

BISOPROLOL SANDOZ®

bisoprolol fumarate film-coated tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Bisoprolol Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT BISOPROLOL SANDOZ IS USED FOR

This medicine is used to treat heart failure. It is usually used in combination with other medicines.

It contains the active ingredient bisoprolol fumarate. Bisoprolol fumarate belongs to a group of medicines called beta-blockers.

It works by affecting the body's response to some nerve impulses, especially in the heart. As a result, it decreases the heart's need for blood and oxygen and therefore reduces the amount of work the heart has to do.

Bisoprolol Sandoz also slows your heart rate, which in turn increases the efficiency of your heart.

Bisoprolol Sandoz can help to reduce the number of heart failure episodes needing hospital admission and also the risk of sudden death.

Heart failure occurs when the heart muscle is weak and unable to pump enough blood to supply the body's needs. Heart failure may start off with no symptoms, but as the condition progresses patients may feel short of breath and notice swelling of the feet and ankles due to fluid build up.

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

Your doctor may have prescribed it for another reason.

This medicine is not recommended for use in children.

This medicine is not addictive.

BEFORE YOU TAKE BISOPROLOL SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- bisoprolol fumarate, the active ingredient, or to any of the other ingredient(s) listed at the end of this leaflet under Product Description.
- any other similar medicines.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you have or have had any of the following medical conditions:

- cardiogenic shock, a serious heart condition causing low blood pressure
- heart conditions where the electrical activity controlling your heart rate does not work properly, causing a very slow heart rate or uneven heart beating
- hypotension, low blood pressure
- severe asthma or chronic obstructive lung disease
- late stages of peripheral arterial occlusive disease
- Raynaud's syndrome, a condition causing numbness, tingling and color change in fingers and toes when exposed to the cold
- untreated pheochromocytoma, a rare tumour of the adrenal gland
- metabolic acidosis, when there is too much acid in the blood.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- asthma, difficulty breathing or other lung problems
- Prinzmetal angina or variant angina
- diabetes
- any allergic conditions
- psoriasis, a skin disease with thickened patches of red skin, often with silvery scales
- hyperthyroidism, an over active thyroid gland
- any blood vessel disorder causing poor circulation in the arms and legs
- kidney problems
- liver problems
- pheochromocytoma, a rare tumour of the adrenal gland.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved. Like most beta-blocker medicines, Bisoprolol Sandoz is not recommended while you are breastfeeding.

Tell your doctor if you plan to have surgery.

The anaesthetist must be told that you are taking Bisoprolol Sandoz before surgery, in order to allow for your condition and medications.

If you have not told your doctor about any of the above, tell him/her before you start taking Bisoprolol Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Bisoprolol Sandoz may interfere with each other. These include:

- calcium antagonists, medicines used to treat high blood pressure and angina such as diltiazem, verapamil
- clonidine, a medicine used to treat high blood pressure
- monoamine oxidase inhibitors, medicines used to treat depression such as phenelzine, tranylcypromine
- anti-arrhythmic drugs used to treat irregular or abnormal heartbeat such as flecainide, amiodarone, disopyramide
- certain medicines used to treat arthritis, pain or inflammation such as indomethacin or ibuprofen
- other beta-blockers, including eye drops
- insulin and oral drugs for diabetes
- anaesthetic agents used in surgery
- digoxin, a medicine used to treat heart failure
- ergot derivatives, medicines commonly used to treat migraines
- tricyclic antidepressants
- barbiturates, medicines used to treat epilepsy
- phenothiazines, a type of medicine used to treat some mental conditions
- rifampicin, a medicine use to treat tuberculosis
- mefloquine, a medicine used to treat malaria
- adrenaline, a medicine used to treat allergic reactions.

These medicines may be affected by Bisoprolol Sandoz, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE BISOPROLOL SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

The usual starting dose is 1.25mg once daily for one week. If well tolerated, your doctor will gradually increase your dose over the next ten weeks. The usual dose for maintenance therapy is 10mg once daily.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Bisoprolol Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets with a glass of water. Do not crush or chew the tablets.

