

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 (160 mg). 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 CARDOL 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	
	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist

	<p>you visit that you are taking CARDOL.</p> <ul style="list-style-type: none"> • Tell your doctor if you become pregnant while taking CARDOL.
Things you should not do	<ul style="list-style-type: none"> • 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 stop taking CARDOL, or lower the dose, without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how CARDOL affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Be careful when drinking alcohol while taking CARDOL.
Looking after your medicine	<ul style="list-style-type: none"> • Keep your medicine where the temperature stays below 30°C.

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

6. Are there any side effects?

Less serious side effects: dizziness, headache, fever, cramps, anxiety, depression, confusion, hallucinations, tiredness, lack of energy, cramps, irritated eyes, blurred vision, worsening of eyesight, increased sensitivity of the eyes to sunlight, eye infections, worsening of psoriasis, thickening of skin, itching, alopecia (hair loss), unusual dreams, sleep disturbances, tingling or numbness in hands or feet, cold limbs, muscle spasm, dry mouth, excessive sweating, dry mouth, unusual bruising or bleeding. **Serious side effects:** chest tightness, wheezing, shortness of breath that may occur together with swelling of the feet or legs due to fluid buildup, chest pain, changes in heartbeat, shortness of breath, skin rash, itching, fainting.

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 using 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 using 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 (160 mg) which belongs to the family of drugs known as beta-blockers. It works by changing the body's response to some nerve impulses, especially in the heart. As a result, it helps the heart to beat more regularly.

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.

2. What should I know before I take CARDOL?

Warnings

Do not take CARDOL:

- **if you are allergic to any:**
 - medicines containing sotalol hydrochloride
 - other beta-blockers
 - ingredients listed at the end of this leaflet.
Some of the symptoms of an allergic reaction may include:
 - skin rash, itching or hives
 - swelling of the face, lips, tongue or any part of the body

- difficulty in swallowing or breathing, wheezing or shortness of breath.

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

- **if you have:**

- any breathing conditions such as asthma, chronic obstructive airway disease or bronchitis
 - a history of allergies or allergic conditions such as hay fever
 - any heart conditions or problems with circulation
 - any problems with amount of magnesium in your blood
 - kidney problems
 - thyroid problems.
- if you are receiving emergency treatment for shock or severely low blood pressure.
 - 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.
 - after the expiry date printed on the bottle.

If you take this medicine after the expiry date, it may not work as well.

- if the packaging shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Tell your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives. In particular remind your doctor if you have asthma, bronchitis or any allergies such as hay fever, food allergies or are allergic to bee or wasp stings.
- have, or have had, any medical conditions, especially the following:
 - any kind of heart disease
 - thyroid disease
 - diabetes
 - phaeochromocytoma, a rare tumour of the adrenal gland
 - trouble with level of salts like potassium or magnesium in your blood
 - history of irregular or slow pulse.

Your doctor may want to take special care if you have any of these conditions.

- plan to have surgery involving a general anaesthetic, even if it is only minor.
- have been given CARDOL (or any other beta-blocker) before and if you had any problems.
- have hardening of the arteries (cold fingers and toes or pain in the back of your legs when you walk).

If you have not told your doctor about any of the above, tell him/her before you start taking CARDOL.

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.

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

CARDOL may affect your baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of taking CARDOL during pregnancy.

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

CARDOL is not recommended for use in breastfeeding women as it passes into breast milk and may affect your baby.

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 used 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 used for nausea or vomiting, such as tropisetron
- medicines used for stomach acid or reflux (proton pump inhibitors), such as omeprazole and esomeprazole
- steroids
- laxatives
- clonidine (sometimes used to treat hot flushes or headaches)

- any other medicines used to treat irregular heart rhythm or beat such as quinidine, disopyramide, mexiletine, flecainide, amiodarone
- digoxin, a medicine used for heart failure and fast irregular heartbeat
- 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 and tablets) and breathing problems such as salbutamol and terbutaline or used for other lung problems
- antihistamine medicine including terfenadine and astemizole that may be used to treat hayfever, allergies or to relieve symptoms of cold and flu
- quinolone antibiotics (medicines used to treat certain types of infections)
- the oral contraceptive pill or hormone medicines containing estrogen
- diuretics (fluid or water tablets)
- neuromuscular blocking agents like tubocurarine
- some medicine used during surgery or emergency situations, such as anaesthetics.

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

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 take CARDOL?

How much to take

- The dose varies from person to person.
- Your doctor will tell you how many tablets you need to take each day and when to take them. It depends on your condition and how well you respond to CARDOL.
- 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 adjusted if you have a kidney problem.

