

Package leaflet: information for the user

Bisoprolol NORMON 10 mg film-coated tablets
Bisoprolol hemifumarate

Read the package leaflet, 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 and do not pass it on to other people. It may harm them, even if their signs of illness are the same as yours.
- If you experience any side effects (including those not listed in this leaflet), please tell your doctor or pharmacist. See section 4.

What is in this leaflet?

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1. What Bisoprolol NORMON is and what it is used for

Bisoprolol belongs to group of medicines called beta-blockers. These medicines work affecting to some nerve impulses in the organism response, especially in the heart. As a result, bisoprolol slows the heart beat and makes heart more effective at the time of pumping blood through the organism. Bisoprolol is used to:

- High blood pressure treatment, (hypertension).
- Chronic stable angina pectoris treatment caused by the lack of oxygen in the heart muscle.
- Chronic stable heart failure treatment, together with other medicines. Heart failure is the heart enough pumping blood inability to attend the body needs.

2. Before you take Bisoprolol NORMON

Do not take Bisoprolol NORMON if you present some of the following conditions:

- If you are allergic (hypersensitive) to bisoprolol or any of the other ingredients of this medicine (listed on section 6).
- If you have severe asthma or severe chronic obstructive pulmonary disease (COPD).
- If 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.
- If you have untreated phaeochromocytoma, a rare tumor of the adrenal gland (medulla).
- If you have metabolic acidosis, a condition when there is too much acid in the blood.

Do not take Bisoprolol NORMON if you present some of the following heart diseases:

- Acute heart failure.
- Heart failure worsening which requires intravenous injection of medicines which increases the heart contraction strength.
- Slow heart rate.
- Low blood pressure.
- Some specific heart problems which causes a very slow heart rate or irregular pulse.
- Cardiogenic shock, a serious and acute heart disease which causes blood pressure decreasing and circulatory insufficiency.

Warnings and precautions

Talk to your doctor if you present some of the following diseases before taking Bisoprolol NORMON; your doctor can take especial precautions (e.g. to provide additional treatment or perform more frequently more tests):

- Diabetes.
- Strict fasting.
- Specific heart diseases as heart rhythm disorders, serious chest pain in rest (Prinzmetal's angina).
- Kidneys and liver diseases.
- Less serious limbs circulatory problems.
- Asthma or less serious chronic respiratory disease.
- History of scaly rash (psoriasis).
- Tumor of the adrenal gland (phaeochromocytoma).
- Thyroid disease.
- First degree heart block (a status where the heart nervous signals are altered, probably provoking the omission of a heartbeat in an occasional way, or irregular heart beating).

In addition, talk to your doctor if you are going to follow:

- Desensitization treatment (e.g. hay fever prevention), due to Bisoprolol NORMON may be more probably you present allergic reaction, or a serious allergic reaction.
- Anesthesia (e.g. for surgery), due to Bisoprolol NORMON may influence on how your body reacts in front of this situation.

Children and adolescent

Bisoprolol NORMON administration is not recommended in children nor adolescents.

Talk with your doctor or pharmacist before start taking Bisoprolol NORMON.

Other medicines and Bisoprolol NORMON

Tell your doctor if you are already taking or have recently taken or you could take any other medication.

Do not take the following medicines with Bisoprolol NORMON without your doctor's advice:

- Specific medicines used to treat irregular or abnormal heart beating (Class I antiarrhythmics drugs like quinidine, disopyramide, lidocaine, phenytoin; flecainide, propafenone).
- Specific medicines used to treat the high blood pressure, angina pectoris or irregular heart beating (calcium antagonists such as verapamil and diltiazem).
- Specific medicines used to treat high blood pressure such as clonidine, methyldopa, moxonidine, rilmenidina. However, **don't stop taking these medicines** without previously asking to your doctor.

Ask to your doctor before take the following medicines together with Bisoprolol NORMON; your doctor may need control more frequently your status:

- Specific medicines used to treat high blood pressure or angina pectoris (calcium antagonists of dihydropyridine type such as felodipine and amlodipine).
- Specific medicines used to treat irregular or abnormal heart beating (class III antiarrhythmics such as amiodarone),
- Beta-blockers applied locally (such astimolol eye drops for glaucoma treatment).
- Specific medicines used to treat Alzheimer disease or glaucoma (parasympathomimetics such as tacrine or carbachol) for instance, or medicines to treat acute heart diseases (sympathomimetics such as iprenoline and dobutamine)
- Antidiabetic medicines including insulin
- Anesthetics agents (e.g., during a surgery).
- Digitalis, used to treat the heart failure.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) used to treat arthritis, pain or inflammation (e.g. ibuprofen or diclofenac).
- Epinephrine, used to treat very serious allergic reactions and heart attack.
- Any medicine which can reduce the blood pressure as an expected or not expected effect, such as antihypertensive, specific medicines for depression (tricyclic antidepressants such as imipramine and amitriptyline), specific medicines used to treat the epilepsy or during the anesthesia (barbiturates such as phenobarbital), or specific medicines for treat mental diseases characterized for losing contact with the reality (phenothiazines such as levopromazine).

