

Package leaflet: Information for the patient

Bisoprolol Fumarate 1.25 mg, 2.5 mg, 3.75 mg, 5 mg & 10 mg 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, please ask your doctor or pharmacist.**
- **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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.**

What is in this leaflet:

1. What Bisoprolol Fumarate is and what it is used for
2. What you need to know before you take Bisoprolol Fumarate
3. How to take Bisoprolol Fumarate
4. Possible side effects
5. How to store Bisoprolol Fumarate
6. Contents of the pack and other information

1. What Bisoprolol Fumarate is and what it is used for

The active substance in this medicine is bisoprolol fumarate. 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, 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 is used:

- To treat stable chronic heart failure. It is used in combination with other medicines suitable for this condition (such as ACE-inhibitors, diuretics, and heart glycosides).
- In treatment of coronary heart disease and chest pain (angina pectoris) caused by shortage of oxygen in the heart muscle.
- In treatment of high blood pressure (hypertension).

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

Do not take Bisoprolol Fumarate:

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

- Allergic to bisoprolol fumarate or any of the other ingredients of this medicine (listed in section 6)
- Severe asthma
- 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, 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 Fumarate if you have one of the following heart problems:

- Acute heart failure
- Worsening heart failure requiring injection of medicines into a vein, that increase the force of contraction of the heart
- Slow heart rate
- Very low blood pressure
- Certain heart conditions causing a very slow heart rate or irregular heartbeat
- Cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure.

Warnings and precautions:

If you have any of the following conditions tell your doctor before taking this medicine; he or she may want to take special care (for example give additional treatment or perform more frequent checks):

- Diabetes
- Strict fasting
- Certain heart diseases such as disturbances in heart rhythm, or severe chest pain at rest (prinzmetal's angina)
- Kidney or liver problems
- Less severe blood circulation problems in your limbs
- Less severe asthma or chronic lung disease
- Previously had or currently have scaly skin rash (psoriasis)
- A tumor of the adrenal gland (pheochromocytoma) or if you are currently undergoing treatment for a tumor of the adrenal gland.
- Thyroid disorder
- Thyroid problems.

During Treatment

Talk to your doctor or pharmacist 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
- Are going to have anaesthesia (for example for surgery), because this medicine may influence how your body reacts to this situation
- Have chronic lung disease or less severe asthma please inform your doctor immediately if you start to experience new difficulties in breathing, cough, wheezing after exercise, etc. when using bisoprolol.

Other medicines and Bisoprolol Fumarate

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 Fumarate without special advice from your doctor:

- If you have chronic heart failure certain medicines used to treat irregular or abnormal heartbeat (e.g. Class I antiarrhythmic medicines such as quinidine, disopyramide, lidocaine, phenytoin; flecainide, propafenone)
- Certain medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (e.g. calcium antagonists such as verapamil and diltiazem)
- Certain medicines used to treat high blood pressure (e.g. clonidine, methyl dopa, 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 Fumarate; your doctor may need to check your condition more frequently:

- Certain medicines used to treat high blood pressure or angina pectoris (e.g. dihydropyridine-type calcium antagonists such as nifedipine, felodipine and amlodipine)
- Certain medicines to treat clinical shock (e.g. adrenaline, dobutamine, noradrenaline)
- Certain medicines used to treat irregular or abnormal heartbeat (Class III antiarrhythmic medicines such as amiodarone)
- Beta-blocking agents applied locally (such as timolol eye drops for glaucoma treatment)
- Certain medicines used to treat for example Alzheimer's disease or glaucoma (parasympathomimetics such as tacrine or carbachol) or medicines that are used to treat acute heart problems (sympathomimetics such as isoprenaline and dobutamine)
- Antidiabetic medicines including insulin
- Anaesthetic agents (for example during surgery)
- Digitalis glycosides, used to treat heart failure
- Non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain or inflammation (for example ibuprofen or diclofenac)
- Medicines for asthma or medicines used for a blocked nose
- Mefloquine, used for prevention or treatment of malaria.
- Any medicine which can lower blood pressure as a desired effect such as antihypertensives, certain medicines for depression (tricyclic antidepressants such as imipramine or amitriptyline), certain medicines used to treat epilepsy or during anaesthesia (barbiturates such as phenobarbital), or certain, medicines to treat mental illness characterised by a loss of contact with reality (phenothiazines such as levomepromazine)
- Depression treatment medicines called monoamine oxidase inhibitors (except MAO-B inhibitors) such as moclobemide.

Pregnancy and breast-feeding:

Bisoprolol Fumarate is not recommended during pregnancy. There is a risk that use of bisoprolol during pregnancy may harm the baby. If you are pregnant or planning to become pregnant, tell your doctor. He or she will decide whether you can take this medicine during pregnancy.

It is not known whether bisoprolol passes into human breast milk.

