P3872T

Package leaflet: Information for patient

# Sotalol Hydrochloride 160mg 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 Sotalol

**Do not take Sotalol**
- If you are allergic (hypersensitive) to sotalol hydrochloride or any of the other ingredients in this medicine (listed in section 6).
- If you have a history of breathing difficulties, wheezing or asthma or any other lung disease
- If you have a very slow heart beat or low blood pressure
- If you have low blood pressure, suffer from severe disturbances in blood circulation in the hands and feet 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 certain type of disturbances in the heart's electrical impulses, suffered from heart disease (such as untreated heart failure or shock), certain types of anaesthesia, or had a recent heart attack that your doctor does not know about.
- If you suffer from a condition called metabolic acidosis.
- If you suffer from an untreated tumour of the adrenal gland, tumours that produce blood pressure-raising substances (pheochromocytoma)
- If you 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 Sotalol. Your doctor may wish to check the level of potassium and magnesium in your blood before you start taking Sotalol. Patients with low levels should not take Sotalol.

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

You must tell your doctor:
- if you are pregnant, planning to become pregnant or are breast-feeding.
- If you have low levels of magnesium or potassium in your blood.
- If you have impaired blood circulation in the hands and feet.
- If you suffer from a type of chest pain (angina) called Prinzmetal's angina because Sotalol can make your angina attacks worse.
- if you have any kidney problems, as your dose of Sotalol 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. Sotalol may also hide or reduce the warning signs of low levels of sugar in your blood (hypoglycaemia) and thus make it more difficult to adjust the dose of medicine.
- If you experience dizziness or fainting spells, seek medical attention immediately.
- 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, 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 Sotalol.
- if you suffer from psoriasis (a skin disease that causes itchy, red, sore patches of skin). Sotalol can in rare cases worsen the symptoms of psoriasis.
- if you suffer from liver problems.

If you need to have surgery, you should tell the doctor or anaesthetist that you are taking Sotalol as it can affect anaesthetics. You may have to stop taking Sotalol before surgery and it should be gradually stopped over a period of one week. Your doctor will tell you if this is necessary.

Before treatment with Sotalol Tablets, it is important to keep in mind that this type of medicine can worsen the symptoms of heart failure and asthmatic diseases. Treatment with Sotalol Tablets must be stopped suddenly.

**Children and adolescents**
Sotalol is not recommended for use in children.

**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. Some medicines can have an effect on each others actions.

You should talk to your doctor before taking Sotalol. If you are taking any other medicine that can cause an electrical disturbance in the heart called prolonged QT interval. These are:
- medicines that treat irregular heartbeats (e.g. disopyramide, flecainide, amiodarone, dronedarone)
- ranolazine, which is used to treat angina
- medicines to treat depression, nervousness, or anxiety, belonging to the group of selective serotonin uptake inhibitors (SSRIs) (e.g., citalopram, fluoxetine, sertraline) or tricyclic antidepressants (e.g., clomipramine, amitriptyline, imipramine), trazodone, hydroxyzine
- medicines for the treatment of mental illness (antipsychotics) (e.g. chlorpromazine, thioridazine, haloperidol, fluvoxamine, amisulpiride, pimozide)
- medicines to relieve nausea and vomiting (e.g. ondansetron, domperidone)
- certain H2 receptor blockers (e.g. cimetidine, famotidine), which are used to reduce the amount of acid in the stomach
- antihistamines, used to treat allergic reactions and itchy skin rashes (e.g. chlorphenamine, diphenhydramine, hydroxyzine)
- antibiotics belonging to the group of fluoroquinolones (e.g. ciprofloxacin, levofloxacin, moxifloxacin) or macrolides (erythromycin, clarithromycin, azithromycin)
- fluconazole and amphotericin, which are used to treat fungal infections
- pentamidine, which is used to treat a type of pneumonia and certain diseases caused by parasites
- medicines used to treat and prevent malaria (e.g. mefloquine, chloroquine, halofantrine, quinine)
- opioids (morphine-like) medicines called methadone and hydrocodone
- donepezil, which is used to treat symptoms of dementia
- medicines for cancer called protein kinase inhibitors (e.g. sunitinib, vandetanib, sorafenib)
- arsenic trioxide, which is used to treat leukemia
- anagrelide, which is used to treat thrombocytopenia