- Mefloquine, used to the prevention or treatment of malaria.
 - Medicines to treat depression named mono amine 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 or pharmacist for advice before taking these medicines.
 - There is a risk about Bisoprolol NORMON may be harmful to the baby during pregnancy. Talk to your doctor if you are pregnant or are planning to have a baby. Your doctor will decide if you can take Bisoprolol NORMON during pregnancy.
 - Lactation is not recommended during treatment with Bisoprolol NORMON because it is not known whether bisoprolol passes into breast milk.

Driving and using machine

This medicine could affect your ability to drive or operate machinery depending on how well you tolerate this medicines.

Take special care at the beginning of the treatment, when the dose is increased or the medicine is changed, and also when combined with alcohol.

Important information for athletes

Athletes are warned about this medicine has a component which may produce a positive result in doping tests.

3. How to take Bisoprolol NORMON

Always take this medicine exactly as your doctor has told you. You should check with your doctor or your pharmacist if you have questions.

Bisoprolol NORMON treatment needs a regular monitoring by your doctor. This is particularly needed at the beginning of the treatment and during the dose increasing. Take the tablet with some water, with or without food at the morning,. Do not crush nor chew. Bisoprolol NORMON treatment is usually prolonged.

Adults:

High blood pressure and angina pectoris treatment

- The starting dose is 5 mg per day.
- If necessary, your doctor may increase in small increments (each two weeks normally) to 10 mg or up to 20 mg as maximum.

The treatment should never be stopped abruptly, gradually reduce the dose over a period of 1-2 weeks.

Stable chronic heart failure treatment:

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.

Patients with kidney or liver failure

In case of mild or moderate kidney or liver failure, it is usually not necessary to adjust the dose. In patients with terminal kidney failure or severe liver failure, you must not exceed the maximum daily dose of 10 mg. Bisoprolol experience in dialysis patients is limited, however, until now it not seem to be necessary to adjust the dose.

Elderly

In general adjustment of the dose is not needed.

Pediatric population

Safety and efficacy to use bisoprolol in pediatric population have not been established, therefore its use is not recommended in this population.

▪ If you take more Bisoprolol NORMON than you should

If you have taken more Bisoprolol NORMON than you should, tell your doctor immediately. Your doctor will decide what measures are necessary. In case of overdose or accidental ingestion, contact your doctor or pharmacist at once, or go to the nearest hospital, indicating the medicine and the amount taken (or received).

In case of overdose the most common symptoms are: decreasing of the heart rate, severe breathing difficulties, dizziness or tremor (due to the decreasing of sugar in blood).

▪ If you forget to take Bisoprolol NORMON

Do not take a double dose to make up for a forgotten dose. Take your habitual dose at the following morning.

If you stop taking Bisoprolol NORMON

Never stop taking Bisoprolol NORMON unless on your doctor's advice. Otherwise your condition could become much worse.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, Bisoprolol NORMON 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 (affects more than 1 person in 10)
- Worsening of heart failure (affects less than 1 person in 10)
- Slow or irregular heartbeat (affects less than 1 person in 100)

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 (affects less than 1 person in 10):

- 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 (affects less than 1 person in 100):

- Sleep disturbances
- Depression
- Dizziness when standing
- Breathing problems in patients with asthma or chronic lung disease
- Muscle weakness, muscle cramps.

Rare (affects less than 1 person in 1,000):

- Hearing problems
- Allergic runny nose
- Dry eyes from reduced tear flow
- Inflammation of the liver which can cause yellowing of the skin or whites of the eyes. High levels of liver enzymes (laboratory tests of AST and ALT).
- Specific unusual blood tests results for the liver function or fat levels.
- Allergy-like reactions such as itching, flush, rash
- Erectile dysfunction
- Nightmares, hallucinations
- Fainting

Very Rare (affects less than 1 person in 10, 000):

- 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 effect listed above or any other not desired or unexpected side effects, talk to your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bisoprolol NORMON

Keep out of the sight and reach of children.

Store below 25°C.

Keep in the original package. Protect from humidity.

Do not use this medicine after the expiry date which is stated on the carton after EXP.: The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicinal products you do not need. This will help protect the environment.

6. Contents of the pack and other information

Bisoprolol NORMON composition:

The active ingredient is bisoprolol (I.N.N.) hemifumarate. Each tablet contains 10 mg of bisoprolol hemifumarate.

The other ingredients are microcrystalline cellulose, maize starch, sodium croscarmellose, colloidal silica, hypromellose, magnesium stearate, disodium phosphate hydrogen anhydrous, titanium dioxide (E-171), yellow iron oxide (E-172) and macrogol 6000.

What Bisoprolol NORMON looks like and contents of the pack

Bisoprolol NORMON are film-coated tablets, yellow, round, biconvex and scored for oral administration.

Presentations

Bisoprolol NORMON 10 mg film-coated tablets comes in pack of 30, 60 and 500 film-coated tablets. Not all pack sizes are marketed in all countries.

Marketing Authorization Holder and Responsible for Manufacturing

LABORATORIOS NORMON, S.A.

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