CARDOL®

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 taking CARDOL?

CARDOL contains the active ingredient sotalol hydrochloride. CARDOL is used to treat "arrhythmias", which is a problem when the heart beats too quickly or with the wrong rhythm.

For more information, see Section 1. Why am I taking CARDOL? in the full CMI.

2. What should I know before I take CARDOL?

Do not use if you have ever had an allergic reaction to sotalol or any of the ingredients listed at the end of the CMI.

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 take CARDOL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CARDOL 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 take CARDOL?

- Follow all directions given to you by your doctor or pharmacist carefully.
- The usual dose is 80 mg to 160 mg twice a day. Your doctor may need to increase this as a very few patients may need up to three to four 160 mg tablets spread over a day. The dosage may need to be different if you have a kidney problem.
- You should take your tablets with water one to two hours before meals. Do not take CARDOL with milk or meals.

More instructions can be found in Section 4. How do I take CARDOL? in the full CMI.

5. What should I know while taking CARDOL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using CARDOL. • Tell your doctor if you become pregnant while taking CARDOL.
Things you should not do	• Do not give your medicine to anyone else, even if they have the same condition as you. • Do not take CARDOL to treat any other complaints unless your doctor tells you to.
Driving or using machines	• Be careful driving or operating machinery until you know how CARDOL affects you.
Looking after your medicine	• Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from moisture. Protect from light. • Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

For more information, see Section 5. What should I know while taking CARDOL? in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with CARDOL. It is important to be aware of them so that you can identify any symptoms if they occur.

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.

CARDOL®

Active ingredient(s): *sotalol hydrochloride*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I taking CARDOL?
2. What should I know before I take CARDOL?
3. What if I am taking other medicines?
4. How do I take CARDOL?
5. What should I know while taking CARDOL?
6. Are there any side effects?
7. Product details

1. Why am I taking CARDOL?

CARDOL contains the active ingredient sotalol hydrochloride which belongs to the family of drugs known as beta-blockers.

CARDOL is used to treat "arrhythmias", which is a problem when the heart beats too quickly or with the wrong rhythm.

CARDOL slows down and steadies the heartbeat, reducing the effort the heart has to put into pumping blood.

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

Your doctor may have prescribed it for another reason.

There is no evidence that this medicine is addictive.

CARDOL is only available with a doctors prescription

2. What should I know before I use CARDOL?

Warnings

Do not use CARDOL if:

- you are allergic to sotalol hydrochloride,
- other beta-blockers,
- or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- skin rash, itching or hives,
- swelling of the face, lips, tongue or any part of the body.

Do not take CARDOL if you have asthma.

You should not take this medicine if you have allergies, or problems with your kidneys or thyroid gland, unless you have discussed it with your doctor.

Check with your doctor if you:

- have any problems with your heart or circulation or amount of magnesium in your blood

You should not take CARDOL with any other medicines your doctor does not know about, particularly if they are to control high blood pressure, heart conditions, depression, hayfever, allergies, infections or diabetes.

Talk to your doctor if you are unsure whether you should start taking this medicine.

Before you start to take it

- Make sure your doctor knows what other medicines you are already taking including ones you have bought yourself at the chemist or supermarket.
- In particular remind your doctor if you have asthma, bronchitis or any allergies such as hayfever, food allergies or are allergic to bee or wasp stings.
- Make sure your doctor is aware of any kind of heart disease, diabetes, phaeochromocytoma, kidney disease or thyroid disease that you have or have had, or if you have been told that your pulse is slow or irregular.
- Tell your doctor if you have ever had trouble with the levels of salts like potassium or magnesium in your blood.
- Remind your doctor if you are going to have surgery involving a general anaesthetic even if it is only minor.
- Tell your doctor if you have been given CARDOL (or any other beta-blocker) before and if you had any problems.
- Remind your doctor if you have hardening of the arteries (cold fingers and toes or pain in the back of your legs when you walk).
- Tell your doctor if you are pregnant, if you are planning to become pregnant, or if you are breast feeding.

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

You should not take this medicine if you are pregnant or are breast feeding, or if you intend to breast feed.

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

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 can affect the way CARDOL works.

You should always tell your doctor about any other medicines you take, even those bought without a doctor's prescription.

