

CARDOL®

sotalol hydrochloride 160 mg

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about CARDOL.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking CARDOL against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What CARDOL is used for

CARDOL is used to prevent and treat an irregular heart rhythm or beat, also called arrhythmia.

CARDOL contains sotalol hydrochloride as the active ingredient which belongs to a group of medicines called 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 slows down and steadies the heart beat, 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 CARDOL for another reason.

There is no evidence that this medicine is addictive.

CARDOL is available only with a doctor's prescription.

Before you take CARDOL

When you must not take it

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.

Do not take CARDOL 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.

Do not take CARDOL if you are receiving emergency treatment for shock or severely low blood pressure.

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.

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

Do not take CARDOL after the expiry date (EXP) printed on the bottle.

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

Do not take CARDOL 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.

Before you start to take it

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.

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.

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

- any kind of heart disease
- thyroid disease
- diabetes
- kidney disease
- phaeochromocytoma, a rare tumour of the adrenal gland
- trouble with levels 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.

Tell your doctor if you have been given CARDOL (or any other beta-blocker) before and if you have had any problems.

Tell 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 plan to have surgery involving a general anaesthetic, even if it is minor.

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

Taking other medicines

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

Some medicines may be affected by CARDOL or may affect how well it 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)
- floctafenine (medicine used for the short-term treatment of mild to moderate pain)
- for the treatment of certain infections (e.g. erythromycin IV, amphotericin B, pentamidine, halofantrine)
- steroids
- laxatives
- clonidine (sometimes used to treat hot flushes or headaches)
- medicines used to treat diabetes including insulin

- medicines (inhalers and tablets) used to control and prevent asthma and breathing problems such as salbutamol and terbutaline or used for other lung problems.
- antihistamine medicines including terfenadine and astemizole that may be used to treat hayfever, allergies or to relieve symptoms of cold and flu
- any other medicines used to treat an irregular heart beat or rhythm such as
 - quinidine
 - disopyramide
 - mexiletine
 - flecainide
 - amiodarone
- antidepressants (medicines used to treat depression)
- quinolone antibiotics, a class of antibiotics used to treat certain types of infections
- digoxin, a medicine used to treat heart failure and fast irregular heart beats
- medicines used to treat angina or other heart conditions
- some diuretics, also known as fluid or water tablets
- neuromuscular blocking agents like tubocarine

- some medicines 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.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking CARDOL.

How to take CARDOL

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

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. This 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 it

Swallow the tablets whole with a glass of water.

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 it for

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.

If you forget to take it

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 (overdose)

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

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

You may need urgent medical attention.

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

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.

While you are taking CARDOL

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking CARDOL.

Tell all the doctors, dentists and pharmacists 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 become pregnant while taking CARDOL, tell your doctor immediately.

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 a fast heart beat.

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

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

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 must not do

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.

Do not use CARDOL to treat any other conditions unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

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

CARDOL may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while taking CARDOL.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CARDOL.

CARDOL is generally well tolerated in most people, but it may have unwanted side effects in some people.

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.

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.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- dizziness, lightheadedness or fainting, especially when you get up from a sitting or lying position. Getting up slowly may help
- headache, fever
- cramps
- anxiety, depression, changes in mood
- confusion, hallucinations
- irritated eyes, blurred vision, worsening of eyesight, increased sensitivity of the eyes to sunlight
- tiredness, lack of energy or weakness
- unusual dreams, sleep disturbances
- changes in taste sensation

- nausea (feeling sick), vomiting, stomach upset, diarrhoea, wind
- problems with sexual function
- worsening of psoriasis
- hearing disturbances
- tingling or numbness in the hands or feet, cold limbs.
- muscle spasms
- excessive sweating
- dry mouth

The above list includes the milder side effects of your medicine.

See your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- chest tightness, wheezing, shortness of breath
- chest pain
- changes in heart beat such as
 - a very slow heart beat
 - a fast, irregular heart beat, palpitations

- 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
- any type of skin rash, itching.
- fainting

The side effects listed above are serious and may require urgent medical attention or hospitalisation.

Tell your doctor if you notice anything that is making you feel unwell while you are taking, or soon after you have finished taking CARDOL, even if it is not on this list.

This is not a complete list of all possible side effects.

Other side effects not listed above may also occur in some people.

After taking CARDOL

Storage

Keep medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine 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.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

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

Do not leave your tablets in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking CARDOL, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

CARDOL 160 mg tablet - 9.5mm, flat bevel edged, white tablet debossed 'SL' breakline '160' on one side and 'alpha symbol' on the other.

Each bottle contains 60 tablets.

Ingredients

The active ingredient in CARDOL is sotalol hydrochloride.

Each CARDOL tablet contains 160 mg of sotalol hydrochloride.

The tablets also contain the following inactive ingredients:

- calcium hydrogen phosphate
- maize starch
- povidone
- sodium starch glycollate
- purified talc
- magnesium stearate.

CARDOL contains trace quantities of sulfites.

Supplier

CARDOL is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

Australian registration numbers:

CARDOL 160 mg tablet - AUST R 43241

CARDOL® is a Viatris company trade mark

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