It is especially important that you tell your doctor if you are taking the following medicines:
- a medicine called a calcium channel blocker, for the treatment of high blood pressure, to treat or prevent angina (chest pain) (e.g. verapamil, diltiazem, lacipine, nifedipine)
- A medicine used to treat high blood pressure by affecting the central nervous system (e.g. Methyldopa, guanethidine)
- Digoxin (for heart problem)
- A medicine called proton pump inhibitor, which is used to reduce the amount of acid that is produced in the stomach (e.g. omeprazole, lansoprazole, esomeprazole).
- floctafenine (medicine used for the short term treatment of mild to moderate pain)
- for the treatment of certain infections

*continued....*

Crescent PHARMA LIMITED

| | |
|---|---|
| Product: | Sotalol Hydrochloride 160mg Tablets |
| Item Code: | P3872T |
| Size: | 175 x 340 mm |
| Min. Point size: | 9pt |
| O. Artwork | 16/03/26 |
| Proof No. | 2 |
| Amendment Date: | 16/03/26 |

| Colours Used | |
|---|---|
| | PANTONE Black CVC |
| | Keyline - Does not print |

P3872T

(e.g. amphotericin B, pentamidine, halofantrine)
- steroids
- laxatives
- clonidine (sometimes used to treat high blood pressure, hot flushe or headaches). Do not stop taking clonidine unless your doctor tells you to. If you have to stop taking clonidine, your doctor will give you detailed instructions on how to do this.
- for the treatment of diabetes (antidiabetic medicine that lowers the amount of glucose in the blood. e.g. metformin or insulin)
- a bronchodialator called a beta-2 agonist (e.g. salbutamol, salmeterol, formoterol) for the treatment of asthma and other diseases of the lung; These are usually as inhalers (e.g. ventolin inhalers) but can also occur in other forms
- for depression, anxiety, nervous disorders and mental disturbances (e.g. methyldopa)
- for allergies such as hay fever (e.g. antihistamines)
- antibiotics
- Drugs that can reduce the amount of potassium in the blood; This includes water tablets (diuretics) (e.g. furosemide, indapamide, bumetanide), steroids (e.g. prednisolone, dexamethasone), laxatives (e.g. bisacodyle, senna).

**Sotalol with food, drink and alcohol**
Sotalol should be taken at least 1 hour before meals as the absorption of the medication may decrease if taken with food.

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 for advice before taking this medicine. You should not be given Sotalol during pregnancy unless your doctor thinks it is essential. There is a risk that the fetus will be affected. Therefore, always consult a doctor before using Sotalol during pregnancy.

Treatment with Sotalol should be discontinued 48-72 hours before the expected date of delivery. If this is not possible, the newborn baby may be affected. Therefore, you should not breastfeed while you are being treated with Sotalol.

**Driving and using machines**
Sotalol is not likely to affect you being able to drive or use machinery. However, if you feel lightheaded or dizzy whilst taking this medicine it is necessary to avoid driving or operating machinery.

**Information about the ingredients of Sotalol**
**This medicine contains lactose**
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

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

## 3 How to take Sotalol

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

**Adults**
The recommended daily dose is between 80 mg and 320 mg. Some patients may need up to 640 mg a day or sometimes the doctor may prescribe a different dose from these. Lower doses are often used for elderly patients or those with kidney disease.

Tablets should be swallowed whole with a glass of water and can be taken with or without food.

The dose may be taken either as a single dose or in two divided doses. Check with your doctor or pharmacist 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:**
Sotalol tablets should not be given to children.

**If you take more Sotalol than you should:**
If you take too many tablets, contact your doctor or go to the nearest hospital emergency department immediately and take tablets and leaflet with you.

The symptoms of overdose include: slower heartbeat (bradycardia), heart failure, low blood pressure (hypotension), difficulty in breathing or wheezing (bronchospasm), low blood sugar levels (hypoglycaemia). At very high doses, other disturbances of heart function may also occur.

