

Cordarone X[®]

Amiodarone hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cordarone X tablets and injection.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. In deciding to give you Cordarone X, your doctor has weighed the risks of you taking Cordarone X against the benefits it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with this medicine.

You may need to read it again.

What Cordarone X is used for

Cordarone X is used to control a fast or irregular heart beat.

It works by lengthening the gap between one heart beat and the next, helping to bring the heart rate to a slower and more regular pace.

Cordarone X is not recommended for use in children.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor or pharmacist if you have any questions about why this medicine has been prescribed for you.

Before you take it

When you must not use Cordarone X

- 1. Do not use Cordarone X if you are allergic to amiodarone or iodine or any of the ingredients listed at the end of this leaflet.**

The symptoms of an allergic reaction may include a rash, itching, swelling, coughing, an asthma attack or hayfever.

- 2. Do not use Cordarone X if you are pregnant or intending to get pregnant.**

Cordarone X is best avoided in the 3 months before getting pregnant and during pregnancy. This is because it can stay in the body for several months even after you stop taking it.

- 3. Do not breastfeed if you are using Cordarone X as it can be found in breast milk.**

If you are breastfeeding, alternative feeding arrangements such as bottle feeding should be made for your baby.

Talk to your doctor about the risks and benefits of taking Cordarone X during pregnancy and breastfeeding.

- 4. Do not use Cordarone X if you have or have had any thyroid problems.**
- 5. Do not use Cordarone X if you have heart problems that may cause you to faint.**

If you have a pacemaker, your doctor may allow the use of it.

- 6. Do not use Cordarone X injection if you have any of the following:**

- Low blood pressure
- Severe problems in breathing
- Heart disease or failure
- Shock

- 7. Do not use Cordarone X injection in neonates (children less than one month of age) or premature neonates.**

Talk to your doctor if you are unsure whether you have any of the conditions listed above.

Make sure your doctor is aware of all medications you are taking as some medications may affect how Cordarone X works.

Do not use Cordarone X after the expiry (EXP) printed on the pack.

It you use the medicine after the expiry date has passed, it may not work as well.

Do not use Cordarone X if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaint unless your doctor says it is safe. Do not give this medicine to anyone else.

Before you start to use Cordarone X

Tell your doctor if you are pregnant or intend to become pregnant.

Tell your doctor if you are breastfeeding or planning to breastfeed.

Tell your doctor if you have or have had any medical conditions, especially the following:

- Other heart conditions
- Blood pressure problems
- Liver problems
- Thyroid problems

If you have not told your doctor about any of the above, tell them before you use this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines may be affected by Cordarone X, or may affect how well Cordarone X works.

You need to tell your doctor if you are using any other medicines, including:

- any medicines for your heart
- any medicines for your blood pressure
- medicines which reduce the activity of your immune system, such as ciclosporin, cortisone or tacrolimus
- diuretics (water tablets)
- antibiotics, including intravenous erythromycin and pentamidine
- stimulant laxatives e.g. Bisacodyl, castor oil, senna
- MAO inhibitors (a type of medicine used to treat depression)
- antipsychotics (medicines used to treat certain mental and emotional conditions)
- phenytoin (a medicine used to treat epilepsy)
- warfarin and other medicines which thin the blood
- simvastatin and other statins (medicines used to lower cholesterol)
- colchicine (a medicine used to treat gout)
- digoxin (a medicine used to treat heart conditions)

- medicines to treat a fast or irregular heart beat such as flecainide and sotalol
- fentanyl (a medicine used to treat pain)
- sildenafil (Viagra)
- triazolam (a medicine used to treat insomnia)
- ergotamine (a medicine used to treat migraine)
- general anaesthesia
- lidocaine (lignocaine) (a topical anaesthetic)
- amphotericin B (amphotericin) (a medicine used to treat fungal infections)
- antiviral medication eg sofosbuvir, daclatasvir, simeprevir, ledipasvir

If you are unsure whether you are taking one of the above drugs, ask your doctor or pharmacist.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell them before you take Cordarone X.

How to use Cordarone X

How to take it (tablets)

Therapy will be started as soon as possible once your heart beat is controlled. An overlap of up to 2 days with the injection may occur.

Swallow Cordarone X tablets whole, with water or another liquid such as tea or milk.

How much to take (tablets)

The usual dose is outlined below:

- 200 mg, three times a day for 1 week.
- Therapy is then continued with 200 mg two times a day for a further week.

- The dose may then be reduced to 200 mg once per day.

Your doctor or pharmacist will tell you how many Cordarone X tablets you should take.

The directions given to you by your doctor or pharmacist may be different from the information in this leaflet.

Talk to your doctor or pharmacist if you are unsure what dose to take.

Do not stop taking it unless your doctor tells you to, even if you feel better.

How to give it (injection)

The injectable dose will only be given in hospitals.

How much to give (injection)

The usual dose is:

- 5 mg/kg given slowly over a period of 20 minutes to 2 hours.

Further doses may also be given based upon your response to the treatment. An overlap of up to 2 days with the tablets may occur.

If you forget to take it

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the dose you missed, and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, or have trouble remembering when to take your medicine, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too

much Cordarone X. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Cordarone X

Things you must do

Be sure to keep all of your doctor appointments so that your progress can be checked.

