

PACKAGE LEAFLET – INFORMATION FOR THE USER

SOTALOL HYDROCHLORIDE 80 mg TABLETS SOTALOL HYDROCHLORIDE 160 mg 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 signs of illness 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 are Sotalol Hydrochloride tablets and what are they used for
2. What you need to know before you take Sotalol Hydrochloride tablets
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1. What are Sotalol Hydrochloride tablets and what are they used for

Sotalol belongs to a group of medicines called ‘Beta-blockers’ or beta-adrenergic receptor blocking drugs.

Sotalol tablets are used for the treatment of certain types of irregular heartbeats.

2. What you need to know before you take Sotalol Hydrochloride tablets

Do not take Sotalol tablets if any of the following apply to you.

- 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**.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sotalol Hydrochloride tablets.

Your doctor may wish to check the level of potassium and magnesium in your blood before you start taking Sotalol Hydrochloride tablets. Patients with low levels should not take Sotalol Hydrochloride tablets.

Regular blood tests may be required during your treatment with Sotalol Hydrochloride 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 Hydrochloride 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 Hydrochloride 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 Hydrochloride tablets can hide the symptoms or make them worse if treatment with Sotalol Hydrochloride 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 Hydrochloride 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 Hydrochloride tablets as it can affect anaesthetics. You may have to stop taking Sotalol Hydrochloride 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 Hydrochloride tablets is **not recommended** for use in children.

Other medicines and SOTALOL HYDROCHLORIDE TABLETS

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)
- Neuromuscular blocking agents like tubocurarine.

SOTALOL HYDROCHLORIDE TABLETS with food, drink and alcohol

Moderate amounts of alcohol will not affect Sotalol Hydrochloride tablets, 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 Hydrochloride tablets during pregnancy unless your doctor thinks it is essential. You should not breastfeed while you are being treated with Sotalol Hydrochloride tablets.

Driving and using machines

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

SOTALOL HYDROCHLORIDE TABLETS contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Sotalol Hydrochloride tablets

Always take this medicine exactly as your doctor or pharmacist has told you. 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 Hydrochloride tablets 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

Sotalol Hydrochloride tablets is **not recommended for use in children.**

If you take more SOTALOL HYDROCHLORIDE TABLETS than you should

If you take too many tablets contact your doctor or go to your nearest hospital emergency department immediately and take the tablets and leaflet with you.

If you forget to take SOTALOL HYDROCHLORIDE 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 HYDROCHLORIDE TABLETS

Do not stop taking Sotalol Hydrochloride 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, this medicine, 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 Hydrochloride tablets (affecting more than 1 in 100 patients) include the following:

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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

5 How to store Sotalol Hydrochloride tablets

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original package.

Do not use your tablets after the expiry date stated on the label or carton.

Medicines should not be disposed of via waste water 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 Hydrochloride Tablet contains?

- The **active** substance is Sotalol Hydrochloride.
- The **inactive** ingredients are lactose, maize starch, sodium starch glycollate (Type A), magnesium stearate, hydroxypropyl cellulose and colloidal anhydrous silica).(*see section 2 for Important information about some of the ingredients of sotalol hydrochloride tablets*).

What Sotalol Hydrochloride Tablet looks like and contents of the pack?

Sotalol Hydrochloride 80 mg tablets are white to off white, round, biconvex, uncoated, debossed with 'DR' on one side and plain on the other side.

Sotalol Hydrochloride 160 mg tablets are white to off white, round, biconvex, uncoated, debossed with 'DS' on one side and plain on the other side.

Sotalol Hydrochloride tablets are available as blister packs in pack sizes of 7, 14, 21, 28, 56 and 100 tablets (Not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Accord Healthcare Limited,
Sage House, 319, Pinner Road,
North Harrow, Middlesex, HA1 4HF,
United Kingdom.

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