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

**If you stop taking Sotalol**
Do not stop taking Sotalol without consulting your doctor and withdrawal should be gradual over 1-2 weeks. 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.**
Very Common Side Effects (May affect more than 1 in 10 people)
- Shortness of breath, chest pain, palpitations, headache
- Diarrhoea, vomiting, weakness
- slow pulse, sleep disorders, dizziness
- fluid retention (edema)
- irregular electrocardiogram reading (ECG abnormalities)

Common Side Effects (may affect up to 1 in 10) include the following:
- irregular heartbeat (cardiac arrhythmia), slow heartbeat, heart failure, chest pain, low blood pressure, difficulty in breathing, swelling, fainting and palpitations.
- nausea/ sick and vomiting, indigestion, abdominal pain, flatulence, diarrhoea, cramps.
- anxiety, depression, mood changes, headache, light-headedness, dizziness, general weakness, tiredness, problems with vision, sleeping, tingling in feet and hands (pins and needles).
- sexual dysfunction, fever, skin rash, hearing problems, problems with vision, changes in the way things taste.
- Other side effects: Not Known (The frequency cannot be estimated from available data):
- Decreased number of cells that help with blood clotting. This increases the risk of bleeding or bruising.
- Restricted blood flow to the extremities (causing cold and/or blue fingers and toes, painful pain in the legs when walking), chest pain (angina pectoris), heart block (atrioventricular block), difficulty breathing (bronchospasm)
- itching, psoriasis, Hair loss, Excessive sweating
- Abnormally low levels of thrombocytes, also known as platelets, in the blood.

**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/blister 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 160mg tablet contains 160mg 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 the contents of the pack:**
- Sotalol Hydrochloride 160mg tablets: White, round, biconvex tablets of diameter 8.9mm–9.1mm and height of 3.8mm- 4.2mm, marked "SOT" on one side and scored on the other.

**Sotalol is available in:**
Sotalol tablets are available in packs of 28 or 56 tablets. Not all pack sizes may be marketed.

**Product Licence Numbers:**
Sotalol Hydrochloride 160mg tablets: PL 20416/0582

**Marketing Authorisation Holder:**
Crescent Pharma Ltd., Key House, Sarum Hill, Basingstoke, RG21 8SR, UK.

**This leaflet was last revised in 03/2026.**

Crescent PHARMA LIMITED

| | |
|---|---|
| Product: | Sotalol Hydrochloride 160mg Tablets |
| Item Code: | P3872T |
| Size: | 175 x 340 mm |
| Min. Point size: | 9pt |
| O. Artwork | 16/03/26 |
| Proof No. | 2 |
| Amendment Date: | 16/03/26 |

| Colours Used | |
|---|---|
| | PANTONE Black CVC |
| | Keyline - Does not print |

# Sotalol Hydrochloride 160mg 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 Sotalol

**Do not take Sotalol**
- If you are allergic (hypersensitive) to sotalol hydrochloride or any of the other ingredients in this medicine (listed in section 6).
- If you have a history of breathing difficulties, wheezing or asthma or any other lung disease
- If you have a very slow heart beat or low blood pressure
- If you have low blood pressure, suffer from severe disturbances in blood circulation in the hands and feet 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 certain type of disturbances in the heart's electrical impulses, suffered from heart disease (such as untreated heart failure or shock), certain types of anaesthesia, or had a recent heart attack that your doctor does not know about.
- If you suffer from a condition called metabolic acidosis.
- If you suffer from an untreated tumour of the adrenal gland, tumours that produce blood pressure-raising substances (pheochromocytoma)
- If you 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 Sotalol.

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

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

You must tell your doctor:
- if you are pregnant, planning to become pregnant or are breast-feeding.
- **If you have low levels of magnesium or potassium in your blood.**
- If you have impaired blood circulation in the hands and feet.
- If you suffer from a type of chest pain (angina) called Prinzmetal's angina because Sotalol can make your angina attacks worse.
- if you have any kidney problems, as your dose of Sotalol 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. Sotalol may also hide or reduce the warning signs of low levels of sugar in your blood (hypoglycaemia) and thus make it more difficult to adjust the dose of medicine.
- If you experience dizziness or fainting spells, seek medical attention immediately.
- 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, 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 Sotalol.
- if you suffer from psoriasis (a skin disease that causes itchy, red, sore patches of skin). Sotalol can in rare cases worsen the symptoms of psoriasis.
- if you suffer from liver problems.

If you need to have surgery, you should tell the doctor or anaesthetist that you are taking Sotalol as it can affect anaesthetics. You may have to stop taking Sotalol before surgery and it should be gradually stopped over a period of one week. Your doctor will tell you if this is necessary.

Before treatment with Sotalol Tablets, it is important to keep in mind that this type of medicine can worsen the symptoms of heart failure and asthmatic diseases. Treatment with Sotalol Tablets must be stopped suddenly.

