PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

SOTAHEXAL 80 (tablets)

SOTAHEXAL 160 (tablets)

Sotalol hydrochloride

Contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking SOTAHEXAL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SOTAHEXAL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What SOTAHEXAL is and what it is used for

Sotalol belongs to a group of medicine called beta-blockers. This medicine is used in the management of hypertension (high blood pressure), angina pectoris (chest pains) and cardiac dysrhythmias (irregular heartbeats).

Sotalol has been given following a heart attack (myocardial infarction) to prevent a following heart attack, and in addition has been given to reduce symptoms of overactivity in hyperthyroidism (a condition due to excessive production of the thyroid gland hormone).

2. What you need to know before you take SOTAHEXAL

Do not take SOTAHEXAL:

- If you are hypersensitive (allergic) to sotalol hydrochloride or any of the other ingredients of SOTAHEXAL (see “WHAT SOTAHEXAL CONTAINS”).
- If you are prone to suffer from abnormal and irregular heartbeat.
- If you have an abnormally slow heartbeat (less than 45 to 50 beats per minute).
- If you have congestive heart failure (ineffective pumping of the heart leading to accumulation of fluid in the lungs), that is not currently being treated.
- If you have cardiogenic shock where your heart cannot pump enough blood to meet your body’s needs.
- If you have phaeochromocytoma (a tumour associated with high blood pressure), you should not receive SOTAHEXAL without your doctor prescribing concomitant therapy (alpha-adrenergic blocking therapy).
- If you are to receive anaesthesia which may cause depression of the heart.
- If you have low blood pressure (except due to irregular heartbeat).

- If you suffer from severe poor blood circulation in your hands and feet (Raynaud's phenomenon).
- If you have bronchospasm (difficulty in breathing due to contraction of the bronchial muscles) or asthma or have a history of obstructive airway disease (a disease where the airways have been blocked).
- If you have metabolic acidosis (a disturbance in the acid balance of the body).
- If you have kidney failure (creatinine clearance < 10 mℓ/min).

Warnings and precautions

Take special care with SOTAHEXAL:

- If you have had surgery you should not stop taking your normal dose of SOTAHEXAL since your angina or high blood pressure may be worsened.
- If you undergo long-term treatment with SOTAHEXAL your doctor will gradually discontinue SOTAHEXAL reducing the dose over a period of 1 to 2 weeks, as abrupt withdrawal may result in the worsening of your angina, cause a heart attack (myocardial infarction), irregular rhythm of the heartbeat or high blood pressure.
- If you develop a very rapid heartbeat (Torsade de pointes), very slow or irregular heartbeat while taking SOTAHEXAL, tell your doctor immediately. Your doctor will monitor your heart and may need to reduce your dose of SOTAHEXAL.
- Your doctor will run blood tests before and during your treatment with SOTAHEXAL to make sure your potassium and magnesium levels are normal. If you are taking medicines which may deplete your body's magnesium and potassium levels together with SOTAHEXAL, and are experiencing prolonged diarrhoea, tell your doctor. Low blood potassium and magnesium levels may cause irregular rhythm of the heartbeat.

- If you are receiving treatment for congestive heart failure (e.g. medicines such as ACE inhibitors, diuretics or digoxin), your condition may be worsened by SOTAHEXAL. Your doctor will give you the lowest possible dose of SOTAHEXAL and monitor your condition.
- If you have recently had a heart attack your doctor will monitor your heart and your dose of SOTAHEXAL.
- If you have a history of anaphylactic reaction (a severe hypersensitivity reaction) towards a variety of allergens. You may have a more severe reaction if it happens again and may need higher doses of the medicines used to treat anaphylaxis.
- It is important that prior to surgery the anaesthetist is aware that you are taking SOTAHEXAL.
- If you have diabetes or a history of episodes of low blood sugar (hypoglycaemia), SOTAHEXAL may mask the signs of acute hypoglycaemia.
- If you have thyroid problems or are prone to develop hyperthyroidism (overactivity of the thyroid gland), SOTAHEXAL may mask the signs of hyperthyroidism and worsen the symptoms if withdrawn abruptly.
- If you have psoriasis (a chronic skin condition characterised by bright red, slightly elevated, round or oval areas that are covered with dry adherent scales that leave bleeding points when removed) SOTAHEXAL may aggravate your condition.
- If you are taking any of the following medicines together with SOTAHEXAL; hypoglycaemic agents for diabetes, phenothiazines for psychological disorders, anti-dysrhythmic agents for irregular heartbeat; medicine interactions may be life-threatening. Tell your doctor if you are taking any of these medicines before taking SOTAHEXAL.
- If you are receiving long term therapy with SOTAHEXAL, your doctor may need to prescribe you with a medicine called digoxin in order to prevent congestive heart failure.

