

## **PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**

### **Bisoprolol 5 mg and 10 mg Film-Coated 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 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
2. What you need to know before you take Bisoprolol
3. How to take Bisoprolol
4. Possible side effects
5. How to store Bisoprolol
6. Contents of the pack and other information

### **1. What Bisoprolol is and what it is used for**

The active ingredient in Bisoprolol is bisoprolol fumarate.

Bisoprolol belongs to a group of medicines called beta-blockers which help to protect the heart against too much activity.

Bisoprolol is used to treat angina pectoris (pains in the chest caused by blockages in the arteries leading to the heart) or hypertension (high blood pressure).

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

#### **Do not take Bisoprolol:**

- if you are allergic to bisoprolol or to any of the other ingredients of this medicine (listed in section 6)
- if you have severe asthma
- if you suffer from 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
- if you have an untreated tumour of the adrenal gland (phaeochromocytoma)
- if you suffer from metabolic acidosis (a condition when there is too much acid in the blood)
- 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
  - low blood pressure
  - certain heart conditions causing a very slow heart rate or irregular heartbeat
  - cardiogenic shock, a 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 as they may want to take special care (e.g. 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)
- a tumour of the adrenal gland (phaeochromocytoma)
- thyroid disorder.

**In addition, tell your doctor if you are going to have:**

- desensitisation therapy (e.g. for the prevention of hay fever), because Bisoprolol may make it more likely that you experience an allergic reaction, or that such a reaction may be more severe
- anaesthesia (e.g. for surgery), because Bisoprolol may influence how your body reacts

If you have chronic lung disease or less severe asthma, please inform your doctor immediately if you start to experience any 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, including those obtained without a prescription. This includes herbal 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, 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 (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 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 (e.g. during surgery)
- digitalis, used to treat heart failure
- non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain or inflammation (e.g. 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 characterised by a loss of contact with reality (phenothiazines such as levomepromazine)

- mefloquine, used for prevention or treatment of malaria
- medicines for depression called monoamine oxidase inhibitors (except MAO-B inhibitors) such as moclobemide

### **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 for advice before taking this medicine.

#### 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. They 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 treatment 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 if the medication is changed, as well as in combination with alcohol.

## **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.
- Take the tablet 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.

The maximum daily dose is 10 mg. 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 accidentally take too many tablets, contact your doctor or nearest hospital department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

**Symptoms of 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**

Take it as soon as you remember, unless it is time for your next dose. If you miss a dose, do not take a double dose to make up for a forgotten dose.

**If you stop taking Bisoprolol**

Treatment with Bisoprolol must not be stopped abruptly unless on your doctor's advice otherwise your condition could become worse.

If you have any further questions about 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.

**If you develop any of the following symptoms, stop taking Bisoprolol Tablets and seek medical advice immediately.**

- allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness
- slowing of heart rate, slow or irregular heartbeat
- worsening of heart failure

**Other side effects**

*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 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
- cramps

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

- hearing problems
- 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, runny nose
- impaired erection
- nightmares
- hallucinations
- fainting

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

- appearance or worsening of scaly skin rash (psoriasis); psoriasis-like rash.

- hair loss
- irritation and redness of the eye (conjunctivitis)

### **Reporting of side effects**

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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 carton/blister after “EXP”. The expiry date refers to the last date of that month.
- Do not store above 25°C.
- Medicines should not be disposed of 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 Tablets contain**

- Each film coated tablet contains 5 mg or 10 mg of bisoprolol fumarate.
- **The other ingredients are:** maize starch, microcrystalline cellulose, croscopovidone, anhydrous calcium hydrogen phosphate, magnesium stearate, colloidal anhydrous silica, hypromellose, titanium dioxide (E171), macrogol 6000, dimeticone 350 and yellow iron oxide (E172). Bisoprolol 10mg Tablets also contain red iron oxide (E172)

### **What Bisoprolol Tablets look like and contents of the pack:**

- Bisoprolol 5 mg are ivory colour, round, biconvex, film-coated tablets with a break line on one side and embossed with “5” on the other side, diameter 7 mm.
- Bisoprolol 10 mg are light brown colour, round, biconvex, film-coated tablets with a break line on one side and embossed with “10” on the other side, diameter 7 mm.

Both strengths are available in blister packs of 28 tablets.

### **Product Licence Numbers:**

Bisoprolol 5 mg Film-Coated Tablets: PL 11311/0725

Bisoprolol 10 mg Film-Coated Tablets: PL 11311/0726

### **Marketing Authorisation Holder**

Tillomed Laboratories Ltd  
220 Butterfield  
Great Marlings  
Luton LU2 8DL  
United Kingdom

### **Manufacturer**

#### **Tillomed Laboratories Limited**

220 Butterfield,  
Great Marlings,  
Luton, LU2 8DL,  
United Kingdom

**Tillomed Malta Ltd.**

Malta Life Sciences Park,  
LS2.01.06 Industrial Estate,  
San Gwann, SGN 3000, Malta

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