

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Sotalol Hydrochloride 40mg and 80mg Tablets

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.

What is in this leaflet:

1. What Sotalol is and what it is used for
2. What you need to know before you take Sotalol
3. How to take Sotalol
4. Possible side effects
5. How to store Sotalol
6. Contents of the pack and other information

1 What Sotalol is and what it is used for

Sotalol Hydrochloride belongs to a group of medicines called Beta-Blockers and works by slowing the electrical impulses in the heart muscle. This helps to regulate and restore disturbances in the heart rhythm.

Sotalol also blocks beta receptors that are found in the heart. This causes the heart to beat more slowly and with less force.

Sotalol Hydrochloride (referred to as Sotalol throughout this leaflet) is used:

- To treat fast and irregular heartbeat (arrhythmias) some of which may be life-threatening.
- As prophylaxis, to prevent the occurrence of new arrhythmias.

2 What you need to know before you take

Do not take Sotalol:

- **If you have a history of breathing difficulties, wheezing or asthma**
- If you are allergic to Sotalol, other Beta-Blockers or any of the other ingredients of this medicine (listed in Section 6)
- If you have an irregular heartbeat caused by sick sinus syndrome, long QT syndromes or Torsades de Pointes
- If you suffer from a condition where the heart beats irregularly or much more slowly than normal (2nd or 3rd degree heart block) **unless you have pacemaker**
- If you have a slower heart beat than normal (bradycardia)
- If you suffer from heart failure which is not controlled by medicine
- If you have had a recent heart attack
- If you are going to have surgery and have an anaesthetic such as cyclopropane or trichloroethylene (see Section 2 'Other medicines and Sotalol')
- If you have an untreated tumour of the adrenal gland (phaeochromocytoma)
- If you suffer from low blood pressure (hypotension) **unless this is a result of the irregular heartbeat**
- If you suffer from poor circulation causing the fingers and toes to be numb and pale (Raynauds phenomenon) or other circulation problems
- If you have an increased amount of acid in your blood (metabolic acidosis)
- If you suffer from kidney failure

Warnings and precautions

Talk to your doctor before taking Sotalol:

- If you already suffer from a pre-existing irregular heartbeat or other heart problems, especially if you are female
- If you are known to have low levels of potassium or magnesium in your blood. Your doctor may want to check the levels before commencing treatment with Sotalol

- If you have severe or prolonged diarrhoea
- If you are taking other medication for heart problems such as ACE inhibitors, diuretics or digitalis etc (see 'Other medicines and Sotalol' section)
- If you have a history of severe allergic reaction (anaphylaxis) (see "Possible side effects" section)
- If you have diabetes or a history of low levels of sugar in your blood
- If you have an overactive thyroid, as Sotalol can hide the symptoms or make them worse if treatment with Sotalol is stopped suddenly
- If you suffer from kidney problems
- If you have a skin disease which causes scaly pink patches (psoriasis)

Other medicines and Sotalol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

Medicines which **should not be taken** with Sotalol:

- Fluoroquinolones used to treat infections (e.g. ciprofloxacin, levofloxacin)
- Medicines used to treat irregular heartbeats such as disopyramide, quinidine, procainamide, amiodarone and bedpridil (antiarrhythmics)
- Anaesthetics such as cyclopropane and trichloroethylene (see Section 2, 'Do not take Sotalol')

Medicines which **may** interact with or be affected by Sotalol:

- Floctafenine, a Non-Steroidal Anti-Inflammatory Drug (NSAID) used for the short-term treatment of mild to moderate pain and inflammation
- Verapamil and diltiazem, used to treat high blood pressure, abnormal heart rhythms, chest pain (calcium channel blockers)
- Medicines used to treat heart failure such as digoxin (digitalis glycosides)
- Medicines used to treat high blood pressure such as reserpine, guanethidine or alpha methyl dopa
- If you are due to have a urine test, Sotalol may interfere with the results
- Medicines used to treat high blood pressure or heart failure, such as lisinopril (ACE inhibitors)

Special care should be taken with the following medicines:

- Medicines that prolong QT interval such as:
 - Phenothiazines, used to treat serious mental and emotional disorders and also severe nausea (feeling sick) and vomiting (being sick)
 - Tricyclic antidepressants, used to treat depression e.g. clomipramine
 - Terfenadine and astemizole, used to treat allergic conditions (antihistamines)
- Medicines which may increase the risk of a life-threatening irregular heartbeat (Torsades de Pointes) such as:
 - Erythromycin IV, an antibiotic used to treat bacterial infections
 - Halofantrine, used to treat malaria
 - Pentamidine, used to treat or prevent pneumonia
 - Medicines that may affect potassium levels such as potassium-depleting diuretics (e.g. chlorothiazide), amphotericin B (IV) used to treat fungal infections, corticosteroids used to relieve inflammation (e.g. prednisolone) and some potassium-depleting laxatives (e.g. bisacodyl)
- Clonidine, used to treat high blood pressure and migraine. If you are taking Sotalol and Clonidine together, Sotalol should be gradually stopped several days before slowly discontinuing Clonidine.
- Medicines used to treat diabetes such as insulin or metformin as the dose may need to be adjusted. Sotalol may also hide or reduce the warning signs of low levels of sugar in your blood (hypoglycaemia)
- Other beta-blockers, such as atenolol
- Magnesium-depleting medicines such as antacids (e.g. cimetidine)

Pregnancy and breast-feeding

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.

