Package Leaflet: Information for the User
Bisocor 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, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms 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 Bisocor Tablets are and what they are used for

Bisocor Tablets belong to a group of medicines called beta-blockers. These medicines protect the heart against too much activity, which makes the heart more relaxed and reduces the blood pressure.

Bisoprolol fumarate may be used to treat **angina pectoris** (pains in the chest caused by blockages in the arteries that supply the heart muscle) or **hypertension** (high blood pressure).

2. What you need to know before you take Bisocor Tablets

Do not take Bisocor Tablets if you:
- have ever suffered from severe wheezing or severe asthma, as they can affect your breathing.
- have a slow or irregular heart rate caused by problems in the heart muscle. Ask your doctor if you are not sure.
- have very low blood pressure which may cause you to feel dizzy when you stand up.
- have severe blood circulation problems (which may cause your fingers and toes to tingle or turn pale or blue).
- are allergic to bisoprolol fumarate or to any of the other ingredients of this medicine (listed in section 6).
- 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.
- have a condition in which there is an accumulation of excessive acid in the body known as metabolic acidosis. Your doctor will be able to advise you.
- you suffer from a tumour of the adrenal glands known as phaeochromocytoma which is untreated.

Tell your doctor if you are not sure about any of the above.

Warnings and precautions:
Talk to your doctor or pharmacist before taking Bisocor Tablets if you;
- have liver or kidney problems.
- have heart failure which may cause breathlessness and ankle swelling.
- are taking medicine for your high blood sugar levels (diabetes). The tablets can hide the symptoms of low blood sugar.
- suffer (or have suffered) from psoriasis (a recurrent skin disorder involving scaling and dry skin rash).
- are treated for hypersensitivity (allergic) reactions.
- are being treated for phaeochromocytoma (a tumour of the adrenal gland).
- have a thyroid problem. The tablets can hide symptoms of an overactive thyroid.
- suffer from wheezing or difficulty breathing (asthma).
- are fasting from solid food.
- are known to have a condition of the heart called 1st degree AV block which causes the heart beat to be slow and irregular.
- suffer from Prinzmetal's angina which is a type of chest pain that may appear while you are at rest and is caused by spasm of the coronary arteries that supply the heart muscle.
- have any problems with the circulation to the extremities of the body such as hands and feet.
- consult a doctor, attend hospital or the dentist for surgery involving an anaesthetic, let them know what medicines you are taking.

This medicine contains an active substance which results in a positive result during antidoping controls for athletes.

Other medicines and Bisocor Tablets:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is particularly important to mention any of the following drugs as their action may be affected:

- Medicines used for controlling blood pressure or medicines used for the treatment of heart problems, such as: adrenaline, amlodipine, amiodarone, bepridil, clonidine, diltiazem, disopyramide, digoxin, dobutamine, flecainide, isoprenaline, lidocaine, methyldopa, moxonidine, noradrenaline, propafenone, quinidine, rilmenidine, verapamil and other beta blocking agents.
- Medicines for the treatment of depression and mental disorders such as tricyclic antidepressants, phenothiazines, monoamine oxidase inhibitors and barbiturates.
- Medicines used as anaesthetics during an operation.
- Anti-inflammatory medicines known as NSAIDS e.g. ibuprofen, naproxen.
- Medicines for the treatment of : malaria e.g. mefloquine and migraine e.g. ergotamine.
- Medicine used for controlling diabetes including insulin and sulfonylureas (e.g. glibenclamide, gliquidone, gliclazide, glipizide, glimepiride or tolbutamide). Bisoprolol could increase the risk of severely low blood glucose levels when used with these medicines.
- Medicines for asthma, blocked nose or certain eye disorders such as glaucoma (increased pressure in the eye) or dilation (widening) of the pupil.

All these medicines may influence your blood pressure and/or heart function.
With medicines used for controlling diabetes bisoprolol fumarate may influence blood sugar levels.

Taking Bisocor Tablets with food, drink and alcohol
Bisocor Tablets may be taken with or without food and should be swallowed whole with a drink of water. The dizziness and light-headedness that may be caused by Bisocor Tablets can be made worse if you drink alcohol. If this happens to you, you should avoid drinking alcohol.

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.

Bisocor Tablets may be harmful to the pregnancy and/or the unborn child. There is an increased possibility of premature birth, miscarriage, low blood sugar level and reduced heart rate of the child. The growth of the baby may also be affected. Therefore, bisoprolol fumarate should not be taken during pregnancy unless clearly necessary. Your doctor will be able to make this decision.

It is not known if bisoprolol fumarate is excreted in the breast milk and therefore it is not recommended while breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicinal product.

Driving and using machines
These tablets may make you feel tired, drowsy or dizzy. If you suffer from these side effects, do not operate vehicles and/or machines. Be aware of the possibility of these effects particularly at the beginning of the treatment, with changes in medication and with use in combination with alcohol.