It is especially important that you tell your doctor if you are taking the following:

- medicines which lower blood pressure (including other beta-blockers)
- medicines to treat pain or inflammation, such as ibuprofen or naproxen (anti-inflammatories)
- floctafenine (medicine used for the short term treatment of mild to moderate pain)
- medicines used for allergic reactions or emergencies, such as adrenaline/epinephrine (e.g. in an EpiPen)
- medicines for colds, flu, or nasal congestion, including products containing phenylpropanolamine
- for the treatment of certain infections (e.g. erythromycin IV, amphotericin B, pentamidine, halofantrine)
- medicines for nausea or vomiting, such as tropisetron
- medicines for stomach acid or reflux (proton pump inhibitors), such as omeprazole or esomeprazole
- steroids
- laxatives
- clonidine (sometimes used to treat hot flushes or headaches)
- any other medicines used to treat irregular heart rhythm or beat
- digoxin, a medicine used for heart failure
- medicines used to treat angina or other heart conditions
- antidepressants (medicines used to treat depression)
- insulin or other drugs used to control diabetes
- medicines for malaria, such as mefloquine
- medicines used to control or prevent asthma (inhalers or tablets) or to control allergies or which are used for other lung problems
- antihistamine medicine including terfenadine and astemizole that may be used to treat hayfever, allergies or to relive symptoms of cold and flu
- quinolone antibiotics (medicines used to treat infections)
- the oral contraceptive pill or hormone medicines containing estrogen
- diuretics (water tablets)
- neuromuscular blocking agents like tubocurarine
- some medicine used during surgery or emergency situations, such as anaesthetics

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

4. How do I use CARDOL?

How much to take

- Your doctor will decide on the dose of CARDOL tablets for you, and may need to change the dose a few times to get the best level for you.
- The usual dose is 80mg to 160mg twice a day. Your doctor may need to increase this as a very few patients may need up to three to four 160mg tablets spread over a day. The dosage may need to be different if you have a kidney problem.

How to take CARDOL

- You should take your tablets with water one to two hours before meals. Do not take CARDOL with milk or meals.

How long to take CARDOL

- If you have been prescribed CARDOL you must be sure to follow your doctors instructions carefully.

Do not stop taking CARDOL tablets suddenly.

The dose needs to be reduced gradually over 7 to 14 days.

If you forget to use CARDOL

It is important not to miss a dose but if you do, take your next dose at the normal time and with the normal amount.

If you use too much CARDOL

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**) for advice, 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.

Too much of this medicine will cause your blood pressure and heart rate to drop to dangerous levels. Serious heart problems may develop and this could be fatal.

5. What should I know while taking CARDOL?

Things you should do

Call your doctor straight away if you:

- If you become pregnant while taking CARDOL. You doctor can discuss with the risks of taking it while you are pregnant.
- If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking CARDOL.

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

Things you should not do

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take CARDOL to treat any other complaints unless your doctor tells you to.
- Do not let yourself run out of tablets over weekends or on holidays.

Driving or using machines

Be careful driving or operating machinery until you know how CARDOL affects you.

As with other medicines it may cause dizziness, light-headedness, drowsiness or fatigue in some people. If this occurs do not drive or operate machinery or undertake any other activity that could be dangerous if you are dizzy, light-headed or drowsy.

Looking after your medicine

Keep your tablets in the original packaging they are provided in until it is time to take them. If you take the tablets out of the blister they will not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from moisture. 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.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

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.

Do not use this medicine after the expiry date.

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.

Less serious/Common side effects

Less serious side effects	What to do
• dizziness, lightheadedness or fainting, especially when you get up from a sitting or lying position. Getting up slowly may help. • tiredness, lack of energy, weakness • headache, fever • cramps • irritated eyes, blurred vision, worsening of eyesight, increased sensitivity of the eyes to sunlight, eye infections • feeling sick, vomiting, stomach upset, diarrhoea, wind • change in taste sensation	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
• anxiety, depression, mood changes • confusion, hallucinations • problems with sexual function • sleep problems, unusual dreams • worsening of psoriasis, thickening of skin, itching, alopecia (hair loss) • hearing disturbances • tingling or numbness in the hands or feet, cold limbs • muscle spasms • excessive sweating • dry mouth	

Serious/Rare side effects

Serious side effects	What to do
• chest tightness, wheezing, shortness of breath • very slow heart beat • fast, irregular heartbeat, palpitations • chest pain • any type of skin rash, itching • shortness of breath (sometimes with tiredness, weakness and reduced ability to exercise), which may occur together with swelling of the feet or legs due to fluid build up • fainting	**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.**

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

CARDOL helps most people with arrhythmia, but it may have unwanted side effects in some people. Rarely, serious heart problems can develop while you are taking normal doses but you must remember that you are taking this medicine because your heart already has a serious problem. It is very important that your doctor keeps a check on your progress.

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 CARDOL contains

Active ingredient (main ingredient)	sotalol hydrochloride
Other ingredients (inactive ingredients)	• maize starch • lactose monohydrate • hyprolose • sodium starch glycollate • colloidal anhydrous silica • magnesium stearate
Potential allergens	sugars as lactose

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

What CARDOL looks like

CARDOL 80 mg tablet - White, round tablets, scored on one side, convex with "SOT" embossed on the other.

They are available in blister packs of 60 tablets. (Aust R 262936).

Who distributes CARDOL

Sponsor

Sandoz Pty Ltd

100 Pacific Highway

North Sydney, NSW 2060

Australia

Tel 1800 726 369

Distributor

CARDOL is distributed in Australia by:

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in June 2026.

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