



PACKAGE LEAFLET: INFORMATION FOR THE USER

Sotalol 80mg Tablets Sotalol 160mg Tablets

sotalol hydrochloride

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Sotalol Tablets are and what are they used for
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1. WHAT SOTALOL TABLETS ARE AND WHAT ARE THEY USED FOR

Sotalol belongs to a group of drugs called beta-adrenergic blocking agents or "beta-blockers". Sotalol is used to treat irregular heartbeats.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SOTALOL TABLETS

Do not take Sotalol Tablets:

- if you are **allergic** to sotalol hydrochloride or any of the other ingredients in this medicine (listed in section 6).
- if you suffer from **asthma**, attacks of wheezing or any other lung disease.
- if you have a very slow heart beat or **low blood pressure**.
- if you suffer from a condition causing discolouration (white or purple) of the hands and feet (Raynaud's syndrome).
- if you suffer from any severe **circulation disorders**.
- if you have suffered from **heart disease** (such as untreated heart failure) or had a recent heart attack that your doctor does not know about.
- if you suffer from a condition called **metabolic acidosis**.
- if you suffer from an untreated tumour of the adrenal gland
- if you suffer from **kidney failure**.

If you are affected by any of the above you should tell your doctor before taking this medicine.

Warning and precautions

Talk to your doctor or pharmacist before taking Sotalol tablets.

Your doctor may wish to check the level of potassium and magnesium in your blood before you start taking Sotalol tablets.

Regular blood tests may be required during your treatment with Sotalol tablets.

You must tell your doctor:

- if you are **pregnant**, planning to become pregnant or are breast-feeding.
- if you have any **kidney problems**, as your dose of Sotalol tablets may need to be changed.
- if you suffer from **diabetes**, as it may be necessary to change the dose of insulin or any other medicines you take to treat your diabetes. Sotalol tablets may also hide or reduce the warning signs of low levels of sugar in your blood (hypoglycaemia).
- if you have an **overactive thyroid**, as Sotalol tablets can hide the symptoms

- or make them worse if treatment with Sotalol tablets is stopped suddenly.
- if you suffer from, or have recently suffered from **diarrhoea**, or if you have recently had severe diarrhoea, or an attack that lasted a long time. This is because it can affect the levels of potassium and magnesium in the body, and you may not be able to take Sotalol tablets.
- if you suffer from **psoriasis** (a skin disease that causes itchy, red, sore patches of skin).
- if you suffer from liver problems.

If you need to have surgery, you should tell the doctor or anaesthetist that you are taking Sotalol tablets as it can affect anaesthetics. You may have to stop taking Sotalol tablets before surgery and it should be gradually stopped over a period of one week. Your doctor will tell you if this is necessary.

Children

Sotalol tablets are **not recommended** for use in children.

Other medicines and Sotalol

Tell your doctor if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. Some medicines can have an effect on each others actions. It is especially important that you tell your doctor if you are taking the following medicines:

- for the treatment of high blood pressure, heart failure or an irregular heartbeat (e.g. digoxin, amiodarone, verapamil)
- floctafenine (medicine used for the short term treatment of mild to moderate pain)
- for the treatment of certain infections (e.g. amphotericin B, pentamidine, halofantrine)
- steroids
- laxatives
- clonidine (sometimes used to treat hot flushes or headaches)
- for the treatment of hypertension (e.g. reserpine, guanethidine or alpha methyl/dopa)
- for the treatment of diabetes (e.g. metformin or insulin)
- for the treatment of asthma and other diseases of the lung (e.g. ventolin inhalers)
- for depression, anxiety, nervous disorders and mental disturbances (e.g. methyl/dopa)
- for allergies such as hay fever (e.g. antihistamines)
- antibiotics
- water tablets (diuretics)

Sotalol with food, drink and alcohol

Moderate amounts of alcohol will not affect Sotalol, however you should check with your doctor first to see if drinking is advisable for you.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not be given Sotalol tablets during pregnancy unless your doctor thinks it is essential.

You should not breastfeed while you are being treated with Sotalol tablets.

Driving and using machines

Sotalol does not usually affect your ability to drive. However, if you feel light-headed or dizzy, do not drive or operate machinery.

Sotalol tablets contain sodium

This medicine contains less than 1mmol sodium (23mg) per tablet, which is to say essentially 'sodium free'

3. HOW TO TAKE SOTALOL TABLETS

Always take Sotalol Tablets exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

The recommended daily dose is between 80 mg and 320 mg. Some patients may need up to 640 mg a day or sometimes the doctor may prescribe a different dose from these. Lower doses are often used for elderly patients or those with kidney disease.

Tablets should be swallowed whole with a glass of water and can be taken with or without food. The dose may be taken either as a single dose or in two divided doses. Check with your doctor or pharmacist if you are not sure.

For the first few weeks after you start your Sotalol treatment your doctor will need to see you regularly to check on your response, and may need to adjust the dose to one that suits you.

Children

This medicine is **not recommended for use in children**.

If you take more Sotalol Tablets than you should

Do not take more tablets than your doctor tells you to. If you take too many, go to the nearest hospital casualty department taking the medicine with you or tell your doctor immediately. Take any tablets leftover with you and also the box, as this will allow easier identification of the tablets.

If you forget to take Sotalol Tablets

If you forget to take a dose, do not worry, just take it as soon as you remember unless it is nearly time for your next dose then you should miss the forgotten dose and continue as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Sotalol Tablets

Do not stop taking your tablets without consulting your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sotalol Tablets can cause side effects, although not everybody gets them. **Tell your doctor immediately if you get any of the following symptoms: swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing. These may be signs of an allergic reaction and the tablets will be stopped.**

Side effects seen with Sotalol tablets (affecting more than 1 in 100 patients) include the following:

- irregular heartbeat, slow heartbeat, heart failure, chest pain, low blood pressure, difficulty in breathing, swelling, fainting and palpitations.
- nausea and vomiting, indigestion, abdominal pain, flatulence, diarrhoea, cramps.
- anxiety, depression, mood changes, headache, light-headedness, dizziness, general weakness, tiredness, sleeping problems, tingling in feet and hands (pins and needles).
- sexual dysfunction, fever, rash, hearing problems, problems with vision, changes in the way things taste.

Patients taking this type of medicine have complained of cold and/or blue fingers and toes, worsening of aches in their legs when walking, skin rash or dry eyes.

Reporting of side effects

If any of these side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You can also report the side effects directly via the yellow card scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of the medicine

5. HOW TO STORE SOTALOL TABLETS

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Store your tablets in the original package.

Do not use this medicine after the expiry date which is stated on the foil blister and carton. The expiry date refers to the last day of that month.

If you are told to stop taking this medicine, return any unused tablets to your pharmacist. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Sotalol Tablets contains

The active substance is sotalol hydrochloride. Each tablet contains sotalol hydrochloride 80mg or 160mg. Other ingredients are calcium hydrogen phosphate dihydrate, maize starch, povidone k30, sodium starch glycolate (type A), talc and magnesium stearate. Sotalol 160mg Tablets also contain indigo carmine (E132).

What Sotalol Tablets looks like and contents of the pack

Sotalol 80mg Tablets are round, white to off-white, flat, beveled-edged tablets with breakline on one side.

Sotalol 160mg Tablets are round, blue, flat, beveled edged tablets with breakline on one side.

The tablets are available in blister packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

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