Package leaflet: Information for the user

Bisoprolol 1.25 mg Orodispersible Tablets
Bisoprolol 2.5 mg Orodispersible Tablets
Bisoprolol 5 mg Orodispersible 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 your 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 is and what it is used for

The active substance in this medicine is bisoprolol fumarate. 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 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).

2. What you need to know before you take Bisoprolol

Do not take Bisoprolol

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

- allergy (hypersensitivity) to bisoprolol or to any of the other ingredients (see section 6 ‘What Bisoprolol contains’)
- 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 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:

- 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
- 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 Bisoprolol; 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
- chronic lung disease or less severe asthma
- history of a scaly skin rash (psoriasis)
- tumour of the adrenal gland (phaeochromocytoma)
- thyroid disorder.

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.

If you 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.

Children and adolescents
Bisoprolol is not recommended for use in children or adolescents.

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 (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 (calcium antagonists such as verapamil and diltiazem)
- certain medicines used to treat high blood pressure such as clonidine, methyldopa, moxonodine, 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 (dihydropyridine-type calcium antagonists such as felodipine and amlodipine)

- certain medicines used to treat irregular or abnormal heartbeat (Class III antiarrhythmic medicines such as amiodarone)
- beta-blockers 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, 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, which can lower blood pressure as a desired or undesired 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 characterized by a loss of contact with reality (phenothiazines 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.

Pregnancy and breast-feeding

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 Bisoprolol during pregnancy.

Breast-feeding
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 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

Always take this medicine exactly as your doctor 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, during dose increase, and when you stop treatment.

The tablet should be placed on the tongue and allowed to disintegrate before swallowing with or without water, according to patient preference. Tablet can be taken with some water in the morning, with or without food. Do not crush or chew the tablet. The scored tablets can be divided into two equal doses.

Treatment with Bisoprolol is usually long-term.

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:

- 1.25 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 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.

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

Symptoms 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
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 product, 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.

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

Common (may affect up to 1 in 10 people):
- 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 (may affect up to 1 in 100 people):
- sleep disturbances
- depression
- dizziness when standing up
- breathing problems in patients with asthma or chronic lung disease
- muscle weakness, muscle cramps.

Rare (may affect up to 1 in 1,000 people):
- hearing problems
- allergic runny nose
- reduced tear flow
- inflammation of the liver which can cause yellowing of the skin or 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. You should see your doctor straight away if you experience more severe allergic reactions, which may involve face, neck, tongue, mouth or throat swelling, or difficulty breathing.
- 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.

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 the side effects directly via the Yellow Card Scheme at: 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

- 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 date 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 contains

Bisoprolol 1.25 mg orodispersible tablets
- The active substance is bisoprolol fumarate. Each orodispersible tablet contains 1.25 mg.

- The other ingredients are:
  Mannitol (E 421), Cellulose microcrystalline (E 460), Croscarmellose sodium (E 468), Acesulfame Potassium (E 950), Orange flavour, Magnesium stearate (E 572).

Bisoprolol 2.5 mg orodispersible tablets
- The active substance is bisoprolol fumarate. Each orodispersible tablet contains 2.5 mg.
- The other ingredients are:
  Mannitol (E 421), Cellulose microcrystalline (E 460), Croscarmellose sodium (E 468), Acesulfame Potassium (E 950), Orange flavour, Magnesium stearate (E 572).

Bisoprolol 5 mg orodispersible tablets
- The active substance is bisoprolol fumarate. Each orodispersible tablet contains 5 mg.
- The other ingredients are:
  Mannitol (E 421), Cellulose microcrystalline (E 460), Croscarmellose sodium (E 468), Acesulfame Potassium (E 950), Orange flavour, Magnesium stearate (E 572).

What Bisoprolol looks like and contents of the pack

Bisoprolol 1.25 mg orodispersible tablets are White to off-white colored, round shaped, flat-face, bevel edge uncoated tablets with break-line on one side and debossed ‘B1’ on other side having approximately 6 mm diameter.

Bisoprolol 2.5 mg orodispersible tablets are White to off-white colored, round shaped, flat-face, bevel edge uncoated tablets with break-line on one side and debossed ‘B2’ on other side having approximately 7 mm diameter.

Bisoprolol 5 mg orodispersible tablets are White to off-white colored, round shaped, flat-face, bevel edge uncoated tablets with break-line on one side and debossed ‘B3’ on other side having approximately 10 mm diameter.

Blisters: Each pack contains 20, 28, 30, 50, 56, 60, 90, or 100 tablets.
Bottles: Each pack contains 100 tablets.

Not all pack sizes may be marketed.

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Novumgen Limited
20-22 Wenlock Road, London,
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