Package leaflet: Information for the user

Bisoprolol 5 mg film-coated tablets
Bisoprolol 10 mg film-coated 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 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. Beta-blocker protects heart from too much activity. This medicine works by affecting the body's response to some nerve impulses, especially in the heart. As a result, Bisoprolol fumarate 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 need. Bisoprolol 5 mg and 10 mg tablet are used in combination with other medicines to treat stable heart failure.

It is used to treat high blood pressure (hypertension) and angina pectoris (chest pain caused by blockages in the arteries that supply the heart muscle).

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).
- You have severe asthma or severe chronic lung disease.
- You have 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.
- You have untreated pheochromocytoma, which is a rare tumour of the adrenal gland (medulla).
- You have metabolic acidosis, which is a condition when there is too much acid in the blood.

- acute heart failure or heart failure that suddenly become worse and/or may require hospital treatment.
- 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
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 have any of the following conditions:

- diabetes
- strict fasting
- certain heart diseases such as disturbances in heart rhythm, or severe chest pain at rest (Prinzmetal's angina)
- kidney or liver disease
- 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 (pheochromocytoma)
- 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.

Other medicines and Bisoprolol

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

<u>Do not take the following medicines with Bisoprolol without special advice from your doctor:</u>
- medicines for controlling the blood pressure or medicines for heart problems (such as digitalis glycosides, quinidine, disopyramide, lidocaine, phenytoin, flecainide, propafenone, verapamil, diltiazem, clonidine, methyldopa, moxonidine, rilmenidine, felodipine,amlodipine and amiodarone)
- medicines used for certain eye disorders such as for glaucoma treatment (increased pressure in the eye) or used to widen the pupil of the eye
- medicines used for anaesthesia during operation (see also "Warnings and Precautions"),certain pain killers (for instance acetylsalicylic acid, ibuprofen, diclofenac, indomethacin, naproxen)
- medicines for depression (such as imipramine or amitriptyline or moclobemide)
- medicines used to treat epilepsy e.g. barbiturates such as phenobarbital
- medicines to treat mental illness e.g. phenothiazines such as levomepromazine.
- medicines for asthma or medicines used for a blocked nose.
- certain medicines to treat clinical shock e.g. adrenaline, dobutamine, noradrenaline
- mefloquine, medicine for malaria

- all these drugs as well as bisoprolol may influence the blood pressure and/or heart function.
- rifampicin for the treatment of infections
- medicines to treat severe headaches or migraines (ergotamine derivatives).

Pregnancy and breast-feeding
Pregnancy
There is a risk that the 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 become pregnant, ask your doctor for advice before taking this medicine. He or she will determine whether you can take Bisoprolol during pregnancy.

Breast-feeding
It is not known whether bisoprolol passes into human breast milk. Therefore, breast-feeding is not recommended during therapy with Bisoprolol.

Driving and using machines
The ability to drive or use machinery may be affected depending on how well you tolerate the medicine. Be especially careful at the beginning of treatment, when the dose is increased or the medication is changed and combined 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 check ups with your doctor. This is particularly important in the initiation of therapy and during dose increase. Bisoprolol should be taken in the morning, with or without food. Swallow the tablet(s) whole with some water and do not crush or chew them. The scored tablets can be divided into equal doses.
Treatment with Bisoprolol is usually prolonged.

The recommended doses are:
Adults:
Chest pain and high blood pressure:
Your doctor will start the treatment with the lowest possible dose (5 mg). Your doctor will monitor you closely at the start of treatment. Your doctor will increase your dose to obtain the best possible dosage for you.
The maximum recommended dose is 20 mg once per day.

Patients with kidney disease:
Patients with severe kidney disease should not exceed 10 mg of Bisoprolol once daily. Please consult your doctor before starting to use this medicine.

Patients with liver disease:
Patients with severe liver disease should not exceed 10 mg of Bisoprolol once daily. Please consult your doctor before starting to use this medicine.

Heart failure:
Before you start using Bisoprolol you should already be taking other medicines for heart failure, including any ACE inhibitor, a diuretic and (as an added option) a cardiac glycoside.

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 (ongoing) therapy.

The maximum recommended daily dose is 10 mg Bisoprolol.

Depending on how well you tolerate the medicine, your doctor may also decide to extend the time between dose increases. If your condition gets worse or you no longer tolerate the medicine, it may be necessary to reduce the dose again or to stop treatment. For 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:
Bisoprolol is not recommended for use in children.

Elderly patient:
In general, adjustment of the dose is not needed. It is recommended to start with the lowest possible dose.

