

APO-SOTALOL

Contains the active ingredient, sotalol (as sotalol hydrochloride)

Consumer Medicine Information

For a copy of a large print leaflet
Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about sotalol. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Sotalol Tablets. It contains the active ingredient sotalol hydrochloride.

It is used to prevent and treat an irregular heart rhythm or heartbeat. This is called "arrhythmia".

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

Sotalol belongs to a group of medicines called beta-blockers. It works by changing the body's response to some nervous impulses, especially in the heart. By doing so, sotalol helps the heart to beat more regularly and reduce the effort to which the heart has to pump blood.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
 - bronchospasm (e.g. bronchial asthma or chronic obstructive airway disease)
 - allergies
 - severe kidney disease
 - certain cardiovascular conditions.Ask your doctor if you have any cardiovascular conditions or diseases that would stop you from taking this medicine.
- **You are going to receive certain anaesthetics.**

You must tell your doctor if you're going to receive an anaesthetic.
- **You are hypersensitive to, or have had an allergic reaction to, sotalol or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. **You have allergies to:**
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. **You have or have had any medical conditions, especially the following:**
 - diabetes
 - kidney problems
 - an overactive thyroid
 - phaeochromocytoma, which is a rare tumour of the adrenal gland
 - any blood vessel disorders causing poor circulation in the arms and legs
 - a recent heart attack
 - certain types of angina (such as Prinzmetal angina or variant angina)
 - any other heart problems
 - problems with the levels of certain salts in your blood
 - psoriasis
 - eye or skin reactions, which were caused from using beta-blockers in the past.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with sotalol. These include:

- other medicines used to treat an irregular heart rhythm or heartbeat
- digoxin, a medicine used to treat heart failure
- some medicines used to treat high blood pressure, angina or other heart conditions
- insulin and other medicines used to treat diabetes
- certain types of diuretics (fluid tablets)
- some medicines used to treat depression
- antihistamines such as terfenadine and astemizole, which are used to treat hay fever and allergies
- some medicines used for asthma or other lung problems
- some medicines used during surgery or emergency situations such as anaesthetics
- some antibiotics.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other interactions not listed above may also interact with sotalol.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This depends on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablets with a glass of water.

Do not take the tablets with a drink that contains milk.

When to take it

Take your medicine on an empty stomach, at least half an hour (ideally 1-2 hours) before, or two hours after, a meal or milk-containing products.

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time for your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking sotalol

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

If you have a history of allergies, there is a chance that sotalol may cause allergic reactions to be worse or harder to treat.

If you are being treated for diabetes, make sure you check your blood sugar levels regularly. Sotalol may affect how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (also called hypoglycaemia), such as a fast heartbeat. Sotalol may also make low blood sugar last longer. Your doctor may need to change the dose of diabetes medicines (such as insulin).

Go to your doctor regularly for a check-up.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other complaints unless your doctor tells you to.

- **Stop taking your medicine, or change the dosage, without checking with your doctor.**

Things to be careful of

Be careful while driving or operating machinery until you know how medicine affects you.

As with other medicines, sotalol may cause dizziness, light-headedness or drowsiness in some people. If this occurs do not drive or operate machinery or any other activity that could be dangerous if dizzy, light-headed or drowsy.

Dizziness, light-headedness or fainting may occur, especially when you get up from a sitting or lying position. Getting up slowly may help.

Make sure you drink enough water in hot weather and during exercise when you are taking sotalol, especially if you sweat a lot.

If you do not drink enough water while taking sotalol, you may feel faint or light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking sotalol or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- dizziness, light-headedness or fainting, especially when getting up quickly
- tiredness, lack of energy, weakness
- cramps
- headache, fever

- irritated eyes, blurred vision, worsening of eyesight, increased sensitivity of the eyes to sunlight
- feeling sick, vomiting, stomach upset, diarrhoea, wind
- change in taste sensation
- anxiety, depression, mood changes
- problems with sexual function
- sleep problems, unusual dreams
- worsening of psoriasis
- hearing disturbances
- tingling or numbness in the hands or feet, cold limbs.

The above list includes the more common side effects. Mostly, these are mild.

If any of the following happen, stop taking your medicine and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest tightness, wheezing, shortness of breath
- very slow heartbeat
- fast, irregular heartbeat, palpitations
- chest pain
- any type of skin rash, itching
- shortness of breath (sometimes with tiredness, weakness and a reduced ability to exercise), which may occur together with swelling of the feet or legs due to fluid build-up.

These are very serious side effects. You may need urgent medical attention.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to sotalol, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take the tablets out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect from light.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Sotalol Tablets looks like

- **80 mg tablets:**
Blue, capsule-shaped, biconvex tablets, engraved APO-80 on one side and scored on the other.
- **160 mg tablets:**
Blue, capsule-shaped, biconvex tablets, engraved APO-160 on one side and scored on the other.

They are packed in a bottle containing 60 tablets.

*Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 80mg or 160 mg of sotalol hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- dextrans
- methylcellulose
- magnesium stearate
- colloidal anhydrous silica
- indigo carmine.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

- APO-Sotalol 80 mg tablets (Bottles):
AUST R 83094.
- APO-Sotalol 160 mg tablets (Bottles):
AUST R 73846.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO- and APOTEX are registered trademarks of Apotex Inc.

This leaflet was last updated in: July 2013.