

PATIENT INFORMATION LEAFLET

Sotalol 40mg, 80mg and 160mg Tablets (Sotalol Hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. 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.

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1. What Sotalol Tablets are and what they are used for

Sotalol Tablets contain the active ingredient Sotalol. 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 (hypersensitive) to sotalol or to any of the other ingredients of this medicine. (listed in section 6).
- if you have certain types of disturbances in the heart's electrical impulses, untreated heart failure or shock, certain types of anaesthesia, tumours that produce blood pressure-raising substances (called pheochromocytoma), low blood pressure, severe disturbances in blood circulation in the hands and feet (Raynaud's disease), asthma or other breathing problems, severe kidney failure, metabolic acidosis.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sotalol Tablets if you:

- have diabetes, as sotalol can reduce the signs of low blood sugar and thus make it more difficult to adjust the dose of medicine.
- have low levels of magnesium or potassium in your blood.
- have impaired kidney function. A reduction in the dose may be necessary.
- if you have impaired blood circulation in the hands and feet.
- if you suffer from a type of chest pain (angina) called Prinzmetal's angina because Sotalol can make your angina attacks worse.

If you experience dizziness or fainting spells, seek medical attention immediately. Sotalol can in rare cases worsen the symptoms of psoriasis.

Before treatment with Sotalol Tablets, it is important to keep in mind that this type of medicine can worsen the symptoms of heart failure and asthmatic diseases. Treatment with Sotalol Tablets must be stopped suddenly.

Children and adolescents

Sotalol Tablets are not recommended for use in children.

Other medicines and Sotalol Tablets

Tell your doctor or pharmacist 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 other's actions.

You should talk to your doctor before taking Sotalol if you are taking any other medicine that can cause an electrical disturbance in the heart called prolonged QT interval. These are:

- medicines that treat irregular heartbeats (e.g. disopyramide, flecainide, amiodarone, dronedarone)
- ranolazine, which is used to treat angina
- medicines to treat depression, nervousness, or anxiety, belonging to the group of selective serotonin uptake inhibitors (SSRIs) (e.g., citalopram, fluoxetine, sertraline) or tricyclic antidepressants (e.g., clomipramine, amitriptyline, imipramine), trazodone, hydroxyzine
- medicines for the treatment of mental illness (antipsychotics) (e.g. chlorpromazine, thioridazine, haloperidol, fluvoxamine, amisulpiride, pimozide)
- medicines to relieve nausea and vomiting (e.g. ondansetron, domperidone)
- certain H2 receptor blockers (e.g. cimetidine, famotidine), which are used to reduce the amount of acid in the stomach
- antihistamines, used to treat allergic reactions and itchy skin rashes (e.g. chlorphenamine, diphenhydramine, hydroxyzine)

- antibiotics belonging to the group of fluoroquinolones (e.g. ciprofloxacin, levofloxacin, moxifloxacin) or macrolides (erythromycin, clarithromycin, azithromycin)
- fluconazole and amphotericin, which are used to treat fungal infections
- pentamidine, which is used to treat a type of pneumonia and certain diseases caused by parasites
- medicines used to treat and prevent malaria (e.g. mefloquine, chloroquine, halofantrine, quinine)
- opioids (morphine-like) medicines called methadone and hydrocodone
- donepezil, which is used to treat symptoms of dementia
- medicines for cancer called protein kinase inhibitors (e.g. sunitinib, vandetanib, sorafenib)
- arsenic trioxide, which is used to treat leukemia
- anagrelide, which is used to treat thrombocytopenia

It is also very important that you inform your doctor if you are taking any of the following:

- a medicine called a calcium channel blocker, which is used to treat or prevent angina (chest pain) or to treat high blood pressure (e.g. verapamil, diltiazem, lacipine, nifedipine)
- a medicine used to treat high blood pressure by affecting the central nervous system (e.g. methyl dopa, guanethidine)
- digoxin (for heart problems)
- floctanin (medicines used for the short-term treatment of mild to moderate pain)
- clonidine (sometimes used to treat high blood pressure, hot flashes, or headaches). Do not stop taking clonidine unless your doctor tells you to. If you have to stop taking clonidine, your doctor will give you detailed instructions on how to do this.
- anti-diabetic medicine: insulin or a medicine that lowers the amount of glucose in the blood
- a bronchodilator called a beta-2 agonist (eg, salbutamol, salmeterol, formoterol) for the treatment of asthma and other lung diseases; These are usually as inhalers but can also occur in other forms
- drugs that can reduce the amount of potassium in the blood; This includes diuretic tablets (e.g. furosemide, indapamide, bumetanide), steroids (e.g. prednisolone, dexamethasone), laxatives (e.g. bisacodyl, senna).
- a medicine called a proton pump inhibitor, which is used to reduce the amount of acid that is produced in the stomach (e.g. omeprazole, lansoprazole, esomeprazole).