- To help prevent unwanted side effects, your doctor may need to perform the following tests, depending on the length of treatment with Cordarone X:
- ECG
- Eye tests
- Chest X-rays
- Liver function tests
- Thyroid tests

Take Cordarone X exactly as your doctor has prescribed.

Tell all the doctors, dentists and pharmacists who are treating you that you are using Cordarone X.

Tell your doctor if you become or intend to become pregnant while using Cordarone X.

Things you must not do

Do not suddenly stop taking Cordarone X without checking with your doctor.

Do not use Cordarone X to treat any other complaints unless your doctor says it is safe.

Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Always use a 30+ sunscreen and wear a hat and protective clothing when you are outdoors. Do not use a sunlamp.

Using Cordarone X may make your skin more sensitive to the sun or sunlamps. This can range from an increased tendency to tan to intense redness and swelling of the skin.

If you are going to have surgery, tell the anaesthetist that you are using Cordarone X.

This medicine may affect some of the medicines that may be needed, such as general anaesthetics.

Tell your doctor or medical professional that you are using Cordarone X before you are given any medical procedure or any new medicines.

Avoid drinking large quantities of grapefruit juice as it may affect the absorption of Cordarone X.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while using Cordarone X.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Treatment with amiodarone may cause serious lung, liver and eye damage and may worsen heart problems.

Tell your doctor if you notice any of the following and they worry you:

- symptoms of an overactive thyroid including increase in appetite, weight loss, restlessness, heat intolerance, increased sweating, tremors, swelling of your neck (goiter) and a rapid heart rate
- symptoms of an underactive thyroid including tiredness, lethargy, muscle weakness, cramps, feeling the cold, a slow heart rate, dry and flaky skin, hair loss, a deep and husky voice and weight gain

- allergic condition which causes joint pain, skin rashes, fever and kidney problems
- a feeling of "pins and needles" or numbness in the hands, legs or feet
- muscle weakness, uncontrolled movements or poor coordination
- small cloudy spots forming on the eyeball. These usually go away after you stop the drug and they rarely affect your sight
- increased skin sensitivity to sunlight - always wear a sunscreen
- bluish skin discolouration
- rash or hives
- pain or swelling at the site where you were injected
- tremor, insomnia or other sleep disorders, vivid dreams or nightmares
- metallic taste
- constipation
- loss of appetite
- slow heart beat

Tell your doctor immediately if you notice any of the following:

- yellowing of the skin or eyes (called jaundice, a symptom of liver changes)
- shortness of breath, wheezing or other difficulty in breathing
- swelling of the face, lips, mouth, tongue or throat
- clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/or speech
- chest pain, cough or spitting up of blood
- nausea or vomiting, stomach pain, yellow skin, unusual tiredness or passing dark-coloured urine
- changes to heartbeat such as pounding heart, very rapid or very slow heartbeat
- faintness or light headedness

- blurring or deterioration of vision, sensitisation of eyes to light
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals

These may be serious side effects of Cordarone X. If any of the above symptoms occurs or you suspect any other drug reaction, please consult your doctor immediately.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Your doctor will monitor you very carefully for side effects. This will involve blood tests to check how well your liver and thyroid are functioning. It will also involve regular chest x-rays, ECGs and eye tests.

Your doctor will tell you how often you need to have these tests. This will depend on how long you are on Cordarone X for and what dose you are on.

After using Cordarone X

Storage

Tablets

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the box or blister pack they may not keep well.

Keep it in a cool, dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Injection

If you need to store it before taking it to a hospital, make sure it is stored in a place where the temperature is between 8 and 25°C. Do not refrigerate.

Cordarone X injection should only be given to you in a hospital.

Disposal

If your doctor tells you to stop taking Cordarone X, or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Tablets

Cordarone X tablets are available in two different strengths:

100 mg tablets

white to off-white biconvex tablet embossed on one side with '100' and 'action potential' and scored on other.

200 mg tablets:

white to off-white biconvex tablet embossed with '200' and 'action potential' on one side and scored on the other.

Each box contains 30 tablets.

Injection

Cordarone X injection is a clear, pale yellow solution. The injection comes as a 3 mL ampoule.

Each box contains 6 ampoules.

Ingredients

Tablets

Active Ingredient:

- 100 mg tablets: each tablet contains amiodarone hydrochloride 100 mg.
- 200 mg tablets: each tablet contains amiodarone hydrochloride 200 mg.

Other Ingredients:

The tablets also contain lactose monohydrate, maize starch, povidone, anhydrous colloidal silica and magnesium stearate.

Injection

Active Ingredient:

Each 3mL ampoule contains amiodarone hydrochloride 150 mg.

Other Ingredients:

The injection also contains benzyl alcohol, polysorbate 80 and water for injections.

Manufacturer

Cordarone X is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Cordarone X is supplied in New Zealand by:

sanofi-aventis new zealand limited

56 Cawley Street

Ellerslie

Auckland

This leaflet was prepared in November 2021

Australian Registration Number:

100 mg Tablets: AUST R 15359

200 mg Tablets: AUST R 15361

Injection: AUST R 15360

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cordarone-x-ccds20-cmiv15-nov21