

Bisoprolol Fumarate 1.25mg, 2.5mg and 3.75mg Tablets

Package leaflet: Information for the user

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 Tablet 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**
- 4. Possible side effects**
- 5. How to store Bisoprolol Fumarate Tablets**
- 6. Contents of the pack and other Information**

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

Bisoprolol Fumarate contains the active ingredient bisoprolol fumarate. Bisoprolol belongs to a group of medicines called beta-blockers. Bisoprolol prevents irregular heart beats (arrhythmia) during stress and decreases cardiovascular workload. Bisoprolol also dilates blood vessels, and thus facilitating blood flow.

Bisoprolol Fumarate is used to

- Treat high blood pressure (hypertension).
- Treat coronary heart disease and chest pain (angina pectoris) pain resulting from lack of oxygen in cardiac muscle.
- Treat heart failure concomitantly with other medications. Heart failure is the inability of your heart to pump enough blood for your body's needs, causing swelling (oedema) of the extremities and shortness of breath.

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

Do not take Bisoprolol Fumarate:

- if you are allergic to bisoprolol or any of the other ingredients of this medicine (listed in section 6),

- if you have heart failure, which has just occurred or which has recently become worse, or you are receiving treatment for circulatory shock due to acute heart failure by intravenous drip feed to help your heart work,
- if you have a very low blood pressure or slow heart rate due to severe cardiac malfunction (so called cardiogenic shock)
- if you have conduction disorders in the heart, such as sick sinus syndrome, sino-atrial block, or second or third degree atrio-ventricular blockade,
- if you have a very slow heart rate,
- if you have a very low blood pressure,
- if you have an untreated tumour which might increase blood pressure (so called phaeochromocytoma),
- if you suffer from severe asthma symptoms or chronic obstructive lung disease,
- if you suffer from severe disturbances in the blood circulation system of the extremities, such as intermittent claudication (easily triggered pain in the legs during walking) or Raynaud's syndrome (with whitish, bluish and finally reddish turning fingers or toes associated with pain),
- if you have a so called metabolic acidosis which is a disturbance in the acid/base balance such as diabetic patients have when the blood sugar has risen too much

Warnings and precautions:

Talk to your doctor or pharmacist before taking this medicine; he or she may want to take special care (for example give additional treatment or perform more frequent checks):

- if you suffer from a symptomless and well-treated heart failure,
- kidney or liver problems,
- if you have problems with the valves of your heart or a congenital heart condition,
- if you have suffered a heart attack during the last three months,
- if you have asthma or a chronic obstruction lung disease (if you use bronchodilating medicines, their doses may have to be adjusted and lung functions may have to be monitored),
- if you are going to have a surgery or other procedure under sedation or spinal anaesthesia (you must inform the anaesthesiologist that you use Bisoprolol Fumarate),
- if you have diabetes mellitus and your blood sugar values vary greatly (Bisoprolol Fumarate may mask the symptoms of hypoglycaemia and decelerate the recovery of blood sugar levels),
- if you are on a strict fast,

- if you have overactive thyroid gland (Bisoprolol Fumarate may mask the symptoms of hyperthyroidism),
- if you receive desensitisation therapy (Bisoprolol Fumarate may strengthen the allergic reactions and more medicines may be needed to treat the allergic reaction),
- if you have a mild conduction disturbance of the heart (first-degree atrio-ventricular blockade),
- if you have chest pain caused by cramping of the heart (coronary arteries (so called Prinzmetal's angina pectoris)
- if you use contact lenses (Bisoprolol Fumarate may reduce the excretion of tear fluid and cause drying of eyes)
- history of a scaly skin rash (psoriasis).
- other drugs that may lower the blood-pressure, such as tricyclic antidepressants (such as imipramine or amitriptyline), phenothiazines such as levomepromazine (to treat psychoses), or barbiturates such as phenobarbital (to treat epilepsy) ,
- adrenaline to treat allergic reactions,
- baclofen and tizanidine (muscle relaxants),
- amifostine (a protective substance during certain cancer therapies),
- mefloquine (an antimalarial),
- rifampicin (an antibiotic),
- insulins and other preparations to treat diabetes mellitus, or
- oral or intravenous cortisone substances,
- so called monoamine oxidase inhibitors i.e. MAO-inhibitors (except MAO-B inhibitors) such as moclobemide or phenelzine (for depression).

Other medicines and Bisoprolol Fumarate

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

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

- quinidine, disopyramide, lidocaine, phenytoin; flecainide, propafenone (used to treat irregular or abnormal heartbeat),
- verapamil and diltiazem (used to treat irregular heartbeat and blood pressure medicine),
- clonidine, methyl dopa, guanfacine, moxonidine and rilmenidine (to treat blood pressure and some neurological diseases),

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:

- nifedipine, felodipine and amlodipine (used to treat high blood pressure or angina or abnormal heart beat)
- amiodarone (used to treat irregular or abnormal heartbeat),
- beta blockers, including eye-drops containing beta blockers, such as timolol for glaucoma treatment,
- digitalis such as digoxin used to treat heart failure,
- donepezil or tacrine (to treat dementia),
- neostigmine or pyridostigmine (to treat myasthenia gravis, a disease which causes muscle weakness),
- physostigmine to treat elevated eye pressure (glaucoma),
- so called ergot alkaloids (to treat migraine or low blood pressure),
- other antihypertensive drugs,

Non-steroidal anti-inflammatory drugs, such as acetylsalicylic acid, diclofenac, ibuprofen, ketoprofen, naproxen, celecoxib, or etoricoxib (especially if used long-term and regularly) may weaken the effectiveness of Bisoprolol Fumarate in treatment of hypertension. However, small daily doses of acetylsalicylic acid, e.g. 100 mg can be used safely concomitantly with Bisoprolol Fumarate to prevent blood clots.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

Bisoprolol Fumarate should not be used during pregnancy unless clearly necessary. If you are planning pregnancy or become pregnant during Bisoprolol Fumarate treatment, contact the doctor for advice on consequential therapy.

