

SOTALOL



Sotalol hydrochloride 80mg and 160mg Tablets

What is in this leaflet

This leaflet answers some common questions about SOTALOL. It does not contain all the information available on this medicine. 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 using SOTALOL against the benefits expected it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may want to read it again.

What SOTALOL is used for and how it works

Your SOTALOL tablets contain the active ingredients sotalol hydrochloride. It belongs to a group of medicines 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.

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

Your doctor may, however, prescribe SOTALOL for another reason. Ask your doctor if you have any questions about why SOTALOL has been prescribed for you.

There is no evidence that SOTALOL is addictive.

SOTALOL is available on prescription from your doctor.

Before you take SOTALOL

When you must not take it

Do not take SOTALOL if:

You are allergic to sotalol hydrochloride or any other ingredients listed at the end of this leaflet

You have certain other heart conditions such as uncontrolled heart failure or an enlarged heart

You suffer from asthma, wheezing, difficulty breathing or other lung problems

You have kidney problems

You have a very slow heart beat that is less than 45-50 beats per minute or a fast irregular heart beat

You are receiving emergency treatment for shock or severely low blood pressure.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Before you take it

Tell your doctor:

If you are pregnant or are planning on becoming pregnant.

If you are breastfeeding or planning to breastfeed.

If you have an irregular heart rate or beat
If you plan to have surgery, as some anaesthesia are not to be used together with sotalol
If you have kidney problems
If you have diabetes
If you have an overactive thyroid
If you have phaeochromocytoma (a rare tumour of the adrenal gland) which is not already being treated with other medicines
If you have any blood vessel disorders causing poor circulation in the arms and legs
If you have had a recent heart attack or have other heart conditions
If you have a certain type of angina called Prinzmetal's angina
If you have had severe diarrhoea or any illness that may affect potassium or magnesium levels in the blood.

Taking other medicines

If you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health food shop, tell your doctor or pharmacist.

Drinking alcohol affects how well SOTALOL works. Because of this you should restrict your alcohol consumption as much as you can.

Medicines that may interfere with SOTALOL include:

- Insulin and oral hypoglycaemics (medicines used to treat diabetes)
- Anaesthetics eg. chloroform or cyclopropane
- Some medicines used for asthma, such as terbutaline and salbutamol
- Calcium channel blockers, a group of medicines used to treat high blood pressure, angina and other heart conditions
- Clonidine
- Catecholamine-depleting agents eg. reserpine or guanethidine
- Certain other medicines used to treat an irregular heart beat or rhythm, such as quinidine, disopyramide, flecainide, mexiletine and amiodarone
- Potassium depleting diuretics
- Digoxin, a medicine used to treat heart failure and fast irregular heart beats
- Some medicines used to treat depression including the tricyclic antidepressants
- Terfenadine and astemizole, medicines used for treating allergy

These medicines may be affected by SOTALOL or may affect how well SOTALOL works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking SOTALOL.

How to take SOTALOL properly

How much to take

Your doctor will tell you how much SOTALOL you need to take each day. It is important that you take SOTALOL as directed by your doctor. Do not take more than the recommended dose.

The dose of SOTALOL varies from patient to patient. Your doctor will decide the right dose for you.

For adults the usual starting dose of SOTALOL is 80mg twice daily. Your doctor may change this dose depending on how well you respond to the treatment.

It is best to take SOTALOL on an empty stomach, preferably 1-2 hours before meals.

How long to take it

To properly control your condition, SOTALOL must be taken everyday. Continue taking SOTALOL for as long as your doctor prescribes.

If you forget a dose

If you forget a dose, just take the next dose when it is due. Do not take more than one dose at a time to make up for missed doses.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking SOTALOL

Tell all doctors, dentists and pharmacists who are treating you that you are taking SOTALOL.

Tell your doctor or pharmacist that you are taking SOTALOL before you start any new medicine.

Tell your doctor if you develop a skin rash or hives while taking SOTALOL. If you have a history of allergies, there is a chance that SOTALOL may cause allergic reactions to be worse and harder to treat.

If you become pregnant while taking SOTALOL tell your doctor.

If you are going to have a surgery, tell the surgeon or anaesthetist that you are taking SOTALOL.

If you are being treated for diabetes, make sure you check your blood sugar level regularly. SOTALOL may affect how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (also called hypoglycaemia) such as a fast heartbeat. SOTALOL may also make low blood sugar last longer. Your doctor may need to change your dose of diabetic medicines, including insulin.

If you are going to have any blood tests, tell your doctor that you are taking SOTALOL.

Do not take SOTALOL to treat any other complaints unless your doctor tells you to.

Do not stop taking SOTALOL or lower the dose without first checking with your doctor. Your doctor may want you to gradually reduce the amount of SOTALOL you are taking before stopping completely. This may help reduce the possibility of heart complications from occurring.

Do not let yourself run out of tablets especially over the weekend or holidays.

Do not give this medicine to anyone else, even if they have the same condition as you.

SOTALOL may cause dizziness or tiredness in some people. Be careful when driving, operating machinery or performing jobs that need you to be alert, until you are certain that SOTALOL does not affect your performance.

Side effects

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

All medicines can have some unwanted 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.

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

- Dizziness, light-headedness, especially when getting up quickly
- Tiredness, lack of energy, weakness
- Headache, fever
- Cramps
- Irritated eyes, blurred vision, worsening of eyesight, increased sensitivity of the eyes to sunlight
- Feeling sick, vomiting, stomach upset, diarrhoea, wind
- Change in taste sensation
- Anxiety, depression, mood changes
- Problems with sexual function
- Sleep disturbances, unusual dreams
- Hearing disturbances
- Tingling or numbness in the hands or feet, cold limbs

These are the more common side effects of sotalol hydrochloride.

Tell your doctor immediately if you experience:

- Chest tightness, wheezing, shortness of breath
- Very slow heart beat
- Fast, irregular heart beat, palpitations
- Chest pain
- Any type of skin rash, severe itching
- Shortness of breath which may occur together with swelling of the feet or legs due to fluid build up
- Fainting

These side effects are rare but serious. You may need urgent medical attention.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of overdose

You should only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any SOTALOL by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the container of SOTALOL with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Do not take this medicine after the expiry date shown on the label or if the packaging shows signs of tampering.

Keep your SOTALOL tablets in the container until it is time to take them.

Store below 30°C and out of reach of children. Avoid exposure to heat, light and moisture.

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

Disposal

If your doctor tells you to stop taking SOTALOL or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What SOTALOL tablets look like

SOTALOL 80mg tablets are round white tablets, which are marked with a "SL/80" on one side and plain on the other.

SOTALOL 160mg tablets are round white tablets, which are marked with a "SL/160" on one side and "α" on the other.

Each SOTALOL tablet contains the active ingredient, sotalol hydrochloride.

Both SOTALOL 80mg and SOTALOL 160mg tablets also contain calcium hydrogen phosphate anhydrous, maize starch, povidone, sodium starch glycollate, purified talc and magnesium stearate.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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