Pregnancy

If you are pregnant you should not take Sotalol unless considered essential by your doctor.

Breast-feeding

If you are breast-feeding, you should not take Sotalol.

Driving and using machines

Sotalol may make you feel dizzy or tired. If you experience these symptoms whilst taking this medicine, it is necessary to avoid driving or operating machinery.

Sotalol contain lactose

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

Sotalol contains sodium

This medicine contains less than 1 mmol sodium (23mg) per 40 / 80mg tablet, that is to say essentially 'sodium-free'.

3 How to take Sotalol

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- These tablets are to be taken orally.
- These tablets can be taken before, with or after meals.
- The score line on the tablet (**80mg strength only**) is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses.

The recommended dose is:

- The recommended first (initial) dose is 80mg, given in either one or two divided doses.
- Dosage should be adjusted gradually allowing 2-3 days between dosing stages.
- Most patients will respond to a daily dose of 160–320mg given in two divided doses at approximately 12 hour intervals.

Patients with life threatening heart problems:

Some patients with life threatening heart problems may need higher doses of up to 480–640mg per day. These doses should be given under specialist supervision and should only be prescribed when the potential benefit outweighs the increased risk of side effects (adverse events).

Patients with kidney problems:

Patients suffering from kidney problems will require a lower dose.

Use in children:

Sotalol tablets should **not** be given to children.

If you take more Sotalol than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of overdose include: slower heartbeat (bradycardia), heart failure, low blood pressure (hypotension), difficulty in breathing or wheezing (bronchospasm), low blood sugar levels (hypoglycaemia).

If you forget to take Sotalol

Take it as soon as you remember, unless it is time for your next dose. If you miss a dose **do not** take a double dose to make up for a forgotten dose.

If you stop taking Sotalol

It is important that you keep taking Sotalol for as long as your doctor has told you to. **Do not** stop taking the tablets even though you may feel better as this could be harmful to you. Your doctor will gradually reduce your dose before you stop taking this medicine.

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.

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, fever, difficulty in breathing, dizziness,

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

- Slower heartbeat (bradycardia)
- Shortness of breath or difficulty in breathing (dyspnoea)
- Chest pain
- Feeling your heartbeat (palpitations)
- Swelling of parts of the body (oedema)
- Abnormalities during ECG tests
- Low blood pressure (hypotension)
- Disrupted heart rhythm (arrhythmias)
- Fainting (syncope)
- Lightheadedness, muscle weakness and feeling faint (presyncope)
- Heart failure
- Rash
- Feeling or being sick (nausea, vomiting)
- Indigestion (dyspepsia)
- Diarrhoea
- Stomach pain
- Feeling bloated/wind (flatulence)
- Cramps (muscle spasms)
- Headache
- Dizziness, lightheadedness
- Tiredness (fatigue)
- Feeling of weakness (asthenia)
- Tingling or numbness in the hands or feet (paraesthesia)
- Abnormal sense of taste (dysgeusia)
- Sleep disturbances
- Mood changes including depression and anxiety
- Sexual problems
- Visual disturbances
- Hearing disturbances
- Fever

Side effects (frequency not known)

- Hair loss (alopecia)
- Excessive sweating (hyperhidrosis)
- Abnormally low levels of thrombocytes, also known as platelets, in the blood
- Cold and/or blue fingers and toes
- Poor circulation causing the fingers and toes to be numb and pale (Raynauds phenomenon)
- Increase in cramp-like pain felt in the calf, thigh or buttock during walking or other exercise (intermittent claudication)
- 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 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

- 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 carton after "EXP". The expiry date refers to the last day of that month.
- Store below 25°C. Store in the original package in order to protect from light.
- 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 to protect the environment.

6 Contents of the pack and other information

What Sotalol contains:

- Each 40mg tablet contains 40mg of Sotalol Hydrochloride
- Each 80mg tablet contains 80mg of Sotalol Hydrochloride

The other ingredients are: maize starch, lactose monohydrate, hydroxypropylcellulose, sodium starch glycollate, colloidal silicon dioxide and magnesium stearate.

What Sotalol looks like and contents of the pack:

- Sotalol Hydrochloride 40mg tablets: white, round, biconvex tablets, with an approximate diameter of 5.5mm, marked "SOT" on one side
- Sotalol Hydrochloride 80mg tablets: white, round, biconvex tablets, with an approximate diameter of 7mm, marked "SOT" on one side and scored on the other

Sotalol is available in:

Sotalol tablets are available in blister packs of 28 or 56 tablets.

Not all pack sizes may be marketed.

Product Licence Numbers:

- Sotalol Hydrochloride 40mg Tablets: PL 11311/0070
- Sotalol Hydrochloride 80mg Tablets: PL 11311/0071

Marketing Authorisation Holder & Manufacturer:

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This leaflet was last revised in August 2020

Till-Ver.9