

APO-BISOPROLOL

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Bisoprolol fumarate?

APO-BISOPROLOL tablets contains the active ingredient bisoprolol fumarate. It is used to treat heart failure. It is usually used in combination with other medicines.

For more information, see Section [1. Why am I using bisoprolol fumarate?](#) in the full CMI.

2. What should I know before I use Bisoprolol fumarate?

Do not use if you have ever had an allergic reaction to bisoprolol fumarate or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use bisoprolol fumarate?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with bisoprolol fumarate and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Bisoprolol fumarate?

- The usual starting dose is 1.25 mg once daily for one week. If well tolerated, your doctor will gradually increase your dose over the next ten weeks. The usual maintenance therapy is 10 mg once daily.
- Follow the instructions provided and use bisoprolol fumarate until your doctor tells you to stop. They may differ from the information contained in this leaflet.

More instructions can be found in Section [4. How do I use bisoprolol fumarate?](#) in the full CMI.

5. What should I know while using Bisoprolol fumarate?

Things you should do	<ul style="list-style-type: none">• Before starting any new medicine, tell your doctor or pharmacist that you are taking APO-BISOPROLOL.• If you become pregnant while taking it, tell your doctor immediately.• If you are going to have surgery, including dental surgery, tell your doctor or dentist that you are taking APO-BISOPROLOL.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking APO-BISOPROLOL or lower the dose without checking with your doctor.• Stopping treatment suddenly may cause your condition to worsen or other heart complications may occur.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how APO-BISOPROLOL affects you.• This medicine 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.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• 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.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in a cool dry place where the temperature stays below 25°C.• Keep your tablets in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while using bisoprolol fumarate?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-BISOPROLOL

Active ingredient(s): *bisoprolol fumarate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using bisoprolol fumarate tablets. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using bisoprolol fumarate.**

Where to find information in this leaflet:

- [1. Why am I using bisoprolol fumarate?](#)
- [2. What should I know before I use APO-BISOPROLOL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use bisoprolol fumarate?](#)
- [5. What should I know while using APO-BISOPROLOL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Bisoprolol fumarate?

The name of your medicine is APO-Bisoprolol tablets. 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.

Bisoprolol fumarate 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 must do. Bisoprolol fumarate also slows your heart rate, which in turn increases the efficiency of your heart.

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

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why bisoprolol fumarate has been prescribed for you.

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

There is no evidence that bisoprolol fumarate is addictive.

Use in children

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

2. What should I know before I use APO-BISOPROLOL?

Warnings

Do not use bisoprolol fumarate if:

- you are allergic to bisoprolol fumarate, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take APO-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 this medicine 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 pheochromocytoma, a rare tumour of the adrenal gland
- metabolic acidosis, a condition when there is too much acid in the blood.

Always check the ingredients to make sure you can use this medicine.

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.

Check with your doctor if you:

- have any other medical conditions, listed above.
- take any medicines for any other condition
- are allergic to any other medicines, foods, dyes or preservatives
- 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
- currently following a strict fasting diet.
- are going to have anaesthesia (for example, for surgery)

Your doctor may want to take special care if you have any of these conditions. Bisoprolol fumarate 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 APO-BISOPROLOL

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Bisoprolol fumarate may affect your developing baby if you take it during pregnancy. Your doctor can discuss with you the risks and benefits of taking bisoprolol fumarate during pregnancy.

Like most beta-blocker medicines bisoprolol fumarate is not recommended while you are breastfeeding. Your doctor can discuss with you the risks and benefits of taking bisoprolol fumarate when breastfeeding.

3. What if I am taking other medicines?

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

Some medicines and APO-BISOPROLOL may interfere with each other.

Do not take the following medicines with APO-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 APO-BISOPROLOL.

Your doctor may need to check your condition more frequently:

- 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
- digoxin, a medicine used to treat heart failure
- 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
- adrenaline, a medicine used to treat allergic reactions
- certain medicines used to treat depression called monoamine oxidase inhibitors, such as phenelzine or tranlycypromine.

These medicines may be affected by APO-BISOPROLOL 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 APO-BISOPROLOL.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect bisoprolol fumarate.

