

Sotalol Sandoz®

Sotalol Tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Sotalol Sandoz.

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 Sandoz 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 SOTALOL SANDOZ IS USED FOR

The name of your medicine is Sotalol Sandoz. It contains the active ingredient sotalol.

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

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

Your doctor may have prescribed it for another reason.

How Sotalol Sandoz works

Sotalol Sandoz 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.

BEFORE YOU TAKE SOTALOL SANDOZ

When you must not take it

Do not take this medicine if:

- you are allergic to the active ingredient or any of the inactive ingredients mentioned at the end of this leaflet under Product Description or any other beta blockers
- Some of the symptoms of an allergic reaction may include:
 - shortness of breath, wheezing or difficulty breathing
 - skin rash, itching or hives
 - swelling of the face, lips, tongue or any part of the body.

Do not take Sotalol Sandoz if you have asthma.

You should not take this medicine if you have allergies, or problems with your kidneys, adrenal or thyroid gland, unless you have discussed it with your doctor.

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

If you have any problems with your heart or circulation or amount of

magnesium in your blood, discuss them with your doctor.

You should not take Sotalol Sandoz 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.

Do not take it if the expiry (EXP) date printed on the pack has passed

Do not take it if the packaging is torn or show signs of tampering

Before you start to take it

- Make sure your doctor knows what other medicines you are already taking including ones you have bought yourself at the chemist or supermarket.
- 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.
- Make sure your doctor is aware of any kind of heart disease, diabetes, phaeochromocytoma, kidney disease or thyroid disease that you have or have had, or if you have been told that your pulse is slow or irregular.
- 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 are pregnant or plan to become pregnant or are breastfeeding.

- Tell your doctor if you have been given Sotalol Sandoz (or any other beta-blocker) before and if you had any problems.
- Remind your doctor if you have hardening of the arteries (cold fingers and toes or pain in the back of your legs when you walk).

Sotalol Sandoz 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 Sotalol Sandoz may interfere with each other. 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
- medicines used to treat angina or other heart conditions
- any other medicines used to treat irregular heart rhythm or beat
- clonidine (sometimes used to treat hot flushes or headaches)
- sulfonamides and quinolone antibiotics (medicine used to treat infections)
- antidepressants (medicines used to treat depression)
- insulin or other drugs used to control diabetes

- diuretics (water tablets)
- antihistamine medicine 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) or to control allergies or which are used for other lung problems
- neuromuscular blocking agents like tubocurarine
- some medicine used during surgery or emergency situations, such as anaesthetics
- digoxin, a medicine used for heart failure.

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

HOW TO TAKE SOTALOL SANDOZ

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

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

How much to take

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

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

The dosage is usually reduced in patients with kidney problems.

How to take it

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

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

If you need to break Sotalol Sandoz 160mg tablets, hold tablet with both hands and snap along break line.

You should not drink alcohol while you are on Sotalol.

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 Sotalol Sandoz. 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.

WHILE YOU ARE TAKING SOTALOL SANDOZ

Things you must do

Tell your doctor if you become pregnant while taking Sotalol Sandoz.

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 Sotalol Sandoz.

Tell any other doctor, dentist, or pharmacist who treats you that you are taking this medicine.

Things you must not do

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

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

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

Things to be careful of

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

As with other medicines it may cause dizziness, 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 if you are dizzy, light-headed or drowsy. This medicine may cause dizziness or light-headedness in some people.

SIDE EFFECTS

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

Sotalol Sandoz helps most people with arrhythmia, but it may have unwanted side effects in some people. 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.

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 as soon as possible if you notice any of the following:

- 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
- cramps
- feeling sick, diarrhoea, wind, vomiting, stomach upset
- change in taste sensation
- headache, fever
- anxiety, depression, mood changes
- confusion, hallucinations
- problems with sexual function
- sleep problems, unusual dreams
- worsening of psoriasis
- hearing disturbances
- tingling or numbness in the hands or feet, cold limbs
- muscle spasms
- excessive sweating
- dry mouth
- irritated eyes, blurred vision, worsening of eyesight, increased sensitivity of the eyes to sunlight, conjunctivitis, dry eyes.

- weight changes, increase in cholesterol and low blood sugar.

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

- 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

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

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 Sotalol Sandoz, even if it is not on this list.

AFTER TAKING SOTALOL SANDOZ

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 Sotalol Sandoz 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.

North Sydney, NSW 2060
Australia
Tel 1800 726 369

This leaflet was revised in
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Australian Register Numbers

Sotalol Sandoz 80 mg tablets:
AUST R 78710

Sotalol Sandoz 160 mg tablets:
AUST R 63724

**PRODUCT
DESCRIPTION**

What it looks like

Sotalol Sandoz 80 mg: Round, white tablets with "SOT" marked on one side and a break mark on the other. They are available in blister packs of 60 tablets.

Sotalol Sandoz 160 mg: Round, white tablets with "SOT" marked on one side and a break mark on the other. They are available in blister packs of 60 tablets.

Ingredients

Active ingredient:

- Sotalol Sandoz 80 mg tablets contain 80 mg sotalol hydrochloride
- Sotalol Sandoz 160 mg tablets contain 160 mg sotalol hydrochloride.

Inactive ingredients:

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

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
100 Pacific Highway