Sotalol Tablets with food, drink and alcohol

Sotalol Tablets should be taken at least 1 hour before meals as the absorption of the medication may decrease if taken with food.

Moderate amounts of alcohol will not affect Sotalol 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 Tablets during pregnancy unless your doctor thinks it is essential. There is a risk that the fetus will be affected. Therefore, always consult a doctor before using Sotalol during pregnancy.

Treatment with Sotalol should be discontinued 48 – 72 hours before the expected date of delivery. If this is not possible, the newborn baby should be closely monitored 48 – 72 hours after birth.

It is possible that a breastfed baby may be affected. Therefore, do not breastfeed while you are being treated with Sotalol Tablets.

Driving and using machines

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

Information on sodium content

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

3. How to take Sotalol 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 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 Tablets is **not recommended for use in children.**

If you take more Sotalol 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.

In the event of overdose, a decrease in heart rate or blood pressure, difficulty breathing, seizures (including seizures caused by low blood sugar) and a slow heart rhythm may occur. At very high doses, other disturbances of heart function may also occur.

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 Sotalol Tablets without consulting your doctor and withdrawal should be gradual over 1-2 weeks. 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.

Very common side effects (may affect more than 1 in 10 people)

- shortness of breath
- chest pain
- diarrhoea
- Palpitations
- headache
- weakness
- Vomiting
- slow pulse
- irregular electrocardiogram readings (ECG abnormalities)
- sleep disorders
- fluid retention (edema)
- dizziness

Common side effects (may affect up to 1 in 10 people)

- depression
- numbness in the hands and feet
- fever
- flatulence
- heart failure
- irregular heartbeat (cardiac arrhythmia)
- rash
- Mood changes
- hearing disorders
- sick/ nausea
- low blood pressure
- abdominal pain
- anxiety
- Sexual disorders
- Taste changes
- acid reflux
- fainting
- visual disturbances
- fatigue
- muscle cramps

Other side effects

Not known (the frequency cannot be estimated from available data):

- Decreased number of cells that help with blood clotting. This increases the risk of bleeding or bruising
- restricted blood flow to the extremities (causing cold and/or blue fingers and toes, painful pain in the legs when walking),
- chest pain (angina pectoris)
- heart block (atrioventricular block)
- difficulty breathing (bronchospasm)
- itching, psoriasis
- Hair loss
- Excessive sweating
- Abnormally low levels of thrombocytes, also known as platelets, in the blood.

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 Website: 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 this medicine.

5. How to store Sotalol Tablets

Keep this medicine out of the sight and reach of children. 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. Do not store the tablets above 25°C.

Store in the original package to protect from light.

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 throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sotalol Tablets contain:

The active substance is Sotalol Hydrochloride. Each tablet contains 40 mg, 80 mg or 160 mg Sotalol Hydrochloride.

The other ingredients are:

Sotalol Hydrochloride 40 mg, 80 mg or 160 mg:
Calcium hydrogen phosphate dihydrate, maize starch, povidone K30, sodium starch glycolate, type A, Talc and magnesium stearate.
Sotalol Hydrochloride 160 mg: Indigocarmine (E 132)

What Sotalol Tablets look like and the contents of the pack:

Sotalol 40mg Tablets are round white to off white, flat bevelled edged tablets.
Sotalol 80mg Tablets are round white to off white flat bevelled edged tablets with a score line on one side.
Sotalol 160mg tablets are round blue, flat bevelled edged tablets with a score line on one side.

Sotalol Tablets, in each of the above strengths, are available in blister packs containing 28, 30, 50 or 56 tablets.

Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer:

Name and address:
Bristol Laboratories Ltd.
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Sotalol 160mg Tablets; PL 17907/0260

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To request a copy of this leaflet in Braille, large print or audio format then please contact the Marketing authorisation holder at the address (or telephone, email) above.

FLAT DIMENSION = 160 x 460 mm
FOLDED DIMENSION = 160 x 28.75-30mm