Package leaflet: Information for the patient

Sotoger 80 mg 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sotoger is and what it is used for

The name of this medicine is Sotoger. Each tablet contains sotalol hydrochloride as the active ingredient.

Sotoger belongs to a group of drugs called beta-adrenergic blocking agents or 'Beta-Blockers'.

Sotoger is used to treat irregular heartbeats.

2. What you need to know before you take Sotoger

Do not take Sotoger:
- if you are allergic to sotalol or any of the other ingredients of 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 certain heart disease (such as untreated heart failure, heart block, sick sinus syndrome) or cardiogenic shock
- if you suffer from a condition called metabolic acidosis
- if you suffer from an untreated tumour of the adrenal gland (see section "warnings and precautions")
- if you suffer from kidney failure
- if you are going to have an operation and need an anaesthetic, tell the anaesthetist or dentist you are taking Sotoger
- if you are being taking intravenous verapamil or diltiazem (medicines to treat irregular heartbeat)

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

Warnings and precautions
Talk to your doctor or pharmacist before Sotoger.

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

Regular blood tests may be required during your treatment with Sotoger.

You must tell your doctor or pharmacist before taking Sotoger:
- if you are pregnant, planning to become pregnant or are breastfeeding
- if you suffer from a heart disease, have an enlarged heart or are being treated for heart failure or if you have suffered from a recent heart attack
- if you suffer from an abnormal heart rhythm (seen on electrical recording of the heart (ECG) as prolonged QT- interval). In such cases, your doctor will take extra care before increasing your dose
- if you have any kidney problems, as your dose of Sotoger 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. Sotoger may also hide or reduce the warning signs of low levels of sugar in your blood (hypoglycaemia)
- if you have an overactive thyroid, as Sotoger can hide the symptoms or make them worse if treatment with Sotoger 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 Sotoger
- if you suffer from psoriasis (a skin disease that causes itchy, red, sore patches of skin)
- if you are allergic to a variety of allergens. When taking this medicine you may have a more severe reaction on repeated challenge. Sotoger may also reduce the effectiveness of medicines used to treat severe allergic reactions, such as adrenaline
- if you suffer from liver problems
- if you have a tumour of the adrenal gland (pheochromocytoma, see section "Do not take this medicine"), the alpha receptors must be blocked with another medicine at the same time.

If you are due to have surgery
You should tell the doctor or anaesthetist that you are taking Sotoger as it can affect anaesthetics or medicines used to help relax muscles during surgery. You may have to stop taking Sotoger before surgery and it should be gradually stopped over a period of one week. Your doctor will tell you if this is necessary.

If you are having laboratory tests, such as a urine test tell your doctor you are taking Sotoger.

Children
Sotoger is not recommended for use in children and adolescents under 18 years of age.

Other medicines and Sotoger
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.

Do not take Sotoger in combination with:
- other medicines to treat abnormal heart beats (e.g. verapamil, quinidine, diltiazem, disopyramide, procainamide, flecainide, amiodarone, bepridil)
- other beta-blockers (medicines which may be used for angina, high blood pressure or prevention of migraine)

It is especially important that you tell your doctor if you are taking any of the following:

- medicines used in the treatment of diabetes (e.g. metformin or insulin)
- medicines used in the treatment of asthma and other diseases of the lung (e.g. salbutamol, terbutaline or isoprenaline inhalers)
- medicines used in the treatment of depression (e.g. imipramine, maprotiline), anxiety, nervous disorders and mental disturbances (e.g. haloperidol)
- medicines used in the treatment of allergies such as hay fever (certain antihistamines such as astemizole and terfenadine)
- water tablets (diuretics)
- medicines used for high blood pressure or to help treat Raynaud's syndrome (e.g. amlodipine, nifedipine)
- methyldopa, reserpine, or quanethidine (medicines used to help control blood pressure)
- medicines used to treat heart failure (e.g. digoxin)
- a medicine called halofantrine (used to treat Malaria)
- certain antibiotics (e.g. pentamidine and 'floxacin' antibiotics such as ciprofloxacin)

Or if you are taking:

- a medicine called clonidine (sometimes used to treat hot flushes or headaches). If you are taking clonidine and sotalol at the same time and clonidine treatment has to be stopped, you should stop taking sotalol, reducing the amount you are taking slowly, before you stop taking clonidine.
- steroids
- laxatives
- a medicine called floctafenine (used to treat pain and inflammation)
- a medicine called amphotericin B (used to treat fungal infections)
- medicines for the treatment of psychiatric disorders (phenothiazines, certain antidepressants), barbiturates, opioids, blood pressure lowering drugs, diuretics or vasodilators may lead to an increased blood pressure drop.

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

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 or pharmacist for advice before taking this medicine.

You should not be given Sotoger during pregnancy unless your doctor thinks it is essential. If taken during pregnancy, sotalol should be stopped 48-72 hours before the calculated date of birth. If this is not possible, the newborn infant must be monitored carefully for 48-72 hours after birth.

