

Package Leaflet: Information for the User
BISOPROLOL FUMARATE 5MG AND 10MG TABLETS

Bisoprolol Fumarate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Bisoprolol Fumarate Tablets is and what it is used for
2. What you need to know before you take Bisoprolol Fumarate Tablets.
3. How to take Bisoprolol Fumarate Tablets.
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5. How to store Bisoprolol Fumarate Tablets.
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1. What Bisoprolol Fumarate Tablets is and what it is used for

These tablets contain Bisoprolol fumarate. Bisoprolol belongs to a group of drugs called beta-blockers (a heart drug). Beta-blockers slow the heart rate, causing the heart to beat slowly and make the heart more efficient at pumping blood around the body.

They are used to treat:

- High blood pressure (hypertension).
- Angina pectoris (chest pain).

2. What you need to know before you take Bisoprolol Fumarate Tablets

Do not take Bisoprolol Fumarate Tablets if you:

- Are allergic (hypersensitive) to Bisoprolol or any of the other ingredients of this medicine (listed in section 6). The symptoms of an allergic reaction include itching, nettle rash, wheezing or swelling of the hands, throat, mouth or eyelids.
- Are suffering from a condition called Cardiogenic Shock – symptoms include low blood pressure, fast pulse, restlessness, thirst and cold, clammy skin.
- Have severe asthma or breathing problems.
- Have untreated heart failure (severe ankle swelling and breathlessness).
- Have sick sinus syndrome – a condition that causes abnormal heart rhythm.
- Suffer from low blood pressure.
- Have heart block - where the heart beats very slowly.
- Have 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.
- Have severe chronic lung disease.
- Have untreated phaeochromocytoma, which is a rare tumour of the adrenal gland.
- Have metabolic acidosis, which is a condition in which the blood is too acidic.
- If you think any of the above points apply to you, do not take the tablets. Talk to your doctor first and follow the advice given.

Warning and precautions:

Talk to your doctor before taking these tablets:

- If you have any heart problems.
- If you are diabetic.
- If you are strict fasting.
- If you have first degree heart block (a condition in which nerve signals to the heart are disturbed, possibly causing it occasionally to skip a beat, or beat irregularly).
- If you have phaeochromocytoma (a tumour near the kidney).

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- Nightmares, hallucinations, anxiety, psychosis, confusion.

- Fainting.
- Muscle and joint ache.
- Blue fingers and toes.
- Sweating.
- Pins and needles, Oedema (swelling).

Very rare (affects less than 1 person in 10,000):

- Irritation and redness of the eye (conjunctivitis).
- Hair loss.
- Appearance or worsening of scaly skin rash (psoriasis); psoriasis-like rash.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bisoprolol Fumarate Tablets

Blister packs: Do not store above 25°C. Store your medicine in the original packaging in order to protect from light and moisture. Do not put them into another container as they might get mixed up. Keep out of the reach and sight of children.

Do not use Bisoprolol Tablets after the expiry date which is stated on the pack.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Bisoprolol Fumarate Tablets contains

The active substance is Bisoprolol fumarate (either 5 mg or 10 mg). The other ingredients are mannitol (E421), microcrystalline cellulose (E460), magnesium stearate (E572), hypromellose (E464), croscarmellose sodium, titanium dioxide (E171) and macrogol 6000.

What Bisoprolol Fumarate Tablets look like and contents of the pack

The tablets are round, white, film-coated convex tablets. The 5 mg tablets have "R5" printed on one side and the 10 mg Tablets have "R6" printed on one side.

The tablets are available in packs of: 20, 28, 30, 50, 56, 98, 100 and 105 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder for your tablets is:

RI Pharma Ltd, 6, St. John's Court, First Floor, Upper Forest Way, Swansea Enterprise Park, Swansea, SA6 BQQ

The manufacturers for your tablets are:

1. Pharmicare Premium Ltd., HHF003 Hal Far Industrial Estate, Birzebbugia, BBG 3000, Malta.
2. Wave Pharma Limited, 4th Floor Cavendish House, 369 Burnt Oak, Edgware, Middlesex, HA85AW, UK

If you would like this leaflet in a different format please contact the licence holder at the following address: 6 St. John's Court, First Floor, Upper Forest Way, Swansea Enterprise Park, Swansea SA6 8QQ or e-mail at info@ri-pharma.com

If you would like to have any further information or want to report any side effects, please email at info@ri-pharma.com

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Take the tablet with some water in the morning, with or without food. Do not crush or chew the tablet.

Dosage in adults

The usual dose for high blood pressure and angina (chest pain) is 10 mg a day. In some patients 5 mg a day may be adequate.

Elderly patients may be prescribed a lower dose. The dose should not exceed 20 mg in one day.

- If you have severe liver or kidney problems, your doctor will prescribe a lower dose.

Children

Bisoprolol Tablets should not be given to children.

If you take more Bisoprolol Fumarate Tablets than you should

An overdose of this medicine may be dangerous. If you take too many tablets or if you (or someone else) swallow a lot of the tablets together tell your doctor or go to the nearest hospital casualty department immediately.

If you have taken too many tablets you may have a slowed heart rate, severe difficulty in breathing, feeling dizzy, or trembling (due to decreased blood sugar).

