

Cordarone X[®]

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Cordarone X?

Cordarone X contains the active ingredient amiodarone hydrochloride. Cordarone X is used to control a fast or irregular heartbeat. For more information, see Section [1. Why am I using Cordarone X?](#) in the full CMI.

2. What should I know before I use Cordarone X?

Do not use if you have ever had an allergic reaction to amiodarone hydrochloride, iodine, or any of the ingredients listed at the end of the CMI. Do not use Cordarone X if you have or have had any thyroid problems, heart problems that may cause you to faint, low blood pressure, severe problems breathing, heart disease or failure, shock, are pregnant, intend to become pregnant or are breastfeeding.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Cordarone X?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cordarone X and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Cordarone X?

- Tablets: Your doctor will tell you how many Cordarone X tablets you should take. Swallow Cordarone X tablets whole, with water or another liquid such as tea or milk.
- Injection: The injectable dose will only be given in hospitals.
- More instructions can be found in Section [4. How do I use Cordarone X?](#) in the full CMI.

5. What should I know while using Cordarone X?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Cordarone X.• Attend your doctor appointments so that your progress can be checked.• Tell your doctor straight away if you become pregnant or intend to become pregnant.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly without checking with your doctor.
Things to be careful of	<ul style="list-style-type: none">• Always use a sunscreen and wear a hat and protective clothing when you are outdoors. Do not use a sunlamp.• Avoid drinking large quantities of grapefruit juice.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Cordarone X affects you.
Looking after your medicine	<ul style="list-style-type: none">• Tablets: Keep it in a cool, dry place where the temperature stays below 30°C. Protect from light.• Injection: If you need to store it before taking it to a hospital, make sure it is stored in a place where the temperature stays between 8 to 25°C. Do not refrigerate. Protect from light.

For more information, see Section [5. What should I know while using Cordarone X?](#) in the full CMI.

6. Are there any side effects?

Treatment with amiodarone may cause serious lung, liver and eye damage and may worsen heart problems. Serious side effects may include changes to heartbeat such as pounding, rapid or very slow heartbeat; allergic reaction; blurring or deterioration of vision, sensitisation of eyes to light; severe blisters and bleeding in the lips, eyes, mouth, nose and genitals; yellow skin or eyes, faintness, light-headedness; nausea, vomiting, stomach pain, unusual tiredness, passing dark-coloured urine; clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements/speech; chest pain, cough or spitting up blood. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Cordarone X[®]

Active ingredient(s): *amiodarone hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cordarone X. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Cordarone X.**

Where to find information in this leaflet:

- [1. Why am I using Cordarone X?](#)
- [2. What should I know before I use Cordarone X?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Cordarone X?](#)
- [5. What should I know while using Cordarone X?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Cordarone X?

Cordarone X contains the active ingredient **amiodarone hydrochloride**. Cordarone X is a Class III antiarrhythmic agent.

Cordarone X is used to control a fast or irregular heartbeat.

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.

Your doctor may have prescribed this medicine for another reason.

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

2. What should I know before I use Cordarone X?

Warnings

Do not use Cordarone X if you:

- are allergic to amiodarone hydrochloride, iodine, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- have or have had any thyroid problems
- have heart problems that may cause you to faint.

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

Do not use Cordarone X injection if you have:

- low blood pressure
- severe problems in breathing
- heart disease or failure
- shock.

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - other heart conditions
 - blood pressure problems
 - liver problems
 - thyroid problems
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use Cordarone X if you are pregnant or intend to become pregnant.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Do not use Cordarone X if you are breastfeeding.

Cordarone X can be found in breast milk.

If you are breastfeeding and must be using or given Cordarone X, alternative feeding arrangements such as bottle feeding should be made for your baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children

Cordarone X is not recommended for use in children.

Neonates (children less than one month of age) or premature neonates

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

3. What if I am taking other medicines?

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

Some medicines may interfere with Cordarone X and affect how it works.

These include:

- medicines for your heart
- 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 (a topical anaesthetic)
- amphotericin B (a medicine used to treat fungal infections)
- antiviral medication e.g. sofosbuvir, daclatasvir, simeprevir, ledipasvir.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Cordarone X.

4. How do I use Cordarone X?

How much to take (tablets)

- The usual starting dose is 200 mg three times a day for 1 week.
- Therapy is then reduced and continued with 200 mg two times a day for a further week.
- The dose may then be reduced to 200 mg once per day.
- Follow the instructions provided by your doctor and use Cordarone X until your doctor tells you to stop.
- 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.

When to take Cordarone X (tablets)

- Cordarone X tablets 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 is given (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.

How to give it (injection)

The injectable dose will only be given in hospitals.

If you forget to take Cordarone X (tablets)

Cordarone X tablets should be taken regularly at the same time each day. If you miss your dose at the usual time, 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 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 Cordarone X

If you think that you have used too much Cordarone X, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **by calling 13 11 26**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Cordarone X?

