

SOPRESSOR 80

Sotalol hydrochloride 80mg

What is in this leaflet

1. What Sopressor is used for
2. How Sopressor works
3. Before you take Sopressor
How to take Sopressor
4. While you are using Sopressor
5. Possible Side effects
6. How to store Sopressor
7. Product description
8. Product Registration Holder and manufacturer

Read this entire leaflet before you start taking the medication.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. WHAT SOPRESSOR IS USED FOR

Sopressor contains the active ingredient Sotalol hydrochloride. Sopressor is used in the treatment of irregular heartbeats (arrhythmias).

2. HOW SOPRESSOR WORKS

Sotalol hydrochloride belongs to a group of medicines called beta-adrenoreceptor antagonist or beta-blocker.

It works by changing the body's response to some nerve impulses, especially in the heart. As a result, it helps the heart to beat more regularly.

3. BEFORE YOU TAKE SOPRESSOR

Do not take Sopressor if you:

- are allergic to sotalol or any other medicines in beta blocker group or any of the other ingredients of this medicine.
- suffered from heart disease (such as untreated heart failure) or had a recent heart attack that your doctor does not know about.

- Had reduced blood potassium concentration (hypokalemia)
- suffer from a condition called metabolic acidosis. (hyperacidity of the blood)
- have a very slow heart beat or low blood pressure.
- suffer from a condition causing discolouration (white or purple) of the hands and feet (Raynaud's syndrome).
- suffer from asthma, attacks of wheezing or any other lung disease.
- suffer from kidney failure.

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 taking Sopressor.

Your doctor may wish to check the level of potassium and magnesium in your blood before you start taking Sopressor. Patients with low levels should not take Sopressor. Regular blood tests may be required during your treatment with Sopressor.

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 Sopressor 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. Sopressor may also hide or reduce the warning signs of low levels of sugar in your blood (hypoglycaemia).
- if you have an overactive thyroid, as Sopressor can hide the symptoms or make them worse if treatment with Sopressor 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 Sopressor.
- 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 Sopressor as it can affect anaesthetics. You may have to stop taking Sopressor before surgery and it should be gradually stopped over a period of one week. Your doctor will tell you if this is necessary.

Taking / using other medicines

Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines and Sopressor may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- 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)
- 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. group of medicines in form of inhalers called fast-acting bronchodilators. Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out.)
- 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) e.g. frusemide and hydrochlorothiazide which may deplete potassium salt in the body and increase the risk of arrhythmias
- Medicines for the treatment of certain infections (e.g. amphotericin B, pentamidine, halofantrine)

Sopressor with food, drink and alcohol

Moderate amounts of alcohol will not affect Sopressor, 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 for advice before taking this medicine. You should not be given Sopressor during pregnancy unless your doctor thinks it is essential.

You should not breastfeed while you take Sopressor.

4. HOW TO TAKE SOPRESSOR

Adults:

The initial dose is 80 mg twice daily. Depending on your response, your doctor may increase your dose gradually.

Dosage for patients with reduced kidney function:

Your doctor will adjust the dosage after taking into account your kidney function.

Use in children and adolescents

Sopressor is not recommended for use in children.

How long to take it

Continue to take your medicine as long as your doctor tells you. This medicine helps to control your condition but does not cure it. It is important to keep taking this medicine even if you feel well.

If you forgot to take

Take your dose as soon as you remember and continue to take it as

you would normally. If it is time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much (overdose)

If you or anyone else takes too many tablets, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

The following symptoms may be observed in overdose:

- light headedness, dizzy or fainting
- slow heart beat
- fast and irregular heart beat

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

5. WHILE YOU ARE USING SOPRESSOR

Things you must do

- Always take Sopressor exactly according to the instructions given to you by your doctor or pharmacist. If you are unsure, check with your doctor or pharmacist.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects get serious or anything else that make you feel unwell.
- If you become pregnant, or plan on becoming pregnant while taking Sopressor tell your doctor immediately.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking Sopressor
- Tell your doctor or dentist that you are being treated with a beta-blocker should you have to have an operation.
- Inform your doctor or pharmacist if you have a severe allergic

reaction to food, medicines or insect stings

- If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.
- Inform your doctor if you have severe or prolonged vomiting or diarrhea while taking Sopressor

Things you must not do

- Do not stop taking your medicines without consulting your doctor. It is important to keep taking your medicine even if you feel well.
- Do not use Sopressor after the expiry date which is stated on the carton and blister.
- Do not give this medication to anyone else, even if they have the same condition as you.

