

CARDOL®

sotalol hydrochloride 80 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 risks and benefits. Your doctor has weighed the risks of you taking CARDOL against the benefits it is expected to have for you.

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

Keep this leaflet with the medicine.

You may want to read it again.

What CARDOL is used for

The name of your medicine is CARDOL. It contains the active ingredient sotalol hydrochloride.

CARDOL is used for the prevention and treatment of supraventricular and ventricular arrhythmias (irregular heartbeats).

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

Your doctor may have prescribed it for another reason.

How CARDOL works

CARDOL 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.

It decreases the heart's need for blood and oxygen and therefore reduces the amount of work the heart has to do. As a result, it helps the heart to beat more regularly.

This medicine is not 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 have an allergy to:

- medicines containing sotalol hydrochloride (e.g. Sotacor)
- other beta-blockers
- any of the inactive ingredients mentioned at the end of this leaflet under Product Description

Some of the symptoms of an allergic reaction may include:

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

Do not take CARDOL if:

- you are pregnant or breastfeeding, or if you intend to breast feed
- you have a condition that causes narrowing of the airways, ie bronchial asthma or chronic obstructive airway disease
- you have allergic disorders (including hay fever) which may

suggest a predisposition to narrowing of the airways

- you take 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 have a particular type of high blood pressure that results in changes to your heart (ask your doctor if unsure)
- you have any problems with your heart or circulation, discuss them with your doctor
- you have significant enlargement of the heart
- you have a slow heart beat (less than 45 to 50 beats/minute)
- you have abnormal electrical impulses in the heart unless a functioning pacemaker is present
- you have shock, including cardiogenic shock (due to very low blood pressure caused by a heart problem) and hypovolaemic shock (due to low blood volume)
- you have uncontrolled heart failure
- you have kidney problems
- you have thyroid problems
- any problems with the amount of magnesium in your blood
- it is past its expiry date or the packaging appears to have been tampered with, or if the tablets do not look right.

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

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines, especially if they are in the same drug class as sotalol
- any other substances, including foods, preservatives or dyes.

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 or are breastfeeding.

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.

Your doctor can discuss with you the risks and benefits involved.

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

- kidney disease
- circulation problems
- angina
- diabetes
- thyroid disease such as an overactive thyroid gland
- a recent heart attack
- any other heart problems
- pheochromocytoma (a rare tumour of the adrenal gland)
- hardening of the arteries (cold fingers and toes or pain in the back of your legs when you walk)
- history of irregular or slow pulse.

Sotalol contains lactose.

If you have been told by your doctor that you have an intolerance to some

sugars, tell your doctor before taking it.

Taking other medicines

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

Some medicines and CARDOL may interfere with each other. These include:

- medicines which lower blood pressure (including other beta-blockers), calcium channel blockers (ie verapamil, nifedipine)
- medicines used to treat angina or other heart conditions
- other antiarrhythmic drugs (medicines to treat irregular heart rhythm or beat) such as disopyramide, quinidine, tocainide, mexiletine
- floctafenine (medicine used for the short-term treatment of mild to moderate pain)
- medicines for the treatment of certain infections (e.g. erythromycin IV, amphotericin B, pentamidine, halofantrine)
- steroids
- laxatives
- some medicine used during surgery or emergency situations, such as anaesthetics
- lidocaine (lignocaine), flecainide, propafenone (not available in Australia), amiodarone, and the class IV antiarrhythmic agents, drugs such as reserpine and guanethidine, all used to treat abnormal or irregular heart beat
- clonidine, used to treat high blood pressure, migraine or some menopausal symptoms
- some antibiotics (quinolone) to treat infections
- some medicines used to treat depression
- insulin and other medicines used to control diabetes

- certain types of diuretics (fluid tablets)
- antihistamine medicines including terfenadine and astemizole that may be used to treat hayfever, allergies or to relieve symptoms of cold and flu
- medicines used to control or prevent asthma (inhalers or tablets), to control allergies or used for other lung problems
- digoxin, a medicine used for heart failure
- neuromuscular blocking agents like tubocarine.

These medicines may be affected by CARDOL or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different 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 this medicine.

How to take CARDOL

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

They may differ from the information contained in this leaflet.

