

Leaflet: information for the user

Bisoprolol NORMON 2.5 mg film-coated tablets
Bisoprolol hemifumarate

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you

- Keep this leaflet, as you may need to read it again.
- If you have any further question, consult 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:

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

Bisoprolol belongs to a group of medicinal products called beta-blockers. These medicines act affecting the body's response to certain nerve impulses, particularly in the heart. As a result, bisoprolol slows the heart rate and makes the heart more effective upon pumping blood throughout the body.

Bisoprolol is used:

- High blood pressure treatment (hypertension).
- Chronic stable angine treatment provoked by the lack of oxygen in the cardiac muscle.
- Chronic stable heart failure treatment. It is used together with other medicines. The heart failure is the heart inability of pumping enough blood to attend the body needs.

2. What you need to know before you take Bisoprolol NORMON

Do not take Bisoprolol NORMON if you experience any of the following conditions:

- Allergy (hypersensitivity) to bisoprolol or any of the other excipients of this medicine (listed on section 6).
- Severe asthma or severe chronic pulmonary disease.
- Severe circulatory problems in the limbs (such as Raynaud's syndrome), that can cause tingling in the fingers and toes or turn them pale or blue.
- Untreated pheochromocytoma, a rare tumour of the adrenal gland.
- Metabolic acidosis, a condition occurring when there is too much acid in blood.

Do not take Bisoprolol NORMON if you have any of the following heart disorders:

- Acute heart failure.
- Worsening of heart failure requiring intravenous injection of medicines, that enhance heart contractility.
- Slow heart rate.
- Low blood pressure.
- Certain heart diseases causing a slow heart rate or irregular pulse.
- Cardiogenic shock, a serious acute heart disease that causes blood pressure lowering and circulatory insufficiency.

Warning and precautions

If you have any of the following problems, tell your doctor before taking Bisoprolol NORMON; your doctor may want to adopt special precautions (for instance, providing additional treatment or performing examinations more regularly):

- Diabetes.
- Strict fasting.
- Certain heart diseases, such as heart rhythm disorders or severe chest pain at rest (Prinzmetal angina).
- Kidney or liver problems.
- Less severe circulatory problems in the limbs.
- Less severe asthma or chronic respiratory disease.
- History of squamous skin rash (psoriasis).
- Adrenal gland tumour (pheochromocytoma).
- Thyroid disorder.
- First grade of heart block (a condition where the heart nervous signals are altered, probably provoking to skip a beat on an occasional basis, or beating irregularly).

In addition, tell your doctor if you are undergoing:

- Desensitization treatment (for instance, for the prevention of hay fever), because Bisoprolol NORMON can make you more likely to experience an allergic reaction or that this reaction becomes more severe.
- Anaesthesia (for instance for surgery), because Bisoprolol NORMON can influence how your body reacts in this situation.

Children and adolescent

It is not recommended Bisoprolol NORMON for children nor adolescent.

Ask to your doctor or pharmacist before start taking Bisoprolol NORMON.

Other medicines and Bisoprolol NORMON

Please tell your doctor or pharmacist if you are taking, or have recently taken, or you could have to take any other medicine.

Do not take the following medicines with Bisoprolol NORMON without special advice from your doctor:

- Certain medicines used to treat irregular or abnormal heart beating (class I antiarrhythmic medicines, such as quinidine, disopyramide, lidocaine, phenytoine; flecainide, propafenone).
- Certain medicines used to treat high blood pressure, angina pectoris or irregular heart beating (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 first asking your doctor.

Ask your doctor before taking the following medicines with Bisoprolol NORMON; your doctor may need to control your condition more frequently:

- Certain medicines used to treat high blood pressure or angina pectoris (calcium antagonists of dihydropyridine type, such as phelodipine and amlodipine).
- Certain medicines used to treat irregular or abnormal heart beating (class III antiarrhythmic medicines, such as amiodarone).
- Beta-blockers applied locally (such as eye drops of timolol for the treatment of glaucoma).
- Certain medicines used to treat, for instance, Alzheimer's disease or for the treatment of glaucoma (parasympathomimetics, such as tacrine or carbacol) or medicines used to treat acute heart diseases (sympathomimetics such as isoprenaline and dobutamine).
- Antidiabetic medicines, including insulin.
- Anaesthetic agents (for instance during surgery).
- Digitalis, used to treat heart failure.
- Non-steroidal anti-inflammatory drugs (NSAIDs) used for the treatment of osteoarthritis, pain or inflammation (for instance, ibuprofen or diclofenac).

- Epinephrine, a medicine used to treat high severe allergic reactions and heart attack.
- Any medicine that can reduce 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 diseases characterised by loss of touch with reality (phenothiazines such as levomepromazine).
- Mefloquine, used for the prevention or treatment of malaria.
- Medicines for the treatment of depression called monoaminooxidase inhibitors (except for 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 this medicine.