**Children and adolescents**
Sotalol is not recommended for use in children.

**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. Some medicines can have an effect on each others actions.

You should talk to your doctor before taking Sotalol. If you are taking any other medicine that can cause an electrical disturbance in the heart called prolonged QT interval. These are:
- medicines that treat irregular heartbeats (e.g. disopyramide, flecainide, amiodarone, dronedarone)
- ranolazine, which is used to treat angina
- medicines to treat depression, nervousness, or anxiety, belonging to the group of selective serotonin uptake inhibitors (SSRIs) (e.g., citalopram, fluoxetine, sertraline) or tricyclic antidepressants (e.g., clomipramine, amitriptyline, imipramine), trazodone, hydroxyzine
- medicines for the treatment of mental illness (antipsychotics) (e.g. chlorpromazine, thioridazine, haloperidol, fluvoxamine, amisulpiride, pimozide)
- medicines to relieve nausea and vomiting (e.g. ondansetron, domperidone)
- certain H2 receptor blockers (e.g. cimetidine, famotidine), which are used to reduce the amount of acid in the stomach
- antihistamines, used to treat allergic reactions and itchy skin rashes (e.g. chlorphenamine, diphenhydramine, hydroxyzine)
- antibiotics belonging to the group of fluoroquinolones (e.g. ciprofloxacin, levofloxacin, moxifloxacin) or macrolides (erythromycin, clarithromycin, azithromycin)
- fluconazole and amphotericin, which are used to treat fungal infections
- pentamidine, which is used to treat a type of pneumonia and certain diseases caused by parasites
- medicines used to treat and prevent malaria (e.g. mefloquine, chloroquine, halofantrine, quinine)
- opioids (morphine-like) medicines called methadone and hydrocodone
- donepezil, which is used to treat symptoms of dementia
- medicines for cancer called protein kinase inhibitors (e.g. sunitinib, vandetanib, sorafenib)
- arsenic trioxide, which is used to treat leukemia
- anagrelide, which is used to treat thrombocytopenia

It is especially important that you tell your doctor if you are taking the following medicines:
- a medicine called a calcium channel blocker, for the treatment of high blood pressure, to treat or prevent angina (chest pain) (e.g. verapamil, diltiazem, lacipine, nifedipine)
- A medicine used to treat high blood pressure by affecting the central nervous system (e.g. Methyldopa, guanethidine)
- Digoxin (for heart problem)
- A medicine called proton pump inhibitor, which is used to reduce the amount of acid that is produced in the stomach (e.g. omeprazole, lansoprazole, esomeprazole).
- floctafenine (medicine used for the short term treatment of mild to moderate pain)
- for the treatment of certain infections (e.g. amphotericin B, pentamidine, halofantrine)
- steroids
- laxatives
- clonidine (sometimes used to treat high blood pressure, hot flushes or headaches). Do not stop taking clonidine unless your doctor tells you to. If you have to stop taking clonidine, your doctor will give you detailed instructions on how to do this.
- for the treatment of diabetes

*continued....*

Crescent PHARMA LIMITED

| | |
|---|---|
| Product: | Sotalol Hydrochloride 160mg Tablets - Mepro Pharma |
| Item Code: | P3864T |
| Size: | 130 x 480 mm |
| Min. Point size: | 9pt |
| O. Artwork | 13/03/26 |
| Proof No. | 2 |
| Amendment Date: | 17/03/26 |

| Colours Used | |
|---|---|
| | Process Black |
| | Keyline - Does not print |

(antidiabetic medicine that lowers the amount of glucose in the blood. e.g. metformin or insulin)
- a bronchodialator called a beta-2 agonist (e.g. salbutamol, salmeterol, formoterol) for the treatment of asthma and other diseases of the lung; These are usually as inhalers (e.g. ventolin inhalers) but can also occur in other forms
- for depression, anxiety, nervous disorders and mental disturbances (e.g. methyldopa)
- for allergies such as hay fever (e.g. antihistamines)
- antibiotics
- Drugs that can reduce the amount of potassium in the blood; This includes water tablets (diuretics) (e.g. furosemide, indapamide, bumetanide), steroids (e.g. prednisolone, dexamethasone), laxatives (e.g. bisacodyle, senna).

**Sotalol with food, drink and alcohol**
Sotalol should be taken at least 1 hour before meals as the absorption of the medication may decrease if taken with food.

