

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
- it is past its expiry date or the packaging appears to have been tampered with, or if the tablets do not look right
- you are pregnant or breastfeeding
- you have a condition that causes narrowing of the airways, i.e. 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 have a particular type of high blood pressure that results in changes to your heart (ask your doctor if unsure)
- you have significant enlargement of the heart
- you have a slow heartbeat (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 severe kidney problems.

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.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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 problems
- circulation problems
- angina
- diabetes
- an overactive thyroid gland
- a recent heart attack
- any other heart problems
- phaeochromocytoma (a rare tumour of the adrenal gland)
- low blood levels of potassium or magnesium

- 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.

These include:

- calcium channel blockers (i.e. verapamil, nifedipine) used to treat high blood pressure,
- angina or other heart conditions
- other antiarrhythmic drugs such as disopyramide, quinidine, tocainide, mexiletine
- and 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 heartbeat
- clonidine, used to treat high blood pressure, migraine or some menopausal
- symptoms
- some antibiotics (quinolone)
- some medicines used to treat depression
- insulin and other medicines used to treat diabetes
- certain types of diuretics (fluid tablets)
- terfenadine and astemizole, medicines used to treat allergies
- some medicines used for asthma or other lung problems
- some anaesthetics (tell your doctor and anaesthetist that you are taking Sotalol Sandoz if you are to have an operation)

- digoxin, a medicine used for heart failure.

These medicines may be affected by Sotalol Sandoz, 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.

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

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 160mg daily, given in two divided doses at approximately twelve hour intervals. 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

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 light-headed and may faint. You may also have a fast and irregular heartbeat or a very slow heartbeat.

WHILE YOU ARE TAKING SOTALOL SANDOZ

Things you must do

Always follow your doctor's instructions carefully.

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

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

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 Sotalol Sandoz 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 Sotalol Sandoz, 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 Sotalol Sandoz. Sotalol Sandoz may affect the results of some laboratory tests.

Things you must not do

Do not stop taking Sotalol Sandoz without your doctor's permission.

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

Do not use Sotalol Sandoz 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 Sotalol Sandoz affects you.

This medicine may cause dizziness or light-headedness in some people.

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 Sotalol Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by the following lists side effects. You may not experience any of them.

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:

- low blood pressure, cold hands or feet, breathlessness, palpitations, swelling, heart tracing abnormalities, fainting, heart failure
- rash
- diarrhoea, nausea/vomiting, flatulence, heartburn, abdominal pain
- headache, tiredness, fever
- dizziness, drowsiness, tiredness, weakness
- sleep disturbances, depression, tingling feelings (i.e. pins and needles), mood changes, anxiety
- visual disturbances (including eye irritation, deterioration of eyesight, blurred vision, light sensitivity), taste abnormalities, hearing disturbances
- sexual problems.

The above list includes serious side effects that may require medical attention.

If any of the following happen, stop taking Sotalol Sandoz, 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 heartbeat
- fast, irregular heartbeat
- 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.

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.

Other side effects not listed above may also occur in some people.

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.

This leaflet was revised in February 2016.

Australian Register Numbers

Sotalol Sandoz 80mg tablets: AUST R 78710

Sotalol Sandoz 160mg tablets: AUST R 63724

PRODUCT DESCRIPTION

What it looks like

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

Inactive ingredients:

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

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

Supplier

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