4. How do I use Bisoprolol fumarate?

How much to take

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

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

- Follow the instructions provided and use bisoprolol fumarate until your doctor tells you to stop. They may differ from the information contained in this leaflet.

How to take it

- Swallow the tablets whole with a full 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 Bisoprolol fumarate tablets

- Take Bisoprolol fumarate tablets in the morning, with or without food.

How long to take it for

- To properly control your condition, APO-BISOPROLOL must be taken every day, usually as a long-term treatment.
- Keep taking it for as long as your doctor recommends.
- It is very important that you do not stop taking APO-BISOPROLOL suddenly.

If you forget to use Bisoprolol fumarate tablets

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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 you missed.

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

If you use too much Bisoprolol fumarate (Overdose)

If you think that you have used too much bisoprolol fumarate, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You may need urgent medical attention.

You should do this even if there are no signs of discomfort or poisoning.

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.

5. What should I know while using APO-BISOPROLOL?

Things you should do

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

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

If you are going to have surgery, including dental surgery, tell your doctor or dentist that you are taking APO-BISOPROLOL.

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

APO-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 fumarate may make hypoglycaemia last longer. Your dose of diabetic medicines, including insulin, may need to change.

Call your doctor straight away if:

- You are to have any medical tests, tell your doctor that you are taking APO-BISOPROLOL. It may affect the results of some tests.
- Visit your doctor regularly so they can check on your progress. 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

Remind any doctor, dentist or pharmacist you visit that you are using bisoprolol fumarate tablets.

Things you should not do

- Do not stop taking APO-BISOPROLOL or lower the dose without checking with your doctor.
- Stopping treatment 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 take APO-BISOPROLOL to treat any other conditions unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful driving or operating machinery until you know how APO-BISOPROLOL affects you.

This medicine 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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.

Looking after your medicine

- Keep your tablets in a cool dry place where the temperature stays below 25°C.
- Keep your tablets in the blister pack until it is time to take them.
- If you take tablets out of the blister pack, they may not keep well.
- Heat and dampness can destroy some medicines

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APO-BISOPROLOL.

APO-BISOPROLOL helps most people with heart failure, but it may have unwanted side effects in some people.

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 this list of possible side effects.

You may not experience any of them.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• 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, including erectile dysfunction.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• muscular weakness or cramps• dizziness or light-headedness (sometimes with fainting), especially on standing up, which may be due to low blood pressure• a very slow heartbeat• hallucinations• depression• irritation or redness of the eye• skin reactions such as rash, flush, itching, worsening of psoriasis• difficulty hearing	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Very Serious side effects

Very Serious side effects	What to do
<ul style="list-style-type: none">swelling of the face, lips, tongue, or throat which may cause difficulty breathing or swallowingsigns of worsening heart failure such as shortness of breath, sometimes with tiredness or weakness, swelling of the feet or legs due to fluid build upchest tightness, wheezing, rattly breathingyellowing of the skin or eyes, dark coloured urine, itching, generally feeling unwellirregular heartbeat. <p>The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.</p>	Tell your doctor immediately, or go to Accident and Emergency at the nearest hospital

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Bisoprolol fumarate contains

Active ingredient (main ingredient)	Each 1.25 mg, 2.5 mg, 3.75 mg, 5 mg or 10 mg of bisoprolol fumarate as the active ingredient.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">colloidal anhydrous silicamicrocrystalline cellulosecroscarmellose sodiumsodium starch glycollate (type A)magnesium stearate

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

Do not take this medicine if you are allergic to any of these ingredients.

What Bisoprolol fumarate looks like

APO-BISOPROLOL comes in three strengths of tablets:

- 1.25 mg:** A white to off white, round, biconvex tablet, debossed '1.25' and plain on the other side. AUST R 182108.
- 2.5 mg:** A white to off white, round, biconvex tablet, debossed '2' bisect '5' and plain on the other side. AUST R 182106.
- 3.75 mg:** A white to off white, round, biconvex tablet, debossed '3.75' and plain on the other side. AUST R 182117.
- 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. AUST R 182114.
- 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. AUST R 182123.

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

Who distributes Bisoprolol fumarate

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

Australia

This leaflet was prepared in September 2024