If you need to break Bisoprolol Sandoz, hold tablet with both hands and snap along break line.

When to take Bisoprolol Sandoz

Take your medicine during or immediately after food in the morning. This will lessen the chance of side effects.

How long to take Bisoprolol Sandoz

Continue taking your medicine for 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 your medicine every day, usually as long term treatment. It is very important that you do not stop taking Bisoprolol Sandoz suddenly.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost 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 that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Bisoprolol Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include dizziness, very slow heart rate, difficulty breathing and shock.

WHILE YOU ARE USING BISOPROLOL SANDOZ

Things you must do

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Bisoprolol Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may check your eyes, thyroid, lipid and blood glucose levels from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Your doctor may think it is not working effectively and change your treatment unnecessarily.

Things you must not do

Do not take Bisoprolol Sandoz to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Stopping Bisoprolol Sandoz suddenly may cause your condition to worsen or other heart complications may occur. Bisoprolol Sandoz should only be reduced gradually over a period of about two weeks before stopping completely.

Things to be careful of

If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.

Bisoprolol Sandoz may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar, called hypoglycaemia, such as fast heart beat. Bisoprolol Sandoz may make hypoglycaemia last longer. Your dose of diabetic medicines, including insulin, may need to change.

Take this medicine with caution under strict fasting conditions. Ask your doctor or pharmacist to answer any questions you may have.

Be careful driving or operating machinery until you know how Bisoprolol Sandoz affects you.

This medicine may cause tiredness, dizziness or light-headedness in some people, especially after the first dose. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Bisoprolol Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- tiredness or exhaustion
- dizziness
- headache
- sleep disturbances, nightmares
- nausea or vomiting
- diarrhoea or constipation
- coldness or numbness in the hands or feet.

These are mild side effects of the medicine, and are short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- muscular weakness or cramps
- dizziness or lightheadedness (sometimes with fainting), especially on standing up, which may be due to low blood pressure
- a very slow heart beat
- hallucinations
- depression
- skin reactions such as rash, itching, worsening of psoriasis
- difficulty hearing.

The above list includes serious side effects that may require medical attention. Serious side effects are rare

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

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- signs of worsening heart failure such as shortness of breath, sometimes with tiredness or weakness, swelling of the feet or legs due to fluid build up
- chest tightness, wheezing, rattly breathing
- yellowing of the skin or eyes, dark coloured urine, itching, generally feeling unwell
- constant flu-like symptoms such as fever, sore throat, lack of energy
- irregular heart beating.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER TAKING BISOPROLOL SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Bisoprolol Sandoz 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 it 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Bisoprolol Sandoz comes in three types of film-coated tablets:

- Bisoprolol Sandoz 2.5mg - white, round film-coated tablets marked with a score line and embossed on one side with 'BIS 2.5'.
- Bisoprolol Sandoz 5mg - yellow, round film-coated tablets marked with score lines and embossed on one side with 'BIS 5'.
- Bisoprolol Sandoz 10mg - light orange, round film-coated tablets marked with score lines and embossed on one side with 'BIS 10'.

Available in blisters of 28 film-coated tablets.

Ingredients

Active ingredient:

- Bisoprolol Sandoz 2.5mg - 2.5mg bisoprolol fumarate
- Bisoprolol Sandoz 5mg - 5mg bisoprolol fumarate
- Bisoprolol Sandoz 10mg - 10mg bisoprolol fumarate.

Inactive ingredients:

- calcium hydrogen phosphate anhydrous
- microcrystalline cellulose
- pregelatinised maize starch
- croscarmellose sodium
- colloidal anhydrous silica
- magnesium stearate
- Opadry II OY-L-28900
- iron oxide yellow CI77492 (5 & 10 mg tablets only)
- iron oxide red CI77491 (10 mg tablet only).

Supplier

Sandoz Pty Ltd

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Australian Register Numbers

- 2.5mg film-coated tablets:
AUST R 144867 (blisters)
- 5mg film-coated tablets:
AUST R 144884 (blisters)

- 10mg film-coated tablets:
AUST R 144888 (blisters)