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

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 recommended initial oral dosing schedule is 160mg daily, given in two divided doses at approximately twelve-hour intervals (80mg twice a day). This dose may be increased, if necessary, after appropriate evaluation, to 240 or 320mg/day.

In most patients, a therapeutic response is obtained at a total daily dose of 160 to 320mg/day, given in two divided doses.

The dosage is usually reduced in patients with kidney problems.

How to take it

CARDOL tablets should be taken with water, preferably one to two hours before meals. Do not take CARDOL with milk or meals.

If you need to break CARDOL 80mg tablets into two halves, place on a flat surface and press down on the scored side with the forefinger.

You should not drink alcohol while you are on Sotalol.

How long to take it for

If you have been prescribed CARDOL you must be sure to follow your doctor's instructions carefully.

If you forget to take it

Take your dose as soon as you remember and continue to take it as you would normally.

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.

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

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 your nearest hospital, if you think you or anyone else has 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 you may feel dizzy or lightheaded and may faint. You may also have a fast and irregular heart beat or a very slow heart beat.

Serious heart problems may develop and this could be fatal.

While you are taking CARDOL

Things you must do

Always follow your doctor's instructions carefully.

Tell your doctor if you become pregnant while taking CARDOL.

Your doctor can discuss with the risks of taking it while you are pregnant.

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking CARDOL.

You should also tell your doctor or dentist that you are being treated with a beta-blocker should you have to have an operation.

If you have a severe allergic reaction to food, medicines or insect stings, tell your doctor immediately. 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 level regularly and report any changes to your doctor.

If you have severe or prolonged vomiting or diarrhoea while taking CARDOL, tell your doctor. These problems may cause your body to lose excess fluid and salts, which in turn may affect your heartbeat.

If you need to have a urine test, tell your doctor that you are taking CARDOL. CARDOL may affect the results of some laboratory tests.

Things you must not do

Do not stop taking CARDOL without your doctor's permission.

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

Your doctor may wish to gradually reduce the amount of CARDOL you are taking before stopping completely. This may help reduce the chance of your condition worsening or other heart complications occurring.

Do not let yourself run out of tablets over weekends or on holidays.

Do not use CARDOL to treat any other complaint unless your doctor says so.

Do not give this medication 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.

This medicine may cause dizziness or light-headedness or drowsiness in some people. If this occurs, do not drive or operate machinery or undertake any other activity that could be dangerous.

It is best to get up slowly from a sitting or lying position if you are feeling dizzy or light-headed.

Side Effects

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

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 the following lists of 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.
- tiredness, lack of energy, weakness
- rash
- nausea (feeling sick), vomiting, stomach upset, diarrhoea, flatulence, heartburn, abdominal pain
- cramps
- headache, fever
- dizziness, drowsiness
- sleep disturbances, unusual dreams
- depression, mood changes, anxiety
- confusion, hallucinations
- visual disturbances (including eye irritation, deterioration of eyesight, blurred vision, increased sensitivity to sunlight)
- taste abnormalities
- hearing disturbances
- tingling feelings (ie pins and needles) or numbness in the hands or feet, cold limbs
- problems with sexual function
- worsening of psoriasis
- muscle spasms
- excessive sweating
- dry mouth

If any of the following happen, stop taking CARDOL, and tell your doctor immediately, or go to

Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- very slow heart beat
- fast, irregular heart beat, palpitations
- chest tightness, wheezing, shortness of breath
- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything else 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.

Other side effects not listed above may also occur in some people and there may be some side effects not yet known.

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 in a cool dry place where the temperature stays below 25°C.

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

Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

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.

Disposal

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

Product description

What it looks like

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

They are available in blister packs of 60 tablets.

Ingredients

Active ingredient:

- CARDOL 80mg tablet contains 80mg of sotalol hydrochloride

Inactive ingredients:

- maize starch
- lactose monohydrate
- hypolose
- sodium starch glycollate
- colloidal anhydrous silica
- magnesium stearate

CARDOL contains sugars as lactose.

Supplier

CARDOL is supplied in Australia by:

Sandoz Pty Ltd

100 Pacific Highway

North Sydney, NSW 2060

Australia

Tel 1800 726 369

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