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 for advice before taking this medicine. You should not be given Sotalol during pregnancy unless your doctor thinks it is essential. There is a risk that the fetus will be affected. Therefore, always consult a doctor before using Sotalol during pregnancy.

Treatment with Sotalol should be discontinued 48-72 hours before the expected date of delivery. If this is not possible, the newborn baby may be affected. Therefore, you should not breastfeed while you are being treated with Sotalol.

**Driving and using machines**
Sotalol is not likely to affect you being able to drive or use machinery. However, if you feel lightheaded or dizzy whilst taking this medicine it is necessary to avoid driving or operating machinery.

**Information about the ingredients of Sotalol**
**This medicine contains lactose**
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

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

## 3 How to take Sotalol

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

**Adults**
The recommended daily dose is between 80 mg and 320 mg. Some patients may need up to 640 mg a day or sometimes the doctor may prescribe a different dose from these. Lower doses are often used for elderly patients or those with kidney disease. Tablets should be swallowed whole with a glass of water and can be taken with or without food.

The dose may be taken either as a single dose or in two divided doses. Check with your doctor or pharmacist 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:**
Sotalol tablets should not be given to children.

**If you take more Sotalol than you should:**
If you take too many tablets, contact your doctor or go to the nearest hospital emergency department immediately and take tablets and leaflet with you.

The symptoms of overdose include: slower heartbeat (bradycardia), heart failure, low blood pressure (hypotension), difficulty in breathing or wheezing (bronchospasm), low blood sugar levels (hypoglycaemia). At very high doses, other disturbances of heart function may also occur.

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

**If you stop taking Sotalol**
Do not stop taking Sotalol without consulting your doctor and withdrawal should be gradual over 1-2 weeks.

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.**

Very Common Side Effects (May affect more than 1 in 10 people)
- Shortness of breath, chest pain, palpitations, headache
- Diarrhoea, vomiting, weakness
- slow pulse, sleep disorders, dizziness
- fluid retention (edema)
- irregular electrocardiogram reading (ECG abnormalities)

Common Side Effects (may affect up to 1 in 10 people) include the following:
- irregular heartbeat (cardiac arrhythmia), slow heartbeat, heart failure, chest pain, low blood pressure, difficulty in breathing, swelling, fainting and palpitations.
- nausea/ sick and vomiting, indigestion, abdominal pain, flatulence, diarrhoea, cramps.
- anxiety, depression, mood changes, headache, light-headedness, dizziness, general weakness, tiredness, problems with vision, sleeping, tingling in feet and hands (pins and needles).
- sexual dysfunction, fever, skin rash, hearing problems, problems with vision, changes in the way things taste.

Other side effects: Not Known (The frequency cannot be estimated from available data):
- Decreased number of cells that help with blood clotting. This increases the risk of bleeding or bruising.
- Restricted blood flow to the extremities (causing cold and/or blue fingers and toes, painful pain in the legs when walking), chest pain (angina pectoris), heart block (atrioventricular block), difficulty breathing (bronchospasm)
- itching, psoriasis, Hair loss, Excessive sweating
- Abnormally low levels of thrombocytes, also known as platelets, in the blood.

**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/blister 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 160mg tablet contains 160mg 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 the contents of the pack:**
- Sotalol Hydrochloride 160mg tablets: White, round, biconvex tablets of diameter 8.9mm–9.1mm and height of 3.8mm- 4.2mm, marked "SOT" on one side and scored on the other.

**Sotalol is available in:**
Sotalol tablets are available in packs of 28 or 56 tablets.

Not all pack sizes may be marketed.

**Product Licence Numbers:**
Sotalol Hydrochloride 160mg tablets: PL 20416/0582

**Marketing Authorisation Holder and Manufacturer:**
Crescent Pharma Ltd.,
Key House, Sarum Hill,
Basingstoke, RG21 8SR, UK.

**This leaflet was last revised in 03/2026.**

P3864T

Crescent PHARMA LIMITED

| | |
|---|---|
| Product: | Sotalol Hydrochloride 160mg Tablets - Mepro Pharma |
| Item Code: | P3864T |
| Size: | 130 x 480 mm |
| Min. Point size: | 9pt |
| O. Artwork | 13/03/26 |
| Proof No. | 2 |
| Amendment Date: | 17/03/26 |

| Colours Used | |
|---|---|
| | Process Black |
| | Keyline - Does not print |