This medicine may interact with SOTAHEXAL (see “Taking other medicines with SOTAHEXAL”); your doctor will therefore closely monitor your condition.

- If you experience any progressive weakness and exhaustibility of voluntary muscles known as myasthenia gravis, tell you doctor. SOTAHEXAL may unmask myasthenia gravis
- Your dose may need to be reduced if you have kidney failure or are elderly.

Other medicines and SOTAHEXAL:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In particular, tell your doctor if you are taking any of the following medicines; your doctor may want to monitor your condition to check that your medicines are not interfering with each other, once you start taking SOTAHEXAL:

- Anti-dysrhythmic medicines such as disopyramide, quinidine, procainamide and flecainide (Class 1a) and others such as amiodarone and bepridil should not be used in combination with SOTAHEXAL.
- Phenothiazines (medicine used for psychological disorders), tricyclic anti-depressants, terfenadine and astemizole (antihistamines). SOTAHEXAL should be given with extreme caution to patients receiving any medicine, which may prolong QT-interval.
- Erythromycin given intravenously (an antibiotic), halofantrine (medicine used for malaria), pentamidine (medicine used to prevent and treat pneumonia) and quinolone antibiotics (e.g. nalidixic acid, ciprofloxacin, moxifloxacin, etc.). The co-administration of SOTAHEXAL with these medicines may increase the risk for Torsade de pointes (irregular heart rhythm).

- Calcium channel blocking medicines such as verapamil and diltiazem (used for angina and high blood pressure).
- Potassium depleting diuretics such as furosemide.
- Other potassium depleting medicines such as amphotericin B (intravenous route), corticosteroids (systemic administration) and some laxatives.
- Clonidine (used for high blood pressure).
- Digoxin glycosides such as digoxin (used for congestive heart failure and irregular heart rhythm).
- Catecholamine depleting agents used for high blood pressure such as reserpine or alpha methyldopa.
- Insulin and oral hypoglycaemics.
- Neuromuscular blocking medicines such as tubocurarine (used in anaesthesia).
- Beta-2-agonists such as salbutamol, fenoterol and terbutaline (used in asthma).

If you are being tested for phaeochromocytoma (a tumour associated with high blood pressure), SOTAHEXAL may influence the urine test. Inform your doctor that you are using SOTAHEXAL before doing a urine test of any kind.

Pregnancy, breastfeeding and fertility

You should not be taking SOTAHEXAL if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

SOTAHEXAL is not expected to influence your ability to drive and use machinery, however, you may experience side effects such as dizziness and fatigue which can impair your ability to react.

SOTAHEXAL contains lactose monohydrate

SOTAHEXAL contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking SOTAHEXAL.
SOTAHEXAL contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take SOTAHEXAL

Do not share medicines prescribed for you with any other person.

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

Hypertension (high blood pressure):

Initial oral dose: 160 mg daily as a single or divided dose, which may be increased by your doctor every two weeks according to your response to 600 mg or more daily.

Angina pectoris (chest pains):

The optimum dose is between 160 mg and 600 mg daily.

Cardiac dysrhythmias (irregular heartbeat):

The usual dose is 120 mg to 480 mg daily.

Post MI to prevent re-infarction (after a heart attack to prevent another heart attack):

The usual dose is 320 mg daily.

To reduce symptoms of overactivity in hyperthyroidism (a condition due to excessive production of the thyroid gland hormone):

The usual dose is 120 mg to 240 mg daily.

If you are elderly, have kidney or liver problems your doctor may reduce your dose of SOTAHEXAL.

Your doctor will tell you how long your treatment with SOTAHEXAL will last. If you have the impression that the effect of SOTAHEXAL is too strong or too weak, tell your doctor or pharmacist.

If you take more SOTAHEXAL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

You may experience very slow heart rate, low blood pressure, low blood sugar and/or difficulty breathing.

Take the remaining tablets and the container with you and show the pack to the doctor.

