

SOTALOL 80 mg

sotalol

Package leaflet: Information for the patient

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
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1 What Sotalol is and what it is used for

- Sotalol belongs to a group of medicines called beta-blockers, which slow the heart beat, so the heart beats more efficiently.
- Sotalol is used to prevent a recurrence of serious heart beat problems.

2 What you need to know before you take Sotalol

DO NOT take Sotalol

- if you are allergic to sotalol, sulphonamides (e.g. co-trimoxazole, sulfadiazine) or any of the other ingredients of this medicine (listed in section 6)
- if you have any heart problems, other than those for which your medicine has been prescribed, in particular:
 - abnormal heart rhythms called 'long QT syndrome'
 - torsades de pointes (life-threatening irregular heart beat)
 - atrioventricular (AV) block or
 - sick sinus syndrome (without a pacemaker) (certain types of heart rhythm disturbances)
 - your heart beats less than 50 times per minute
 - uncontrolled heart failure
 - shock due to heart problems (a condition which may be associated with low blood pressure, cold skin, a weak pulse, mental confusion and anxiety)
- if you suffer from any of the following conditions:
 - asthma or any other breathing difficulties
 - Prinzmetal's angina (chest pain and palpitations at rest, usually during sleep)
 - problems with your circulation (e.g. Raynaud's phenomenon or pain in the calf muscles on walking)
 - phaeochromocytoma (a benign adrenal tumour) which is not being treated
 - low blood pressure (which is not due to an irregular heartbeat)
 - severe kidney problems
 - metabolic acidosis (acidification of the blood)
- if you are due to have a general anaesthetic
- if you are also taking other medicines to correct an abnormal heart rhythm, e.g. quinidine, hydroquinidine or disopyramide (called class Ia antiarrhythmic agents) or amiodarone, dofetilide or ibutilide (called class III antiarrhythmic agents)
- if you are also taking medicines used to treat schizophrenia and other serious mental disorders e.g. sulpiride, sultopride, amisulpride, thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, tiapride, pimozide, haloperidol, droperidol (called neuroleptics)
- if you are also receiving injections of erythromycin (an antibiotic) or vincamine (which may be used to treat some forms of brain disease, notably dementia), or if you are taking bepridil (used to treat angina), cisapride (used to treat certain gastrointestinal problems), diphenamil (which may be used to treat a slow heart beat), mizolastine (used to treat hayfever), moxifloxacin (an antibiotic) or floctafenine (used to treat pain).

If you are elderly, it is especially important for you not to take Sotalol if any of the above applies to you.

Warnings and precautions

Sotalol may sometimes make an abnormal heart beat worse or cause new heart rhythm problems.

You must tell your doctor if you are pregnant, planning to become pregnant or are breast feeding.

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

- slow heartbeat (less than 50-55 beats per minute)
- heart failure which is being treated or a heart rhythm disorder called 'first degree atrioventricular (AV) block', or you have recently had a heart attack
- an electrolyte imbalance (low levels of potassium and magnesium in your blood)
- severe or prolonged diarrhoea
- frequent allergic reactions
- an over-active thyroid gland, as Sotalol can hide the symptoms or make them worse if treatment with Sotalol is stopped suddenly.
- psoriasis (patches of itchy, thickened, red and sore skin)
- diabetes, treated with insulin or sulphonylureas, as warning signs of low blood sugar may be less obvious than usual. It may be necessary to change the dose of insulin or any other medicines you take to treat your diabetes.
- kidney disease.
- liver problems

Other precautions you should take:

- Tell the hospital staff or dentist you are taking Sotalol if you are to have an operation requiring an anaesthetic or need X-rays requiring iodised contrast media.
- Never stop taking Sotalol abruptly (see 3. How to take Sotalol).

Athletes should note that Sotalol can cause positive results in drug tests.

Other medicines and Sotalol

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 must not be taken at the same time as Sotalol. These are listed above, under the heading 'Do not take Sotalol'.

Talk to your doctor if you are taking any of the medicines listed below.

Sotalol should not generally be taken at the same time as the following medicines because of the risk of further heart problems:

- halofantrine (used to treat malaria)
- pentamidine (used to treat pneumonia)
- fluoroquinolones used to treat infections (e.g. sparfloxacin, ciprofloxacin, levofloxacin)
- methadone (which may be used to treat cough, pain and heroin addiction)
- diltiazem or verapamil (called calcium channel blockers or antagonists, used to treat abnormal heart beats)
- medicines that can cause high blood pressure such as monoamine oxidase inhibitors (MAOIs) e.g. moclobemide, phenelzine, isocarboxazid.