Things to be careful of

Driving and using machines:

Taking Sopressor may cause dizziness or light-headedness, particularly at the first dose or after dose is increased. Drinking alcohol may worsen the symptoms. If you have any of these symptoms, do not drive or operate any machinery.

6. 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 Sopressor include the following:

Common (may affect up to 1 in 10 people)

- anxiety, confusion, sleep disturbances, mood changes, depressive mood
- dizziness, drowsiness, headache, sensory disorders such as tingling and numbness (paraesthesia), short-term fainting (syncope) or conditions which almost lead to fainting (pre-syncope conditions), taste disturbances
- visual disturbances
- hearing disturbances
- abnormal heart rhythm (*torsade de pointes*)

- irregular heartbeat, slow heartbeat, heart failure, palpitations and other abnormalities in heart rhythm and beats, shortness of breath (*dyspnoea*), chest pain
- low blood pressure
- abdominal pain, feeling sick (nausea), being sick (vomiting), diarrhoea, indigestion, flatulence, dry mouth
- muscle cramps
- sexual dysfunction
- fever, tiredness, general weakness, accumulation of water in tissue (oedema).

Uncommon (may affect up to 1 in 100 people):

- difficulty in breathing or wheezing (*bronchospasm*) can occur in patients with bronchial asthma or a history of asthmatic complaints.

Very rare (may affect up to 1 in 10,000 people)

- dry eye

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

- Sensation of cold, numbness or pain at extremities (including Raynaud's syndrome), worsening of pain and weakness brought on by walking
- rash, worsening of symptoms of psoriasis (thickened patches of red/silver skin)
- loss of hair, increased sweating
- reduction in blood platelets, which increases risk of bleeding or bruising
- changes to some of the cells or other parts of your blood.

Patients taking such type of medicine have complained of tiredness, slow heartbeat, and shortness of breath (*dyspnoea*), provocation of irregular heartbeat or worsening of a pre-existing one, general weakness and dizziness.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. HOW TO STORE

SOPRESSOR

Store in a cool, dry place, not above 30°C. Protect from heat, light and moisture.

Keep out of the reach and sight of children.

Disposal

Do not use Sopressor after the expiry date which is stated on the carton or blister.

If your doctors tell you to stop taking Sopressor or the expiry date has passed, ask your pharmacist the proper way to dispose the remaining medicines.

8. PRODUCT DESCRIPTION

What Sopressor looks like and contents of the pack.

White, round tablets, scored on one side, convex with "SOT" embossed on the other side

Sopressor tablet is packed in a box of (10x10 tablets) and (4x25 tablets).

What Sopressor contains

The active substance is:

Sotalol hydrochloride

Each tablet contains: 80 mg Sotalol HCl

The other ingredients are:

Maize starch, lactose monohydrate, magnesium stearate, colloidal silicon dioxide, hydroxypropylcellulose, sodium starch glycolate.

Registration Number:

MAL19970929AZ

9. PRODUCT REGISTRATION HOLDER AND MANUFACTURER

Product Registration Holder:

IMEKS Pharma Sdn. Bhd.

5 & 9, Jalan Udang Harimau 2,

Medan Niaga Kepong

51200 Kuala Lumpur. Malaysia

Manufactured by:

Salutas Pharma GmbH Otto-von-

Guericke-Allee 1,

39179 Barleben, Germany

For:

HEXAL® AG Industriestraße 25

D-83607 Holzkirchen Germany

Date of revision:

26/04/2022

Serial Number

NPRA(R2/1)220216/836