If you forget to take Bisoprolol Fumarate Tablets

If you forget to take a dose take it as soon as you remember, but do not take two doses at the same time.

If you stop taking Bisoprolol Fumarate Tablets

Do not stop taking your tablets suddenly unless on your doctor's advice, otherwise your condition could become much worse. If your treatment is to be stopped your doctor will gradually reduce your dose by halving it each week.

4. POSSIBLE SIDE EFFECTS

Like all medicines, these tablets can cause side effects, although not everybody gets them.

Serious side effects –

If you get any of the side effects shown in the list below STOP TAKING the tablets and seek medical attention:

- Sudden attacks of unconsciousness.
- Allergic reactions such as itching or rash or swelling of the hands, feet, ankles, mouth, throat or face.
- Shortness of breath or wheezing.
- Light-headedness.
- Worsening of heart failure causing increased breathlessness and / or retention of fluid.
- If you already have Raynaud's disease (a condition in which the fingers and toes become white, numb and painful in cold weather) or intermittent claudication (pain in the legs while walking) Bisoprolol may make these worse.

Known side effects are listed below according to how frequently they may occur:

Common (affects less than 1 person in 10):

- Tiredness, dizziness, headache.
- Feeling of coldness or numbness in hands or feet.
- Low blood pressure.
- Stomach or intestine problems such as nausea.
- Vomiting, diarrhoea, or constipation.

Uncommon (affects less than 1 person in 100):

- Interference with normal heart rate, slow pulse.
- Worsening heart failure.
- Sleep disturbances (including vivid dreams).
- Depression.
- Breathing problems in patients with asthma or chronic lung disease.
- Feeling weak, muscle weakness, muscle cramps.
- Dizziness when standing up.

Rare (affects less than 1 person in 1,000):

- Hearing problems.
- Allergic runny nose, sneezing and itching.
- Reduced tear flow (dry eyes), impaired vision.
- Inflammation of the liver which can cause yellowing of the skin or the whites of the eyes.
- Certain blood test results for liver function or fat levels differing from normal.
- Allergy-like reactions such as itching, flush, rash.
- Impaired erection.

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- If you have ever suffered from asthma, wheezing or breathing problems.
- If you have Prinzmetal's angina (an uncommon form of angina pectoris that occurs at rest in cycles, typically at night).
- If you have kidney or liver problems.
- If you have any problems with the circulation in your limbs.
- If you have psoriasis - a condition in which your skin becomes red and dry and pieces of dead skin fall off.
- If you are due to undergo an anesthetic.
- If you have thyroid disorder (Bisoprolol can hide symptoms of an overactive thyroid).
- If you are going to have desensitization therapy (for example for the prevention of hay fever), because Bisoprolol may make it more likely that you experience an allergic reaction, or such reaction may be more severe.

Other medicines and Bisoprolol Fumarate tablets

Tell your doctor before taking this medicine if you are already taking any of the following:

- Certain medicines used to treat high blood pressure and angina (such as verapamil, diltiazem, nifedipine or amlodipine).
- Certain medicines used to treat high blood pressure such as clonidine, methyldopa, moxonidine, rilmenidine., However, do not stop taking these medicines without checking with your doctor first.
- Digoxin – used to treat various heart conditions.
- Monoamine oxidase inhibitors (MAOIs) – used to treat depression.
- Medicines to treat abnormal heart rhythms (such as disopyramide, quinidine or amiodarone).
- Insulin or tablets used to treat diabetes.
- Anaesthetic agents (for example during surgery).
- Non-steroidal anti-inflammatory drugs (NSAIDs) – used to treat pain and inflammation (such as ibuprofen or indomethacin).
- Beta-blockers applied locally (such as timolol eye drops for glaucoma treatment).
- Rifampicin – used to treat tuberculosis (TB).
- Medicines such as adrenaline (used to increase heart rate and blood pressure) or ephedrine (found in some cold remedies).
- Tricyclic antidepressants used to treat depression e.g. amitriptyline.
- Medicines used to treat mental problems e.g. chlorpromazine.
- Medicines used to treat insomnia and epilepsy e.g. Barbiturates.
- Moxisylyte, which is used to treat circulatory problems like Raynaud's syndrome.
- Mefloquine, used for prevention or treatment of malaria.

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Bisoprolol Fumarate Tablets with alcohol

Do not drink alcohol whilst taking Bisoprolol as it could cause your blood pressure to fall too low.

Pregnancy and breast-feeding.

Bisoprolol is not recommended if you are pregnant as it can cause you to give birth prematurely and can cause problems in the baby.

Breast-feeding is not recommended while taking Bisoprolol as it could be passed on to your baby through the milk.

Driving and using machines

Your ability to drive or use machinery may be affected depending on how well you tolerate the medicine. Please be especially cautious at the start of treatment, when the dose is increased or the medication is changed, as well as in combination with alcohol.

Some of the possible side effects listed in section 4 below could affect you when driving. If you feel tired, dizzy or faint or get any muscle weakness or cramps you should not drive.

3. How to take Bisoprolol Fumarate Tablets

Always take Bisoprolol Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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