

Bisoprolol Fumarate 2.5mg, 5mg & 10mg Tablets

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, pharmacist or nurse.
- This medicine has been prescribed for you only. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. **What Bisoprolol Fumarate Tablets are and what they are used for**
2. **What you need to know before you take**
3. **How to take**
4. **Possible side effects**
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6. **Contents of the pack and other information**

1. **What Bisoprolol Fumarate Tablets are and what they are used for**

The active substance in Bisoprolol Fumarate Tablets is bisoprolol. 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, bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body.

Heart failure occurs when the heart muscle is weak and unable to pump enough blood to supply the body's needs. Bisoprolol Fumarate Tablets are used to treat stable chronic heart failure. They are used in combination with other medicines suitable for this condition (such as ACE-inhibitors, diuretics and heart glycosides).

2. **What you need to know before you take**

Do not take Bisoprolol:

Do not take Bisoprolol if one of the following conditions applies to you:

- if you are allergic to bisoprolol fumarate or to any of the other ingredients of this medicine (listed in section 6)
- severe asthma or severe chronic 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, which is a rare tumour of the adrenal gland
- metabolic acidosis, which is a condition when there is too much acid in the blood.

Do not take Bisoprolol if you have one of the following heart problems:

- heart failure that suddenly becomes worse and/or that may require hospital treatment
- slow or irregular heart rate
- very low blood pressure

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Bisoprolol especially if you have any of the following conditions; he or she may want to take special care (for example give additional treatment or perform more frequent checks):

- diabetes (bisoprolol can hide the symptoms of low blood sugar)

- strict fasting
- certain heart diseases such as disturbances in heart rhythm, or severe chest pain at rest (Prinzmetal's angina)
- kidney or liver problems
- blood circulation problems in your limbs
- asthma or chronic lung disease
- history of a scaly rash (psoriasis)
- tumour of the adrenal gland (phaeochromocytoma)
- thyroid disorder (bisoprolol can hide symptoms of an overactive thyroid)

In addition, tell your doctor 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
- anaesthesia (for example for surgery), because bisoprolol may influence how your body reacts to this situation.

Other medicines and Bisoprolol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- Certain medicines used to treat irregular or abnormal heartbeat (medicines such as quinidine, disopyramide, lidocaine, phenytoin; flecainide, propafenone)
- Certain medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (calcium antagonists such as verapamil and diltiazem)
- 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.

Check with your doctor before taking the following medicines with Bisoprolol; your doctor may need to check your condition more frequently:

- Certain medicines used to treat high blood pressure or angina pectoris (such as felodipine and amlodipine)
- Certain medicines used to treat irregular or abnormal heartbeat (medicines such as amiodarone)
- Timolol eye drops (and related medicines) for glaucoma treatment
- Certain medicines used to treat for example Alzheimer's disease or glaucoma (such as tacrine or carbachol) or medicines that are used to treat acute heart problems (such as isoprenaline and dobutamine)
- Antidiabetic medicines including insulin
- Anaesthetic agents (for example during surgery)
- Digoxin, used to treat heart failure
- Non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain or inflammation (for example ibuprofen or diclofenac)
- Any medicine, that can lower blood pressure such as antihypertensives, certain medicines for depression (such as imipramine or amitriptyline), certain medicines used to treat epilepsy or during anaesthesia (such as phenobarbital), or certain medicines to treat mental illness (such as levomepromazine)
- Mefloquine, used for prevention or treatment of malaria
- Depression treatment medicines called monoamine oxidase inhibitors (except MAO-B inhibitors) such as moclobemide
- Some medicines for migraine (ergotamine derivatives).

Pregnancy and breast-feeding

There is a risk that use of bisoprolol during pregnancy may harm the baby. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

It is not known whether bisoprolol passes into human breast milk. Therefore, breastfeeding is not recommended during therapy with bisoprolol.

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.

Bisoprolol Tablets contain lactose

Bisoprolol Tablets contain milk sugar (lactose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take

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

Treatment with bisoprolol requires regular monitoring by your doctor. This is particularly necessary at the start of treatment and during dose increase.

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

Treatment with bisoprolol is usually long-term.

The tablet can be divided into equal doses.