Bisocor Tablets contain lactose
Bisocor Tablets contain milk sugar (lactose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Bisocor 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 tablets should be swallowed whole with water and taken in the morning
- Your doctor will tell you your correct dosage and will usually start with the lowest dose (5 mg). The normal regular dose is 10 mg once daily with a maximum recommended dose of 20 mg. The tablets should be taken at about the same time each day.

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

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

Use in children and adolescents
Not recommended as there is no experience with this medicine in children under 12 years and adolescents.

If you take more Bisocor Tablets than you should
If you have accidentally taken more than the prescribed dose, tell your doctor/pharmacist immediately. Take any remaining tablets or this leaflet with you so the medical staff know exactly what you have taken.

Symptoms of overdose may include dizziness, light-headedness, fatigue, breathlessness and/or wheezing. Also there may be reduced heart rate, reduced blood pressure, insufficient action of the heart and a low blood glucose level (which may involve feelings of hunger, sweating and palpitations).

If you forget to take Bisocor Tablets
If you forget to take a tablet, take it if you remember within 12 hours of your usual time. If more than 12 hours have passed, you should not take the missed tablet but should take your next tablet at the normal time when it is due.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Bisocor Tablets
Treatment with Bisocor Tablets must not be stopped abruptly, particularly if you have had angina or a heart attack. If you suddenly stop the use of bisoprolol fumarate your condition may get worse or your blood pressure may start to rise again. Instead, it must be reduced gradually over one or two weeks as advised by your doctor.

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.

While taking this medicine, you may experience some of the following side effects. If you do, mention it to your doctor:

Common (may affect up to 1 in 10 people):
- Tiredness, dizziness, headache (especially at the beginning of therapy; these are generally mild and often disappear within 1-2 weeks).
- Feeling of coldness or numbness in the extremities (fingers or toes, ears and nose); more frequent occurrence of a cramp-like pain in the legs when walking
- Feeling sick (nausea), being sick (vomiting).
- Diarrhoea.
- Abdominal pain.
- Constipation.
- Light headedness, due to low blood pressure particularly on sudden standing

Uncommon (may affect up to 1 in 100 people):
- Sleep disturbances.
- Depression.
- Slow or irregular heart beat.
- Worsening of heart failure.
- Patients with asthma or a history of breathing problems may experience difficulty in breathing.
- Muscular weakness, cramps and joint ache.

Rare (may affect up to 1 in 1,000 people):
- Nightmares.
- Hallucinations.
- Fainting.
- Hearing impairment.
- Inflammation of the lining of the nose, causing a runny nose with irritation.
- Allergic reactions (itching, flushed appearance, rash).

- Dry eyes from reduced tear flow (which can be very troublesome if you use contact lenses).
- Inflammation of the liver (hepatitis), causing abdominal pain, loss of appetite and sometimes jaundice with yellowing of the whites of the eyes and skin, and dark urine.
- Changes to blood tests for liver function and increased fats in the blood.
- Reduced sexual performance (impotency).

Very Rare (may affect up to 1 in 10,000 people):
- This medicine may aggravate the skin condition psoriasis or cause a similar dry, scaly rash and hair loss.
- Itchiness or redness of the eye (conjunctivitis).

Patients with pre-existing heart failure may also experience: slow heart rate (very common); worsening of heart failure causing breathlessness and tiredness (common).

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Bisocor Tablets

Keep this medicine out of the sight and reach of children.

Do not use Bisocor Tablets after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Store Bisocor Tablets below 30˚C.

Do not use Bisocor Tablets if you notice your tablets become discoloured or show any other signs of deterioration, and return to your pharmacist for advice.

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 to protect the environment.

6. Contents of the pack and other information

What Bisocor Tablets contain
- The active substance is bisoprolol fumarate.
  Each 5 mg tablet contains 5 mg of bisoprolol fumarate.
  Each 10 mg tablet contains 10 mg of bisoprolol fumarate.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, magnesium stearate and crospovidone

Each 5 mg tablet also contains a yellow colour (which contains lactose and iron oxide yellow).
Each 10 mg tablet also contains a beige colour (which contains lactose and iron oxide red and yellow).

What Bisocor Tablets look like and contents of the pack

The 5 mg tablets are mottled yellow, round and convex, debossed with BI centrally above a breakline with 5 below. The tablets can be divided into two equal halves.
The 10 mg tablets are mottled beige, round and convex, debossed with BI centrally above a breakline with 10 below. The tablets can be divided into two equal halves.
The tablets are packed in aluminium PVC/PVdC blisters which are contained within a printed box board carton.
Each carton will contain either 10, 20, 28, 30, 50, 56, 60, 90 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Unichem Laboratories Limited,
Studio 8B, Ard Gaoithe Commercial Centre, Ard Gaoithe Business Park,
Cashel Road, Clonmel, Co. Tipperary

Manufacturer
Niche Generics Limited
Unit 5, 151 Baldoyle Industrial Estate
Dublin 13
Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:
Ireland: Bisocor 5 &10 mg Tablets

This leaflet was last revised in 12/2025.