If you forget to take SOTAHEXAL

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Not all side effects reported for SOTAHEXAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SOTAHEXAL, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

The following side effects have been experienced frequently:

- Anxiety.
- Sleep disturbances.
- Mood changes.
- Depression.
- Dizziness.
- Light-headedness.
- Headache.
- Abnormal tactile sensation such as burning, tingling, prickling and/or creeping on the skin (paraesthesia).
- A temporary loss of consciousness due to a fall in blood pressure (syncope).
- State consisting of light-headedness and muscular weakness (pre-syncope).
- Taste abnormalities.
- Blurred vision and pain.
- Hearing disturbances.
- Irregular heart rhythm (arrhythmia).
- Specific type of abnormal heart rhythm known as torsade de pointes.
- Sudden shortness of breath (dyspnoea).
- Chest pain.
- Abnormally slow heartbeat (bradycardia).
- Noticeably rapid, strong, irregular heartbeat (palpitations).
- Heart block.
- Heart failure.

- Low blood pressure.
- Stomach pain.
- Nausea.
- Vomiting.
- Diarrhoea.
- Indigestion.
- Accumulation of gas (flatulence).
- Dry mouth.
- Muscle cramps.
- Sexual dysfunction.
- Extreme tiredness (fatigue).
- Abnormal physical weakness (asthenia).
- Fever.
- Oedema (swelling of soft tissue).

The following side effects have been experienced less frequently:

- Reduced tear production.
- In patients with bronchial asthma or a history of asthmatic complaints, bronchitis and other lung diseases, bronchospasm (difficulty breathing due to constricted airways) may occur.

The following side effects have been experienced at an unknown frequency:

- A rash of purple spots on the skin caused by internal bleeding from small blood vessels not related to a deficiency of platelets (non-thrombocytopenic purpura).
- Bruising and slow blood clotting after injury due to deficiency of blood platelets (thrombocytopenia).

- A deficiency of certain white blood cells which make the body more prone to infection (agranulocytosis).
- A temporary increase of certain white blood cells (transient eosinophilia).
- Seeing or hearing things that are not there (hallucinations).
- Confusion.
- Injury to the nerves that supply sensation to the arms and the legs (peripheral neuropathy).
- Poor blood circulation in the hands and feet which leads to pain, numbness and in severe cases gangrene (Raynaud's disease).
- Aggravation of muscle pain or fatigue experienced during exercise which subsides when resting.
- Painful and cold hands and/or feet.
- Acute inflammation of lung tissue (pneumonitis).
- Chronic inflammation and progressive forming of tissue without blood or lymphatic vessels in the lungs leading to difficulty in breathing and death (pulmonary fibrosis).
- Inflammation of the membranes covering the lungs (pleurisy).
- Constipation.
- Skin rash.
- Itching.
- Baldness, absence of hair where it is normally present (alopecia).
- Abnormal excessive sweating, not related to exercise (hyperhidrosis).
- Worsening of the symptoms of the skin condition psoriasis.
- Muscle weakness.
- Abnormal hardening and inflammation of the membrane that lines the cavity of the abdomen (sclerosing peritonitis).

- Formation of scar tissue behind the membrane that lines the cavity of the abdomen (retroperitoneal fibrosis).
- Autoimmune disease.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of SOTAHEXAL.

Suspected adverse reactions can also be reported directly to the Holder of the registration certificate (HCR) via Patientsafety.sacg@novartis.com.

5. How to store SOTAHEXAL

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Protect from light.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SOTAHEXAL contains

- The active substance is sotalol hydrochloride.
- The other ingredients are colloidal silicon dioxide, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, maize starch and sodium starch glycolate.

SotaHexal 80 tablets contains sugar (26,75 mg lactose monohydrate).

SotaHexal 160 tablets contains sugar (53,5 mg lactose monohydrate).

What SOTAHEXAL looks like and contents of the pack

SotaHexal 80: White, round tablets, scored on one side, convex with “SOT” embossed on the other side.

6,9 to 7,1 mm (diameter); 2,8 to 3,2 mm (height)

SotaHexal 160: White, round biconvex tablets. Scored on one side with “SOT” imprint on the other side.

8,9 to 9,1 mm (diameter); 3,8 to 4,2 mm (height)

SotaHexal is packed in securitainers containing 100 tablets.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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Magwa Crescent West

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Jukskei View

2090

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Registration number(s)

SOTAHEXAL 80: 29/5.2/0749

SOTAHEXAL 160: 29/5.2/0750

Access to the corresponding Professional Information

Not applicable

[1]Company Reg. No.: 1990/001979/07