

APO-Bisoprolol

Bisoprolol fumarate

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about bisoprolol. 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 using this medicine against the benefits they expect it will have for you.

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

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

What this medicine is used for

APO-Bisoprolol contains the active ingredient bisoprolol fumarate.

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

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.

Bisoprolol belongs to a group of medicines called beta-blockers.

These medicines work 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 also slows your heart rate, which in turn increases the efficiency of your heart.

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

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.

Bisoprolol is not recommended for use in children, as the safety and efficacy in children have not been established.

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

There is no evidence that this medicine is addictive.

Before you take this medicine

When you must not take it

Do not take this medicine if you are hypersensitive to or have had an allergic reaction to bisoprolol or any of the ingredients listed at the end of this leaflet.

Some of the 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 hayfever-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.

Do not take bisoprolol if you have any of the following heart problems:

- severe heart failure that is not controlled medically
- worsening heart failure requiring injection of medicines into a vein
- cardiogenic shock, a serious heart condition causing low blood pressure and circulatory failure
- certain heart conditions where the electrical activity controlling your heart rate does not work properly, causing a very slow heart rate or uneven heart beating
- low blood pressure.

Do not take bisoprolol if you have any of the following medical conditions:

- severe asthma or severe chronic obstructive lung disease (COPD)
- severe blood circulation problems in your limbs (such as Raynaud's syndrome), which may cause

- your fingers and toes to tingle or turn pale or blue
- untreated phaeochromocytoma, a rare tumour of the adrenal gland
- metabolic acidosis, a condition 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.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

Bisoprolol may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits whilst taking it during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Bisoprolol is not recommended while breastfeeding. Your doctor will discuss the risks and benefits of taking this medicine when breastfeeding.

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

- asthma, difficulty breathing or other lung problems
- certain heart diseases such as disturbances in heart rhythm or Prinzmetal angina
- diabetes
- any allergic conditions
- psoriasis, a skin disease with thickened patches of red skin, often with silvery scales
- thyroid disorder
- any blood vessel disorder causing poor circulation in the arms and legs

- kidney problems
- liver problems
- phaeochromocytoma, a rare tumour of the adrenal gland.

Your doctor may want to take special care if you have any of the above conditions.

Tell your doctor if you are going to have anaesthesia (for example, for surgery).

Bisoprolol may influence how your body reacts to this situation.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Taking bisoprolol may change the effect of some medicines, and some medicines may affect how well bisoprolol works. You may need different amounts of your medication or to take different medicines.

Do not take the following medicines with bisoprolol without special advice from your doctor:

- certain anti-arrhythmic medicines such as disopyramide, lidocaine, phenytoin or flecainide, used to treat irregular or abnormal heartbeat
- certain calcium antagonists such as diltiazem or verapamil, used to treat high blood pressure and angina
- certain medicines used to treat high blood pressure such as clonidine, methyldopa or moxonidine.

However, do not stop taking these medicines without checking with your doctor.

Check with your doctor before taking the following medicines with bisoprolol:

- anti-arrhythmic medicines such as amiodarone, used to treat irregular or abnormal heartbeat
- calcium antagonists such as felodipine or amlodipine, used to treat high blood pressure and angina
- certain medicines used to treat arthritis, pain or inflammation, such as ibuprofen or diclofenac
- eye drops for glaucoma treatment
- insulin and oral drugs for diabetes
- anaesthetic agents used in surgery
- certain medicines used to increase cardiac output, such as digoxin
- ergot derivatives, medicines commonly used to treat migraines
- rifampicin, a medicine used to treat tuberculosis
- tricyclic antidepressants
- barbiturates, medicines used to treat epilepsy
- phenothiazines, medicines used to treat some mental conditions
- mefloquine, a medicine used to treat malaria
- certain medicines used to treat allergic reactions and nervous system disorders, such as adrenaline
- certain medicines used to treat depression called monoamine oxidase inhibitors, such as phenelzine or tranylcypromine.

Your doctor may need to check your condition more frequently.

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

How to take this medicine

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

How much to take

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

If your conditions worsen, or you no longer tolerate the drug, it may be necessary to reduce the dose again or to interrupt treatment. In some patients a maintenance dose lower than 10 mg may be sufficient. Your doctor will tell you what to do.

Your doctor will monitor your blood pressure, heart rate and other vital signs carefully after you start treatment with bisoprolol and during dose increase.

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

How to take it

Swallow your tablet(s) with a glass of water.

Do not crush or chew the tablets.

If you crush or chew the tablets, they will not work as well.

When to take it

Take bisoprolol in the morning, with or without food.

How long to take it

To properly control your condition, bisoprolol must be taken every day, usually as a long-term treatment.

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

It is very important that you do not stop taking bisoprolol suddenly.

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 as usual.

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

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

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 to help you remember.

