give you a dose of 150mg to 300mg as a slow injection over 3 minutes.

Use in children and adolescents

- Medicines administered intravenously containing benzyl alcohol should be used with caution in children younger than 3 years old (see also "Cordarone X contains Benzyl alcohol").

Elderly

- The doctor may give you a lower dose of Cordarone X and monitor your heart rate and thyroid function more closely.

This medicinal product must not be mixed with other preparations in the same syringe. Do not inject other preparations in the same line.

If you use more Cordarone X than you should

Your doctor will carefully calculate how much Cordarone X you should get. Therefore, it is unlikely your doctor, nurse or pharmacist will give you too much of this medicine. But, if you think that you have been given too much or too little Cordarone X, tell your doctor, nurse or pharmacist.

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Cardiopulmonary resuscitation

The recommended dose for ventricular fibrillations/pulseless ventricular tachycardia resistant to defibrillation is 300 mg (or 5 mg/kg body-weight) diluted in 20 ml 5% dextrose and rapidly injected. An additional 150 mg (or 2.5 mg/kg body-weight) IV dose may be considered if ventricular fibrillation persists.

Special warnings and precautions for use – Monitoring advice

Cordarone X Intravenous should only be used in a special care unit under continuous monitoring (ECG and blood pressure).

IV infusion is preferred to bolus due to the haemodynamic effects sometimes associated with rapid injection. Circulatory collapse may be precipitated by too rapid administration or overdosage (atropine has been used successfully in such patients presenting with bradycardia).

Do not mix other preparations in the same syringe. Do not inject other preparations in the same line. If Cordarone X should be continued, this should be via intravenous infusion.

Repeated or continuous infusion via peripheral veins may lead to injection site reactions. When repeated or continuous infusion is anticipated, administration by a central venous catheter is recommended.

The following effects may happen: feeling dizzy, faint, sick, tired or confused. Having an abnormally slow or fast heartbeat. Too much amiodarone can damage the heart and liver.

If you forget to use Cordarone X

Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However, if you think you may have missed a dose, then talk to your doctor or nurse.

If you stop using Cordarone X

It is important for you to keep using Cordarone X injections until your doctor decides to stop them. If you stop using this medicine the uneven heartbeats may come back. This could be dangerous.

Tests

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

Your doctor may do regular thyroid tests while you are taking this medicine. This is because Cordarone X contains 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 using Cordarone X.

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 can cause side effects, although not everybody gets them.

Cordarone X may stay in your blood for up to a month after stopping treatment. You may still get side effects in this time.

Stop using Cordarone X and tell a doctor, nurse or pharmacist or go to a hospital straight away if:

Very rare (may affect up to 1 in 10,000 people)

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- Your heartbeat becomes very slow or stops beating. You may also feel dizzy, unusually tired and short of breath. This may occur especially in people over 65 years old or people with other heartbeat problems.
- Your heartbeat becomes even more uneven or erratic. This can lead to a heart attack, so you should go to hospital straight away.

- 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 very dangerous.
- 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 very dangerous.

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

- You have life-threatening irregular heart beat (Torsade de pointes).
- Symptoms include blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson syndrome.
- You have a severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body. You may also feel generally unwell, have a fever, chills and aching muscles (Toxic Epidermal Necrolysis).
- Inflammation of the skin characterized by fluid filled blisters (bullous dermatitis).
- You have flu like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophila) and enlarged lymph nodes (DRESS).

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

Very rare (may affect up to 1 in 10,000 people)

- 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.

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

Common (may affect up to 1 in 10 people)

- Scaly and itching rashes (eczema)
- Dizziness, lightheadedness, fainting. This may occur temporarily and is due to lowering of blood pressure.

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

- Inflammation of the pancreas which causes severe pain in the abdomen and back (pancreatitis)
- You may get more infections than usual. This could be caused by a decrease in the number of white blood cells (neutropenia).

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When given by infusion Cordarone X may reduce drop size and, if appropriate, adjustments should be made to the rate of infusion.

Anaesthesia: Before surgery, the anaesthetist should be informed that the patient is taking amiodarone.

Incompatibilities

Cordarone X Intravenous is incompatible with saline and should be administered solely in 5% dextrose solution. Cordarone X Intravenous, diluted with 5% dextrose solution to a concentration of less than 0.6mg/ml, is unstable. Solutions containing less than 2 ampoules

Cordarone X Intravenous in 500ml dextrose 5% are unstable and should not be used.

The use of administration equipment or devices containing plasticizers such as DEHP (di-2-ethylhexylphthalate) in the presence of amiodarone may result in leaching out of DEHP. In order to minimise patient exposure to DEHP, the final amiodarone dilution for infusion should preferably be administered through non DEHP-containing sets.

- Severe reduction in the number of white blood cells which makes infections more likely (agranulocytosis).
- 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'.
- Feeling extremely restless or agitated, weight loss, increased sweating and being unable to stand the heat. These could be signs of an illness called 'hyperthyroidism'.

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

Common (may affect up to 1 in 10 people)

- Slightly slower heart beat
- You have pain, swelling, irritation, reddening or skin discolouration in the area you have been injected with Cordarone X.
- Decrease in sex drive

Very rare (may affect up to 1 in 10,000 people)

- Changes in the amount of liver enzymes at the beginning of treatment. This can be seen in blood tests.
- Feeling sick (nausea)
- Headache
- Sweating
- Hot flushes
- Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called 'syndrome of inappropriate antidiuretic hormone secretion' (SIADH).

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

- Life-threatening irregular heart rhythm
- Life-threatening complication after heart transplantation (primary graft dysfunction) in which the transplanted heart stops working properly (see section 2, Warnings and precautions).
- Hives (itchy, lumpy rash)
- Back pain
- Seeing, hearing or feeling things that are not there (hallucinations)

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cordarone X

This medicine will be kept by your doctor or pharmacist in a safe place where children cannot see or reach it.

Do not use Cordarone X 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 container. Only clear solutions free of particles should be used.

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 contains

- Each 3ml ampoule contains 150mg of the active substance, amiodarone hydrochloride
- The other ingredients are benzyl alcohol, polysorbate and water for injections

What Cordarone X looks like and contents of the pack

Cordarone X is a pale, yellow solution and is available as 3ml glass ampoules in cartons of 6 or 10. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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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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Shelf life

24 months.

Special precautions for storage

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