APO-Bisoprolol

Contains the active ingredient bisoprolol fumarate

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 bisoprolol. 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.

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 need to read it again.

What this medicine is used for

The name of your medicine is APO-Bisoprolol.

It contains the active ingredient bisoprolol fumarate.

It 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.

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.

There is no evidence that this medicine is addictive.

How it works

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.

Use in children

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

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**
- **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**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**
- **The expiry date (EXP) printed on the pack has passed.**

  If you take this medicine after the expiry date has passed, it may not work.

Before you start to take it

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

- **You are allergic to any other medicines, foods, dyes or preservatives.**
- **You are pregnant or plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.**
- **You are breastfeeding or wish to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.**
- **You are fasting.**
- **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.
- **You are going to have anaesthesia (for example for surgery).**

If you think any of these situations apply to you, or you have any doubts or questions about taking bisoprolol, consult your doctor or pharmacist.

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 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 has 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 gets worse 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 for

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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you become pregnant or are planning to become pregnant
- you are planning to breast-feed
- If you are to undergo anaesthesia and/or surgery
- 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 heart beat. 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. 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 any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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:

- Do not give this medicine to anyone else, even if they have the same condition as you.
- 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 stop taking your tablets because you are feeling better, unless advised by your doctor.
- 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.

Possible 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 or pharmacist if you notice any of the following:.

- 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 lightheadedness (sometimes with fainting), especially on standing up, which may be due to low blood pressure
- irregular heartbeat e.g. a very slow heart beat
- worsening heart failure, e.g. shortness of breath, fatigue
- hallucinations
- depression
- irritation or redness of the eye
- skin reactions such as rash, flush, itching, worsening of psoriasis
- difficulty hearing
- liver disorders e.g. abnormal liver test results, yellowing of the skin and poor appetite

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

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

Tell your doctor if you notice any other effects.

Allergic reactions

If you think you are having an allergic reaction to bisoprolol, 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, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

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

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:

- silica colloidal anhydrous
- 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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This leaflet was last updated in:

April 2012.