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.

Symptoms of an overdose may include slowed heart rate, difficulty breathing, marked drop in blood pressure, severe heart failure, or a decrease in blood sugar.

While you are taking this medicine

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking this medicine.

Tell all the doctors and pharmacists treating you that you are taking this medicine.

If you become pregnant or are planning to become pregnant while taking this medicine, tell your doctor.

If you are to undergo anaesthesia and/or surgery, including dental, tell your doctor or pharmacist that you are taking this medicine.

If you are being treated for diabetes, make sure you check your blood sugar level regularly

and report any changes to your doctor

Bisoprolol 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 heartbeat. Bisoprolol may make hypoglycaemia last longer. Your dose of diabetic medicines, including insulin, may need to change.

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

Bisoprolol may affect the results of some tests.

Go to your doctor regularly for a check-up. Your doctor may check your eyes, thyroid, lipid and blood glucose levels.

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 stop taking this medicine or change the dosage, without checking with your doctor.

Stopping bisoprolol suddenly may cause your condition to worsen or other heart complications may occur.

If you have to stop treatment, your doctor will usually advise you to reduce the dose gradually.

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

Do not use this medicine to treat any other conditions unless your doctor tells you to.

Things to be careful of

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

Bisoprolol may cause tiredness, dizziness or light-headedness in some people, especially after the first dose. If any of these occur, do not drive,

operate machinery or do anything else that could be dangerous.

Be careful getting up from a sitting or lying position.

Dizziness, light-headedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

Suggestions to help manage your condition

- Physical activity - regular exercise when symptoms are absent or mild helps improve heart function. Before starting any exercise, ask your doctor for advice.
- Weight reduction - your doctor may suggest losing some weight to help lessen the amount of work your heart has to do.
- Diet - eat a healthy low fat diet which includes plenty of fresh fruit and vegetables, bread, cereals and fish. Also, try to eat less fat and sugar.
- Salt restriction - too much salt can make your heart failure worse. Try to avoid using salt in cooking and at the table.

Side effects

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

Bisoprolol helps most people with heart failure, but it may have effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

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

- tiredness, feeling weak

- dizziness
- headache
- sleep disturbances, nightmares
- nausea, vomiting
- diarrhoea, constipation
- feeling of coldness or numbness in hands or feet
- allergic runny nose
- hair loss
- sexual problems.

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

- muscular weakness or cramps
- dizziness or light-headedness (sometimes with fainting), especially on standing up, which may be due to low blood pressure
- irregular heartbeat e.g. a very slow heart beat
- symptoms of worsening heart failure such as, shortness of breath, fatigue, swelling
- chest pain or tightness
- hallucinations
- depression
- irritation or redness of the eye
- skin reactions such as rash, flush, itching, worsening of psoriasis
- difficulty hearing
- liver disorders such as, abnormal liver test results, yellowing of the skin and poor appetite
- symptoms of an allergic reaction including cough, shortness of breath, wheezing, difficulty breathing, swelling of the face, lips, tongue or throat, rash, itching, hives on the skin, fainting, or hayfever-like symptoms.

The above list includes serious side effects that may require urgent medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you experience any of the above.

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

Tell your doctor if you notice any other effects.

Storage and disposal

Storage

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

If you take your medicine out of its original packaging it may not keep well.

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

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 or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Bisoprolol looks like

1.25 mg: A white to off white, round, biconvex tablet, debossed '1.25' and plain on the other side

2.5 mg: A white to off white, round, biconvex tablet, debossed '2' bisect '5' and plain on the other side

3.75 mg: A white to off white, round, biconvex tablet, debossed '3.75' and plain on the other side

5 mg: A white to off white, round, biconvex tablet, debossed '5' on the

left of a break line and plain on the other side

10 mg: A white to off white, round, biconvex tablet, debossed '10' on the left of a break line and plain on the other side

Blister packs of 7, 10, 28, 30, 42, 56 and 100 tablets

Ingredients

Each tablet contains 1.25 mg, 2.5 mg, 3.75 mg, 5 mg or 10 mg of bisoprolol fumarate as the active ingredient.

It also contains the following inactive ingredients:

- colloidal anhydrous silica
microcrystalline cellulose
- croscarmellose sodium
- sodium starch glycollate (type A)
- magnesium stearate

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

Australian Registration Numbers

APO-Bisoprolol 1.25 mg tablet
(Blister pack): AUST R 182108.

APO-Bisoprolol 2.5 mg tablet
(Blister pack): AUST R 182106.

APO-Bisoprolol 3.75 mg tablet
(Blister pack): AUST R 182117.

APO-Bisoprolol 5 mg tablet (Blister pack): AUST R 182114.

APO-Bisoprolol 10 mg tablet (Blister pack): AUST R 182123.

Sponsor

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Australia

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