

SOTALOL

Sotalol hydrochloride 80 mg and 160 mg tablets



What is in this leaflet

Please read this leaflet carefully before you start taking SOTALOL.

This leaflet answers some common questions about SOTALOL.

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 SOTALOL against the benefits they expect it will 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 need to read it again.

What SOTALOL is used for

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

SOTALOL tablets contain the active ingredient 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.

Your doctor may have prescribed this medicine for another reason.

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

This medicine is available only with a doctor's prescription.

There is no evidence that SOTALOL is addictive.

Before you take SOTALOL

When you must not take it

Do not take SOTALOL if you have an allergy to:

- any medicine containing sotalol hydrochloride
- any of the ingredients listed at the end of this leaflet

Some of the 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.

Do not take SOTALOL if:

- you have certain heart conditions such as uncontrolled heart failure or an enlarged heart
- you have low levels of potassium or magnesium in your blood.
- you suffer or have ever suffered from asthma, wheezing, difficulty breathing or other lung problems
- you have kidney problems
- you have a very slow heart beat that is less than 50 beats per minute or a fast irregular heart beat
- you are receiving emergency treatment for shock or severely low blood pressure.
- You have low blood pressure.
- You have a serious electrolyte disorder which is an imbalance in the body's acid-base balance.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

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 have allergies to any other medicines, foods, preservatives or dyes.

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

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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them

before you start taking SOTALOL.

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking SOTALOL.

Some medicines may interfere with SOTALOL. These include:

- insulin and oral hypoglycaemics (medicines used to treat diabetes)
- anaesthetics e.g. 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 e.g. resperidone 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
- some groups of antibiotics (e.g. sparfloxacin and erythromycin),
- some lipid reducing medicines (probucof)
- some drugs used to treat malaria (halofantrine)
- Some medicines used to treat urinary frequency and incontinence (terodiline)

These medicines may be affected by SOTALOL or may affect how well it works. You may need

different amounts of your medicines, or you may need to take different medicines.

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

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

How to take SOTALOL

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 on the bottle, ask your doctor or pharmacist for help.

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.

The safety and efficacy of sotalol has not been established in children and adolescents up to 18 years

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

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.

Take your medicine on an empty stomach, preferably 1 to 2 hours before meals.

Food can interfere with the absorption of this medicine.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Do not abruptly stop taking sotalol unless you are closely monitored by your doctor. It is recommended that sotalol be reduced gradually over a period of 8-14 days if sotalol needs to be stopped and during time the patient's progress is assessed

If you forget to take it

If you forget a dose, skip the dose you missed and take your next dose when you are meant to.

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

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

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

While you are taking SOTALOL

Things you must do

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 about to be started on any new medicine, tell your

doctor and pharmacist that you are taking SOTALOL.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

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

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

Do not stop taking SOTALOL or lower the dosage without 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.

Things to be careful of

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

This medicine may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or

standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

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 allergic reactions are worse and harder to treat due to treatment with SOTALOL.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much SOTALOL. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention

Side effects

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

This medicine helps most people with irregular heart beat or rhythm, but it may have unwanted side effects in a few 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.

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

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

- dizziness, vertigo, light-headedness, especially when getting up quickly

- chest pain, slow heart rate, palpitations, low blood pressure
- shortness of breath, difficulty in breathing
- 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
- anxiety, depression, mood changes
- confusion, hallucinations
- problems with sexual function
- sleep disturbances, unusual dreams
- hearing disturbances
- tingling or numbness in the hands or feet, cold limbs, muscle spasms
- dry mouth
- psoriasis, thickening of skin, itching

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest tightness, wheezing, shortness of breath
- very slow heart beat
- fast, irregular heartbeat, 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

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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people. Tell your doctor if you notice any other effects.

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

After taking SOTALOL

Storage

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

If you take the tablets out of the bottle they may not keep well.

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

Do not store SOTALOL 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.

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

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.

Ingredients

Active ingredient:

SOTALOL contains either 80 mg or 160 mg of sotalol hydrochloride as the active ingredient.

Inactive ingredient(s):

SOTALOL also contains:

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

This medicine does not contain lactose or gluten.

If you want to know more

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

Who supplies this medicine

SOTALOL is distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: 0800 579811

Date of Preparation

27 October 2020
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