BEPROL™ 1.25, 2.5, 3.75, 5, 7.5 & 10

Bisoprolol fumarate film-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions people ask about BEPROL.

It does not contain all of 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 BEPROL 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 the medicine. You may need to read it again.

What BEPROL is used for

BEPROL 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.

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

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

Your doctor may have prescribed BEPROL for another reason.

Always ask your doctor if you need more information.

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

BEPROL is available only with a doctor's prescription.

There is no evidence that BEPROL is addictive.

Before you take it

Tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not take it:

Do not take BEPROL if you are allergic to medicines containing bisoprolol 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.

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

Do not take BEPROL 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; or
- low blood pressure.

Do not take BEPROL 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; or
- metabolic acidosis, a condition when there is too much acid in the blood.

Do not take BEPROL after the use by (expiry) date printed on the pack has passed.
It may have no effect at all or an unexpected effect if you take it after the expiry date.

Do not take BEPROL if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

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

Tell your doctor if you are breastfeeding or wish to breastfeed.
Like most beta-blocker medicines, BEPROL is not recommended while you are breastfeeding. Your doctor will discuss the risks and benefits of taking BEPROL 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; or
- phaeochromocytoma, a rare tumour of the adrenal gland.

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

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

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.
Some medicines and BEPROL may interfere with each other.

Do not take the following medicines with BEPROL 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); or
- 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 BEPROL.

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; or
- certain medicines used to treat depression called monoamine oxidase inhibitors, such as phenelzine or tranylcypromine.

These medicines may be affected by BEPROL 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 or pharmacist can tell you what to do if you are taking any of these medicines.

How to take it

Follow all directions given to you by your doctor carefully.
They may differ from the information contained in this leaflet.

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

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 BEPROL and during dose increase.

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

How and when to take it:

Swallow the tablets with a glass of water.

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

Take BEPROL in the morning, with or without food.

How long to take it:

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

Keep taking BEPROL for as long as your doctor recommends.

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

If you forget to take it:

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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 take too much (overdose):

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 for Australia) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much BEPROL. 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 it

Things you must do:

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking BEPROL.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking BEPROL.

If you become pregnant while taking BEPROL, tell your doctor.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking BEPROL.

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

BEPROL 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. BEPROL 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 BEPROL.
BEPROL 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.

Things you must not do:

Do not stop taking BEPROL, or lower the dose, without checking with your doctor.
Stopping BEPROL 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 use BEPROL to treat any other conditions unless your doctor tells you to.

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

Things to be careful of:

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

BEPROL may cause tiredness, dizziness or lightheadedness 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 BEPROL.

BEPROL 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 treatment 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.

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; or
- 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;
- a very slow heart beat;
- hallucinations;
- depression;
- irritation or redness of the eye;
- skin reactions such as rash, flush, itching, worsening of psoriasis;
- difficulty hearing; or
- fainting.

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

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- swelling of the face, lips, tongue throat which may cause difficulty breathing or swallowing;
- 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; or
- irregular heart beating.

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

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

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

After taking it

Storage:

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

Keep your tablets in the blister pack until it is time to take them.
If you take the tablets out of the blister pack they may not keep well.

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

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

Do not leave BEPROL in the car or on window sills.
Heat and dampness can destroy some medicines.

Disposal:

If your doctor tells you to stop taking BEPROL, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What BEPROL looks like

BEPROL* 1.25, 2.5, 3.75, 5, 7.5 & 10 (1.25, 2.5, 3.75, 5, 7.5 & 10 mg bisoprolol fumarate) are presented in pack sizes of 28, 30 or 100 tablets in blister.

BEPROL 1.25
White, circular, biconvex, film-coated tablets debossed with ‘P’ on one side and ‘1’ on the other side.

BEPROL 2.5
White, circular, biconvex, film-coated tablets debossed with ‘P and break line’ on one side and ‘2’ on the other side.

BEPROL 3.75
White, circular, biconvex, film-coated tablets debossed with ‘P’ and

break line' on one side and '3' on the other side.

BEPROL 5
White, circular, biconvex, film-coated tablets debossed with 'P' and break line' on one side and '5' on the other side.

BEPROL 7.5
White, circular, biconvex, film-coated tablets debossed with 'P' and break line' on one side and '7' on the other side.

BEPROL 10
White, circular, biconvex, film-coated tablets debossed with 'P' and break line' on one side and '10' on the other side.

* Some of these pack sizes and strengths are not marketed.

Ingredients

Active ingredient:
Bisoprolol fumarate

Other ingredients:

- microcrystalline cellulose;
- calcium hydrogen phosphate;
- colloidal anhydrous silica;
- crospovidone;
- magnesium stearate; and
- Opadry white 03B28796.

Sponsor/Marketing Authorisation Holder

Aurobindo Pharma Australia Pty Ltd
6 Eastern Road
South Melbourne
Victoria 3205
Australia

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BEPROL™ 1.25 blister pack: AUST R 175924

BEPROL™ 2.5 blister pack: AUST R 175921

BEPROL™ 3.75 blister pack: AUST R 175916

BEPROL™ 5 blister pack: AUST R 175926

BEPROL™ 7.5 blister pack: AUST R 175927

BEPROL™ 10 blister pack: AUST R 175923

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