Therefore, breast-feeding is not recommended during therapy with Bisoprolol Fumarate.

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.

3. How to take Bisoprolol Fumarate Tablets

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

This treatment should be initiated by a specialist in cardiology or internal medicine.

Adults and the Elderly:

Hypertension or angina pectoris

The maximum daily dose is 20mg once a day.

Stable chronic heart failure

The treatment should be managed by a doctor experienced in treating chronic heart failure.

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:

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

The maximum recommended dose is 10 mg once daily.

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 10 mg bisoprolol may be sufficient.

Your doctor will tell you what to do.

Kidney or liver disease

Patients with hypertension or angina pectoris: The dosage should not exceed 10 mg once daily in patients with severe kidney or liver problems.

Use in children and adolescents

Bisoprolol Fumarate is not recommended for use in children and adolescents.

Take your medicine

Bisoprolol Fumarate Tablets should be taken in the morning, before, with or after breakfast. Swallow the tablet/s whole with some water and do not chew or crush them. The 2.5 mg, 5 mg and 10 mg tablets can be divided into equal doses. The 1.25 mg and 3.75 mg tablets should not be broken.

If you take more Bisoprolol Fumarate than you should

Contact your doctor or local emergency ward immediately. Take this leaflet and any tablets you still have with you. Your doctor will decide what measures are necessary.

The most common signs of an overdose may include slowed heart rate, severe difficulty in breathing feeling dizzy, or trembling (due to decreased blood sugar).

If you forget to take Bisoprolol Fumarate

If you forget to take a dose, take it as soon as you remember it unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Bisoprolol Fumarate

Do not stop treatment suddenly or change the recommended dose without talking to your doctor first. If you need to stop treatment, it must be done gradually, to avoid side effects.

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

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 (may affect more than 1 in 10 people)
- Worsening of heart failure (may affect up to 1 in 10 people)
- Slow or irregular heartbeat (may affect up to 1 in 100 people)

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

Other **serious side effects** are:

Uncommon (may affect up to 1 in 100 people):

- depression
- breathing problems in patients with asthma or chronic lung disease

Rare (may affect up to 1 in 1,000 people):

- inflammation of the liver which can cause yellowing of the skin or whites of the eyes
- allergic reactions such as itching, redness and skin rash. You should see a doctor straight away if you experience more severe allergic reactions, which may involve face, neck, tongue, mouth or throat swelling, or difficulty breathing.

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

Common (may affect up to 1 in 10 people):

- Tiredness*
- Headache*
- Feeling of coldness or numbness in hands or feet
- Low blood pressure
- Stomach or intestine problems such as nausea, vomiting, diarrhoea, or constipation.

* These symptoms occur at the beginning of therapy in patients with hypertension or angina pectoris. They are usually mild and disappear within 1-2 weeks.

Uncommon (may affect up to 1 in 100 people):

- Sleep disturbances
- Muscle weakness and muscle cramps
- Changes in the normal heart rate
- Dizziness when standing up.

Rare (may affect up to 1 in 1,000 people):

- Hearing problems
- Allergic runny nose
- Reduced tear flow
- Certain blood test results for liver function or fat levels differing from normal
- Impaired erection
- Nightmares, hallucinations
- Fainting.

Very rare (may affect up to 1 in 10,000 people):

- 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 Website 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

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 blister and the carton.

The expiry date refers to the last day of that month. This medicine does not require any special storage conditions.

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 contains:

The active substance is bisoprolol fumarate.

Each 1.25 mg tablet contains 1.25 mg bisoprolol fumarate.

Each 2.5 mg tablet contains 2.5 mg bisoprolol fumarate.

Each 3.75 mg tablet contains 3.75 mg bisoprolol fumarate.

Each 5 mg tablet contains 5 mg bisoprolol fumarate.

Each 10 mg tablet contains 10 mg bisoprolol fumarate.

The other ingredients are microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium, sodium starch glycollate (type A) and magnesium stearate.

What Bisoprolol Fumarate Tablets look like and contents of the pack:

1.25 mg: White to off white round biconvex tablets.

2.5 mg: White to off white round biconvex tablets with a break line on one side.

3.75 mg: White to off white round biconvex tablets.

5 mg: White to off white round biconvex tablets with a break line on one side.

10 mg: White to off white round biconvex tablets with a break line on one side.

Bisoprolol Fumarate 2.5 mg, 5 mg and 10 mg Tablets only: The tablet can be divided into equal doses.

Blisters: Pack sizes of 20, 21, 28, 30, 50, 56, 60, 90 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Healthcare Pharma Limited, Longdene House, Hedgehog Lane, Haslemere, Surrey, GU27 2PH, United Kingdom.

Manufacturer:

Chanelle Medical, Loughrea, Co Galway, Ireland

McDermott Laboratories Ltd (t/a Gerard Laboratories), 35-36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

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