Things you should do

Be sure to attend 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 your doctor if you become or intend to become pregnant while using Cordarone X.

Remind any doctor, dentist or pharmacist you visit that you are using Cordarone X.

Things you should not do

- Do not stop using this medicine suddenly 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 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Cordarone X affects you.

There is no evidence that amiodarone impairs the ability to drive a vehicle or operate machinery.

Looking after your medicine

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. Protect from light.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Do not use this medicine after the expiry date printed on the pack. Do not use Cordarone X if the packaging is torn or shows signs of tampering.

Keep it where young 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 stays between 8 to 25°C. Do not refrigerate. Protect from light.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

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.

Less serious side effects

Less serious side effects	What to do
<p>Alertness and sleep-related:</p> <ul style="list-style-type: none"> tremor, insomnia or other sleep disorders, vivid dreams or nightmares. <p>Allergy-related:</p> <ul style="list-style-type: none"> allergic condition which causes joint pain, skin rashes, fever and kidney problems rash or hives. <p>Sight, hearing, smell, taste or touch-related:</p> <ul style="list-style-type: none"> small cloudy spots forming on the eyeball. These usually go away after you stop the drug and they rarely affect your sight. metallic taste a feeling of "pins and needles" or numbness in the hands, legs or feet. <p>Heart-related:</p> <ul style="list-style-type: none"> slow heartbeat. <p>Hormone-related:</p> <ul style="list-style-type: none"> symptoms of an overactive thyroid including increase in appetite, weight loss, restlessness, heat intolerance, increased sweating, tremors, swelling of your neck (goitre) and a rapid heart rate 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> 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. <p>Skin and muscle-related:</p> <ul style="list-style-type: none"> muscle weakness, uncontrolled movements or poor coordination. increased skin sensitivity to sunlight - always wear a sunscreen bluish skin discolouration pain or swelling at the site where you were injected. <p>Stomach and gut-related:</p> <ul style="list-style-type: none"> constipation loss of appetite. 	

Serious side effects

Serious side effects	What to do
<p>Alertness and sleep-related:</p> <ul style="list-style-type: none"> faintness or light-headedness. <p>Allergy-related:</p> <ul style="list-style-type: none"> signs of an allergic reaction, such as shortness of breath, wheezing or other difficulty in breathing, swelling of the face, lips, mouth, tongue or throat; rash, itching or hives on the skin. <p>Heart and chest-related:</p> <ul style="list-style-type: none"> changes to heartbeat such as a pounding heart, very rapid or very slow heartbeat chest pain, cough or spitting up of blood. <p>Sight-related:</p> <ul style="list-style-type: none"> blurring or deterioration of vision, sensitisation of eyes to light. <p>Skin-related:</p> <ul style="list-style-type: none"> severe blisters and bleeding in the lips, eyes, mouth, nose and genitals yellowing of the skin or eyes (jaundice, a symptom of liver changes). <p>Other:</p> <ul style="list-style-type: none"> nausea or vomiting, stomach pain, yellow skin, unusual 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>These may be serious side effects of Cordarone X. If any of these symptoms occurs or you suspect any other drug reaction, please consult your doctor immediately.</p>

Serious side effects	What to do
<p>tiredness or passing dark-coloured urine</p> <ul style="list-style-type: none"> clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/or speech. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

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

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Cordarone X contains

Active ingredient (main ingredient)	<p>Tablets</p> <p>100 mg tablets: each tablet contains amiodarone hydrochloride 100 mg.</p> <p>200 mg tablets: each tablet contains amiodarone hydrochloride 200 mg</p> <p>Injection</p> <p>Each 3mL ampoule contains amiodarone hydrochloride 150 mg.</p>
Other ingredients (inactive ingredients)	<p>Tablets</p> <ul style="list-style-type: none"> lactose monohydrate maize starch povidone anhydrous colloidal silica magnesium stearate. <p>Injection</p> <ul style="list-style-type: none"> benzyl alcohol polysorbate 80 water for injections.
Potential allergens	<p>Tablets</p> <ul style="list-style-type: none"> sugars (lactose).

Do not take this medicine if you are allergic to any of these ingredients.

Cordarone X 100 mg tablets are white to off-white biconvex tablets embossed on one side with '100' and 'action potential' and scored on other (AUST R 15359).

Cordarone X 200 mg tablets are white to off-white biconvex tablet embossed with '200' and 'action potential' on one side and scored on the other (AUST R 15361).

Each box contains 30 tablets.

Cordarone X injection is a clear, pale yellow solution. The injection comes as a 3 mL ampoule. Each box contains 6 ampoules (AUST R 15360).

Who distributes Cordarone X

Distributed by:

sanofi-aventis australia Pty Ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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