How to take CARDOL

- Swallow the tablets whole with a glass of water one to two hours before meals. Do not take CARDOL with milk or meals.

When to take it

- Take CARDOL tablets on an empty stomach, for example, one to two hours before a meal.
- Do not take CARDOL tablets with food or milk.
- Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take CARDOL

- **Keep taking CARDOL for as long as your doctor tells you to.**

CARDOL helps control your condition but does not cure it, so it is important to take it every day.

- **Do not stop taking CARDOL tablets suddenly.**
The dose needs to be reduced gradually over 7 to 14 days.

If you forget to take CARDOL

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

If you are not sure what to do or have any questions, ask your doctor or pharmacist.

If you take too much CARDOL

If you think that you or anyone else has taken too much CARDOL, urgent medical attention maybe needed.

You should immediately:

- phone the Poisons Information Centre (**Australia telephone 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.

If you take too much CARDOL, you may feel dizzy or faint, have trouble breathing, have a very slow heartbeat or a fast and irregular heartbeat.

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

- **If you become pregnant while taking CARDOL tell your doctor immediately.**
- **Before starting any new medicine, tell your doctor or pharmacist that you are taking CARDOL.**
- **Tell all the doctors, dentists and pharmacist who are treating you that you are taking CARDOL.**
- **Since CARDOL is meant to be taken every day, keep a continuous supply of medicine so you**

don't run out, especially over weekends or holidays.

- **If you plan to have surgery (that requires a general anaesthetic), including dental surgery, tell your doctor or dentist that you are taking CARDOL.**
- **If you have a severe allergic reaction to foods, medicines or insect bites or stings, tell your doctor immediately.**

If you have a history of allergies, there is a chance that CARDOL may cause allergic reactions to be worse and harder to treat.

- **If you are being treated for diabetes, make sure you check your blood sugar regularly and report any changes to your doctor.**

CARDOL may affect how well your diabetes is controlled. It may also cover up some of the symptoms of hypoglycaemia (low blood sugar levels) such as fast heartbeat.

- **If you have severe or prolonged vomiting or diarrhoea while taking CARDOL, tell your doctor.**

Severe or prolonged vomiting and diarrhoea may cause your body to lose excess fluid and salts, which in turn may affect your heartbeat.

- **If you need to have any urine tests, tell your doctor that you are taking CARDOL.**

CARDOL may affect the results of some tests.

- **Visit your doctor regularly so they can check on your progress.**

Things you should not do

- **Do not give your medicine to anyone else, even if their symptoms seem similar to yours.**
- **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.**
- **Do not stop taking CARDOL, or lower the dose, without checking with your doctor.**

Stopping CARDOL suddenly may cause unwanted heart complications. Your doctor will tell you how to gradually reduce the amount of CARDOL you are taking before stopping completely.

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

Driving or using machines

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

As with other medicines it may cause dizziness, light-headedness or 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.

Drinking alcohol

Be careful when drinking alcohol while taking CARDOL.

Your doctor may suggest you avoid alcohol while being treated with CARDOL.

Looking after your medicine

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

Keep your medicine where the temperature stays below 30°C.

Follow the instructions in the bottle on how to take care of your medicine properly.

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.

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 side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• 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	<p>Speak to your doctor if you have any of these less serious side effects and they worry you. These side effects are common.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● irritated eyes, blurred vision, worsening of eyesight, increased sensitivity of the eyes to sunlight, eye infections ● nausea (feeling sick), vomiting, stomach upset, diarrhoea, wind ● change in taste sensation ● anxiety, depression, mood changes ● confusion, hallucinations ● problems with sexual function ● sleep disturbances, 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 	

Less serious side effects	What to do
<ul style="list-style-type: none"> • unusual bruising or bleeding 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • chest tightness, wheezing, shortness of breath • very slow heartbeat • 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 	<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>Serious side effects are rare.</p>

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	Sotalol hydrochloride (160 mg)
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(main ingredient)	
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> ● calcium hydrogen phosphate ● maize starch ● povidone ● sodium starch glycollate ● purified talc ● magnesium stearate
Potential allergens	<ul style="list-style-type: none"> ● trace quantities of sulfites

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

What CARDOL looks like

CARDOL is a 9.5mm, flat bevel edged, white tablet debossed 'SL' breakline '160' on one side and 'alpha symbol' on the other (AUST R 43241).

Each bottle contains 60 tablets.

Who distributes CARDOL

Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

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CARDOL® is a Viartis company trade mark

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