NEW ZEALAND CONSUMER MEDICINE INFORMATION

SOTALOL
Sotalol hydrochloride 80 mg and 160 mg tablets

What is in this leaflet

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

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.

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 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:

- 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.

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 him/her before you start taking SOTALOL.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and SOTALOL may interfere with each other. 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. resperidine or guanethidine
- Certain other medicines used to treat an irregular heart beat or rhythm, such as quinidine, disopyramide, flecaainide, 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 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 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.

**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 1-2 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.

**If you forget to take it**

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.

**If you are about to be started on any new medicine, remind 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 your medicine 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 SOTALOL may cause allergic reactions to be worse and harder to treat.

**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 attention if you get some of the side effects.

**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 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

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.

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

It 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

Distributed in New Zealand by:

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

Telephone: (09) 579 2792

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