You should not breast-feed while you are being treated with Sotoger.

Driving and using machines
Sotoger does not usually affect your ability to drive. However, if you feel tired or light-headed or dizzy, do not drive or operate machinery.

3. How to take Sotoger

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not stop taking Sotoger without consulting your doctor.

Adults
The recommended starting dose is 80 mg administered either singly or as two divided doses. The dose will be adjusted gradually increasing every 2-3 days. Most patients will get 160 mg to 320 mg every day. Some patients may need up to 640 mg a day. Lower doses are often used for older people or those with kidney disease.

The tablet can be divided into equal doses. Tablets or doses (half of a tablet) must not be chewed or crushed and should be swallowed whole with a glass of water and can be taken before, during or after food, but make sure that you take it the same way each day as your doctor has told you.

The dose should be taken in two divided doses approximately 12 hours apart. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse 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.

Use in children and adolescents
Sotoger is not recommended for children and adolescents under 18 years of age.

If you take more Sotoger than you should
If you take too many tablets contact your doctor or go to your nearest hospital emergency department immediately.
Depending on the extent of the overdose the following symptoms can occur: a marked fall in blood pressure, low pulse, heart rhythm disorders, heart failure, difficulty breathing, narrowing/spasms of the airways and symptoms of low blood sugar (feeling hungry, sweating, dizziness, tiredness, blurred vision, trembling or shakiness, anxiety or irritability, going pale, fast pulse or palpitations).

If you forget to take Sotoger
Do not take a double dose to make up for a forgotten dose.
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.

If you stop taking Sotoger
Treatment with beta-receptor blockers **must not be discontinued abruptly**. If the treatment is to be discontinued this should always be done slowly over period of at least 1 to 2 weeks.

Abrupt discontinuation of beta-receptor blockers can increase the risk of a heart attack or heart rhythm problems occurring. It may also cause an increase in symptoms of poor blood supply to the heart (angina), which may cause chest pain especially when moving around or exercising, or an increase in blood pressure.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell your doctor immediately or go to your nearest hospital 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.

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

- Cardiac arrest (which causes sudden collapse, no pulse, no breathing and loss of consciousness)

Other possible side effects

Common (may affect up to 1 in 10 people):

- irregular heart beat, slow heart beat, chest pain, low blood pressure, difficulty in breathing, swelling, fainting and palpitations, alterations in heart rhythm (Torsade de pointes, QT interval prolongation, AV conduction disorder, ventricular tachycardia), exacerbation in angina pectoris (which causes chest pain)
- exacerbation of peripheral occlusive disease, cold limbs
- nausea and vomiting, indigestion, abdominal pain, flatulence, diarrhoea, cramps
- anxiety, depression, confusion, mood changes, headache, light-headedness, dizziness, general weakness, tiredness, problems with sleeping, tingling in feet and hands (pins and needles)
- sexual dysfunction, impotence, fever, rash, skin reactions, hearing problems, problems with vision, changes in the way things taste

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

- Abnormally low levels of thrombocytes, also known as platelets, in the blood
- hallucinations, abnormal dreams
- blurred vision, conjunctivitis, inflammation of the cornea (keratoconjunctivitis), reduced flow of tears (particularly when using wearers of contact lenses)
- dry mouth
- psoriasis (skin disease) may be triggered or exacerbated, hair loss, excessive sweating
- increase in fats and decrease of sugar in the blood

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 you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; Email: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sotoger

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 bottle or carton after EXP. The expiry date refers to the last day of that month.

Blister packs
Store in the original carton in order to protect from light.

Securitainers or bottles
Keep the container tightly closed in order to protect from the light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer in use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sotoger contains

- The active substance is sotalol hydrochloride. The 80 mg tablet contains 80 mg of sotalol hydrochloride.
- The other ingredients are: calcium hydrogen phosphate, maize starch, povidone, sodium starch glycolate, talc and magnesium stearate.

What Sotoger look like and contents of the pack
Your medicine comes as a white bevel-edged tablet. Sotoger 80 mg Tablets are marked "SL | 80" on one side and blank on the other side.

Sotoger Tablets are available in securitainers or in bottles of:
80 mg Tablets of 20, 28, 30, 40, 50, 60, 100 and 300 tablets

Sotoger Tablets are available in blister packs of:
80 mg Tablets of 20, 28, 30, 40, 50, 60, 90, 100 and 300 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.
Mylan Hungary Kft.2900 Komárom, Mylan utca 1. Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Sotalol Viatris Tabletter 80 mg
Greece	Sotalol/Mylan Tablets 80mg/TAB
Ireland	Sotoger 80 mg Tablets
Italy	Sotalol Mylan Generics 80 mg compresse
The Netherlands	Sotalol HCl Viatris 80 mg, tabletten

This leaflet was last revised in January 2024.