Caution is also needed if you are taking:

- diuretics (water tablets)
- laxatives (used to treat constipation)
- glucocorticoids (used to treat inflammation and allergic skin reactions)
- tetracosactide (mainly used to diagnose or treat adrenal glands disorders)
- amphotericin B (administered intravenously) (used to treat fungal infections)
- guanfacine (used to treat attention deficit hyperactivity disorder [ADHS])
- digitalis glycosides including digoxin (used to treat irregular heart rhythms or impaired heart function)
- class Ic antiarrhythmic agents (such as propafenone or flecainide) or intravenously administered lidocaine (used to control irregular heart rhythm)
- mefloquine (used to prevent or treat malaria)
- cholinesterase inhibitors such as donepezil, rivastigmine, tacrine, galantamine, neostigmine, pyridostigmine or ambenonium (used to treat Alzheimer's disease)
- pilocarpine (used to treat dry mouth or high pressure in the eye)
- other beta-blocking agents, clonidine, dihydropyridines or alpha-methylidopa (used to treat high blood pressure)
- volatile halogenated anaesthetics (used in surgery)
- metformin or insulin and hypoglycaemic sulphonamides (used to treat diabetes)
- baclofen (used to treat muscle spasm)
- non steroidal antiinflammatory drugs (NSAIDs) such as ibuprofen, diclofenac (used to treat pain, fever or inflammations)

- tricyclic antidepressants (e.g. imipramine), phenothiazine neuroleptics (used to treat psychiatric disorders)
- amifostine (used during chemo- or radiotherapy)
- dipyridamole (administered intravenously) (used to prevent formation of a blood clot)
- antihypertensives e.g. reserpine, guanethidine or alpha methyl dopa
- medicines to treat asthma and other lung diseases (e.g. ventolin inhalers)
- medicines to treat allergies such as hay fever (e.g. antihistamines)

Interactions with laboratory tests:

If you have a blood test, please inform your doctor that you are taking sotalol, as it may influence the results of some blood tests.

Athletes

Athletes should be aware that this medicine contains an active substance which may cause a positive reaction to "anti-doping tests".

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 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.

Your doctor may prescribe Sotalol during pregnancy if it is clearly necessary. Do not take Sotalol unless your doctor tells you to and always take it exactly as prescribed.

Breast-feeding is not recommended during treatment with Sotalol.

Driving and using machines

Sotalol may affect your eyesight or make you feel dizzy.

Do not drive or operate any tools or machines if you are affected.

Sotalol 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

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

The recommended dose is:

Adults (including the elderly):

The initial dose is 80 mg sotalol taken once daily or in two divided doses at 12 hour intervals. Your doctor will then gradually increase this according to your needs.

The recommended dose is between 160 mg and 320 mg sotalol taken in two or three divided doses each day.

For certain patients who have a life-threatening irregular heart beat, the dose can be increased up to 480 mg or 640 mg sotalol daily.

Patients with kidney problems or elderly patients may require a lower dose.

Use in children:

Due to a lack of data Sotalol is not recommended for use in children. Please check with your doctor.

Method of administration:

You should swallow the tablets whole with a full glass of water and can be taken with or without food.

The tablet can be divided into equal doses.

If you take more Sotalol than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Sotalol

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten tablet. Take the remaining doses at the correct time.

If you stop taking Sotalol

You must not stop taking Sotalol suddenly, as this could cause severe heart problems, including heart attack and death. Your doctor will decide when and how you should stop taking Sotalol. You must follow your doctor's instructions.

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.

Other side effects:

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

- blood disorders (such as changes in the numbers of white or red blood cells) which may be characterised by fever or chills, sore throat, ulcers in the mouth or throat. Abnormally low levels of thrombocytes, also known as platelets, in the blood. If you develop these symptoms, you should contact your doctor.
- low blood sugar
- cold hands and/or feet
- problems with sight
- problem with hearing
- slow heartbeat, breathlessness, wheezing, chest pain, palpitations, ankle swelling, ECG (cardiogram) abnormalities, low blood pressure, worsened irregular heartbeat, fainting, heart failure
- skin rashes, itching, sweating, sensitivity to light
- hair loss
- excessive sweating
- nausea, vomiting, diarrhoea, indigestion, abdominal pain and flatulence
- cramp, muscle or joint pain
- sexual problems including impotence
- fatigue, dizziness, feeling of weakness, tiredness, headaches, depression, mood changes, sleeping difficulties, pins-and-needles, anxiety, fever.

In exceptional cases, there have been reports of inflammation of the joints and connective tissue (e.g. tendons) with skin rashes. These symptoms usually disappear once treatment is stopped.

If you have psoriasis, or intermittent claudication (cramp-like leg pain brought on by walking), your symptoms may become worse.

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

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. Keep the blister in the outer carton 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 protect the environment.

6 Contents of the pack and other information

What Sotalol contains:

- The active substance is sotalol hydrochloride
- Each tablet contains 80 mg of sotalol hydrochloride.
- The other ingredients are lactose monohydrate, maize starch, magnesium stearate, povidone and indigo carmine (E132).

What Sotalol looks like and contents of the pack:

Sotalol 80 mg: Light blue, oval shaped tablet, scored on one side and debossed with the number "93" and "61" on each side of the score, plain on the other side.

Sotalol 80 mg is available in pack sizes* of 20, 28, 30, 40, 50, 60, 90 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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