It is not known if bisoprolol of Bisoprolol Fumarate is excreted into breast-milk. Therefore, breast-feeding is not recommended during Bisoprolol Fumarate treatment.

Driving and using machines

Bisoprolol Fumarate Tablets have only minimal or nonexistent impact to the ability to drive. Side effects related to the fall in blood pressure may include dizziness, headache, tiredness, or other side effects (see section 4) which might impair the ability to drive or to operate machinery. Would such side effects occur, you should refrain from driving and other activities requiring alertness. This should be noted especially at the beginning of the treatment and after increasing the dosage. Bisoprolol Fumarate does not usually affect the ability to drive if the therapy is well-balanced.

Bisoprolol Fumarate tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Bisoprolol Fumarate tablets

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

The recommended dose is

Adults:

To treat hypertension and angina pectoris

- Initial dose is usually 5 mg once daily.
- The doctor may increase the dose in increments (usually every few weeks) to 10 mg or 20 mg at maximum if necessary.

To treat stable 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,

The maximum recommended daily dose is 10 mg 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 10 mg 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 and adolescents (less than 18 years):

There is not enough experience on the use of Bisoprolol Fumarate Tablets in children, and thus the use is not recommended with children or adolescents under 18 years of age.

Elderly:

Dosage adjustment is not necessary for elderly people unless they have a renal or hepatic insufficiency, see below.

Patients suffering from renal or hepatic insufficiency:

The dosage should be increased very gradually and cautiously in patients with severe kidney or liver problems. The dosage should not exceed 10mg once daily in patients with severe kidney or liver problems.

Method of administration

Swallow the tablet with a sufficient amount of fluid (e.g. one glass of water) usually once a day in the morning. Tablets are not to be chewed. Eating does not affect the absorption of the medicine.

If you take more Bisoprolol Fumarate than you should

If you or anyone else has taken an overdose of Bisoprolol Fumarate contact a doctor or hospital emergency room immediately.

In case of nausea or dizziness, place the patient in a lying down position and seek medical assistance. An unconscious patient must be turned to the recovery position however the legs may be elevated.

If you forget to take Bisoprolol Fumarate

Take the next tablet normally, when it is the time to take it. Do not take a double dose to make up for a forgotten dose.

If you stop taking Bisoprolol Fumarate

Treatment with Bisoprolol Fumarate should not be stopped abruptly especially if the patient has a coronary disease. The dosage should be reduced gradually according to instructions provided by the doctor, e.g. over 1 to 2 weeks. Otherwise symptoms of a cardiac disease may worsen.

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 where the most common side effects have been too slow a heart beat, excessive decrease of blood pressure, dizziness and fatigue.

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

Very common (may affect more than 1 in 10 people)

- too slow heartbeat (in patients with heart failure)

Common (may affect up to 1 in 10 people)

- dizziness, headache
- worsening of symptoms of heart failure (in patients with pre-existing heart failure)
- feeling coldness or numbness in the extremities
- too low blood pressure (in patients with heart failure)

- gastrointestinal complaints, such as nausea, vomiting, diarrhoea, or constipation
- asthenia (in patients with heart failure), fatigue

Uncommon (may affect up to 1 in 100 people)

- depression, sleep disorders
- heart block (conduction disturbances in the heart)
- too slow heartbeat (in patients with hypertension or coronary heart disease)
- bronchospasm (wheezing, in patients with asthma or chronic obstructive pulmonary disease)
- muscle weakness, muscle cramps
- asthenia (in patients with hypertension or angina pectoris)
- low blood pressure in upright position (orthostatic hypotension).

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

- nightmares, hallucinations
- fainting (syncope)
- reduced tear flow (take this into account if you wear contact lenses)
- hearing disorders
- hepatitis (causing upper abdominal pain)
- hypersensitivity reactions, such as itching, flush, or rash
- potency disorders
- increased levels of liver enzymes (laboratory tests ALAT or ASAT).
- allergic rhinitis (blocked, runny, itchy nose)

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

- conjunctivitis (eye inflammation)
- hair loss (alopecia), worsening of psoriasis or psoriasis like rash.

Reporting of suspected adverse reactions

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 after EXP. 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 Tablets 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.

Other ingredients are cellulose microcrystalline, silica colloidal anhydrous, croscarmellose sodium, sodium starch glycolate (Type A) and magnesium stearate.

What Bisoprolol Fumarate Tablets looks like and contents of the pack

Bisoprolol Fumarate 1.25mg tablets are white to off-white, round, biconvex tablets.

Bisoprolol Fumarate 2.5mg tablets are white to off-white, round, biconvex tablets with a break line on one side.

Bisoprolol Fumarate 3.75mg tablets are white to off-white, round, biconvex tablets.

Package includes 20, 21, 28, 30, 50, 56, 60, 90, or 100 tablets (not all pack sizes may be marketed).

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