If you notice that the bisoprolol dose is too strong or does not work well enough, please consult your doctor or pharmacist

If you take more Bisoprolol than you should
If you take too much medicine or if a child has swallowed the medicine by mistake tell your doctor or go to the nearest hospital casualty department immediately. Take this leaflet and any tablet you still have with you. Symptoms of an overdose may include slow heart-beat, severe breathing difficulties, dizziness or tremor (due to decreased blood sugar).

If you forget to take Bisoprolol
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
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.

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 heart function:
- Slowing of heart rate (may affect more than 1 in 10 people with chronic heart failure and may affect up to 1 in 100 people with hypertension or angina pectoris)
- Worsening of heart failure (may affect up to 1 in 10 people with chronic heart failure and may affect up to 1 in 100 people with hypertension or angina pectoris)
- Slow or irregular heartbeat (may affect up to 1 in 10 people with chronic heart failure)

- Worsening of symptom of blockage of the main blood vessel to the legs, especially at the start of treatment (Frequency not known)

If you feel dizzy, 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 (In patient with chronic heart failure), dizziness, headache
- Feeling of coldness or numbness in hands or feet
- Low blood pressure especially in patient with heart failure
- Stomach or intestine problems such as nausea, vomiting, diarrhoea or constipation.

Uncommon (may affect up to 1 in 100 people):
- Sleep disturbances
- Depression
- Breathing problems in patients with asthma or chronic lung disease
- Muscle weakness, muscle cramps.
- Feeling weak (In patient with hypertension or angina pectoris)

Rare (may affect up to 1 in 1,000 people):
- Hearing problems
- Allergic runny nose (Blocked or runny nose)
- Reduced tear flow (can be a problem if you wear contact lenses)
- Inflammation of the liver which may cause yellowing of the skin or whites of the eyes
- Some blood test results for liver function or fat levels differing from normal value
- 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.
- Impaired erection (reduced sexual performance)
- Nightmares, hallucinations
- Fainting

Very rare (may affect up to 1 in 10,000 people):
- Irritation and redness of 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: 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 medicinal product does not require any special storage condition.

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 5 mg film-coated tablets:
  The active substance is bisoprolol fumarate. Each film coated tablet contains 5 mg bisoprolol fumarate.
  The other ingredients are:
  Tablet core: Cellulose, Microcrystalline; Calcium hydrogen phosphate; Starch, Pregelatinised; Crospovidone; Silica, Colloidal Anhydrous; Magnesium Stearate
  Film coating: Hypromellose (E464); Titanium Dioxide (E171); Iron Oxide Yellow (E172); Macrogols.

- Bisoprolol 10 mg film-coated tablets:
  The active substance is bisoprolol fumarate. Each film coated tablet contains 10 mg bisoprolol fumarate.
  The other ingredients are:
  Tablet core: Cellulose, Microcrystalline; Calcium hydrogen phosphate; Starch, Pregelatinised; Crospovidone; Silica, Colloidal Anhydrous; Magnesium Stearate
  Film coating: Hypromellose (E464); Titanium Dioxide (E171); Iron Oxide Yellow (E172); Macrogols; Iron Oxide Red (E172).

What Bisoprolol looks like and contents of the pack

Bisoprolol 5 mg film-coated tablets: Yellowish-white, approximately 8.00 mm, round shaped biconvex film coated tablets debossed with 'C' and deep notch on one side and '39' on other side.

Bisoprolol 10 mg film-coated tablets: Pale-orange, approximately 8.00 mm, round shaped, biconvex film coated tablets debossed with 'C' and deep notch on one side and '37' on other side.

Bisoprolol 5 mg and 10 mg film-coated tablets are supplied in Alu-Alu blister with pack size of 10 tablets, 28 tablets.

Bisoprolol 5 mg Film-coated Tablets are supplied in HDPE bottle
Pack sizes: 30 tablets, 32 tablets, 100 tablets, 105 tablets, 112 tablets, 300 tablets, 1000 tablets

Bisoprolol 10 mg Film-coated Tablets are supplied in HDPE bottle
Pack sizes: 30 tablets, 32 tablets, 100 tablets, 105 tablets, 300 tablets, 1000 tablets
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Ipca Laboratories UK Ltd.
Unit 97 -98, Silverbriar,

Sunderland Enterprise Park East,
Sunderland, SR5 2TQ,
United Kingdom
Telephone: + 44 (0) 1915166517
Fax: + 44 (0) 1915166526
Email:regulatoryfrm.mumbai@ipca.com

This leaflet was last revised in 09/2021