Use in adults including the elderly

Treatment with bisoprolol must be started at a low dose and increased gradually. Your doctor will decide how to increase the dose, and this will normally be done in the following way:

- 1.25mg bisoprolol once daily for one week
- 2.5mg bisoprolol once daily for one week
- 3.75mg bisoprolol once daily for one week
- 5mg bisoprolol once daily for four weeks
- 7.5mg bisoprolol once daily for four weeks
- 10mg bisoprolol once daily for maintenance (on-going) therapy.

The maximum recommended daily dose is 10mg bisoprolol.

Depending on how well you tolerate the medicine, your doctor may also decide to lengthen the time between dose increases. If your condition 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 10mg bisoprolol may be sufficient. Your doctor will tell you what to do.

If you have to stop treatment entirely, your doctor will usually advise you to reduce the dose gradually, as otherwise your condition may become worse.

Use in children

Bisoprolol is not recommended for use in children.

If you take more Bisoprolol than you should

If you have taken more bisoprolol than you should, tell your doctor immediately. Your doctor will decide what measures are necessary.

Symptoms of an overdose may include dizziness, light-headedness, fatigue, breathlessness and/or wheezing. Also, there may be reduced heart rate, reduced blood pressure, insufficient action of the heart and a low blood glucose level (which may involve feelings of hunger, sweating and palpitations).

If you forget to take Bisoprolol

Do not take a double dose to make up for a forgotten dose. Take your usual dose the next morning.

If you stop taking Bisoprolol

Never stop taking bisoprolol unless on your doctor's advice. Otherwise your condition could become much worse.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

To prevent serious reactions, speak to a doctor immediately if a side effect is severe, occurred suddenly or gets worse rapidly.

The most serious side effects are related to the heart function:

- Slowing of heart rate (affects more than 1 person in 10)
- worsening of heart failure (affects less than 1 person in 10)
- slow or irregular heartbeat (affects less than 1 person in 100)

If you feel dizzy or weak, or have breathing difficulties please contact your doctor as soon as possible.

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

Common: (affects less than 1 person in 10)

- tiredness, feeling weak, 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)

- sleep disturbances
- depression
- breathing problems in patients with asthma or chronic lung disease
- muscle weakness, muscle cramps.

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

- hearing problems
- allergic runny nose
- dry eyes from reduced tear flow (can be troublesome if you use contact lenses)
- inflammation of the liver which can cause yellowing of the skin or whites of the eyes
- allergy-like reactions such as itching, flush, rash
- reduced sexual performance (potency disorder)
- nightmares
- hallucinations
- fainting
- certain blood test results for liver function or fat levels differing from normal.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Do not store Bisoprolol Tablets above 30°C.

Do not use this medicine if you notice your tablets become discoloured or show any other signs of deterioration and return to your pharmacist for advice.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bisoprolol Fumarate Tablets contain

- The active substance is bisoprolol fumarate.
Each 2.5mg tablet contains 2.5mg of bisoprolol fumarate.
Each 5mg tablet contains 5mg of bisoprolol fumarate.
Each 10mg tablet contains 10mg of bisoprolol fumarate.
- The other ingredients are lactose monohydrate, cellulose microcrystalline [E460], magnesium stearate [E572] and crospovidone [E1202].
Each 5mg tablet also contains a yellow colour (which contains lactose monohydrate and iron oxide yellow [E172]).
Each 10mg tablet also contains a beige colour (which contains lactose monohydrate and iron oxide red and yellow [E172]).

What Bisoprolol Fumarate Tablets look like and contents of the pack

The 2.5mg tablets are white, oblong, uncoated, break-line on both top and bottom sides, “BI” and “2.5” debossed on either side of the break-line on the top.

The 5mg tablets are pale yellow mottled, round and convex, uncoated, “BI” and “5” debossed on either side of a break-line on the top side, plain on the bottom side.

The 10mg tablets are beige mottled, round and convex, uncoated, “BI” and “10” debossed on either side of a break-line on the top side, plain on the bottom side.

The tablets are packed in blisters comprising of uPVC/PVdC/aluminium foil contained within a printed cardboard carton.

Each carton will contain either 10, 14, 20, 28, 30, 50, 56, 60, 90 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Actavis Group PTC ehf.
Reykjavíkurvegi 76-78,
220 Hafnarfjörður

Iceland.

Manufacturer:

Niche Generics limited
Unit 5, 151 Baldoyle Industrial Estate,
Dublin
Ireland.

Actavis Group PTC ehf.
Reykjavikuvegi 76-78
IS-220 Hafnarfjörður
Iceland

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