There is a risk that the use of Bisoprolol NORMON during pregnancy can damage the baby. If you are pregnant or plan to get pregnant, tell your doctor. Your doctor will decide whether you can take Bisoprolol NORMON during pregnancy.

It is not known if bisoprolol enters human nursing milk. Therefore, nursing is not recommended during treatment with Bisoprolol NORMON.

Driving and using machines

Your ability to drive or use machinery may be affected, depending on how you tolerate the medicine. Be extremely cautious at the start of treatment, when the dose is increased or the medicine modified and also in combination with alcohol.

Important information for athletes

Athletes are informed that this medicine contains a component that can establish a positive doping control laboratory result.

3. How to take Bisoprolol NORMON

Follow exactly the instructions of administration for this medicine indicated by your doctor. Ask your doctor or pharmacist if you have any doubt.

Treatment with Bisoprolol NORMON requires regular monitoring by your doctor. This is particularly necessary at the start of treatment and during dose increases.

Take the tablet with some water in the morning, with or without food. Do not crush or chew the tablet.

Treatment with Bisoprolol NORMON is usually long term.

Adults:

For high blood pressure and angine treatment

- The initial dose is 5 mg once at day.
- If it is required, the doctor can increase in small intervals (each few weeks normally) from 10 mg to 20 mg as maximum.

Treatment should never be stopped suddenly. The dose should be gradually reduced over 1-2 weeks.

For chronic stable 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 be performed usually as follows:

- 1.25 mg of bisoprolol once a day for one week.
- 2.5 mg of bisoprolol once a day for one week.
- 3.75 mg of bisoprolol once a day for one week.
- 5 mg of bisoprolol once a day for four weeks.

- 7.5 mg of bisoprolol once a day for four weeks.
 - 10 mg of bisoprolol once a day, as maintenance therapy (continuous).

The recommended maximum daily dose is 10 mg of bisoprolol.

Depending on how well you tolerate this medicine, your doctor may also decide to prolong the time between dose increases. If your condition worsens or you no longer tolerate the medicine, it may be necessary to reduce the dose again or discontinue treatment. In some patients, a maintenance dose below 10 mg of bisoprolol can be sufficient.

Your doctor will tell you what to do.

In general, if you need to discontinue your treatment completely, your doctor will advise you to reduce the dose gradually as otherwise your condition may worsen.

Kidney or liver impairment

In patients with mild or moderate kidney or liver impairment it is not normally necessary to adjust the dose. In patients with severe kidney or severe liver impairment, you should not be more than a daily maximum of 10 mg.

The experience with bisoprolol in dialysis patients is limited, however, until this moment it has not been demonstrated that the posology has to be modify for this patients.

Elderly patients

It is not need to adjust the dose.

Pediatric population

There is not pediatric experience with bisoprolol, therefore its use is not recommended its use in pediatric 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 usual dose the next morning.

If you stop taking Bisoprolol NORMON

Never stop taking Bisoprolol NORMON unless medically advised. Otherwise your condition might worsen markedly.

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

4. Possible side effects

Like all medicines, Bisoprolol NORMON can cause side effects, although not everybody experiences them.

To prevent severe reactions, speak to a doctor immediately if a side effect is severe, occurred suddenly or gets worse rapidly.

The most serious side events are related to heart function:

- Slowing down of heart rate (affecting more than 1 out of 10 people).
- Worsening of heart failure (affecting less than 1 out of 10 people).
- Slow or irregular heart beating (affecting less than 1 out of 100 people).

If you feel dizzy or weak or breathless, contact your doctor as soon as possible.

The side events are listed below by frequency of possible occurrence:

Common (affecting less than 1 out of 10 people):

- Tiredness, weakness, dizziness, headache.
- Feeling of cold or numbness in the hands or feet.
- Low blood pressure.
- Stomach or bowel problems, such as nausea, vomiting, diarrhoea, or constipation.

Uncommon (affecting less than 1 out of 100 people):

- Sleep disturbances.
- Depression.
- Light-headedness when standing up.
- Respiratory problems in patients with asthma or chronic respiratory disease.
- Muscle weakness, muscle cramps.

Rare (affecting less than 1 out of 1000 people):

- Hearing problems.
- Allergic nasal mucosity.
- Reduced tearing.
- Liver inflammation that can cause a yellow colour of the skin or white of the eyes.
- Elevated levels of liver enzymes (laboratory tests (ALT or AST)).
- Some abnormal results of blood tests for liver function or fat levels were out of normal.
- Allergic-like reactions, including itching, reddening, skin rash.
- Erectile dysfunction.
- Nightmares, hallucinations.
- Fainting.

Very rare (affecting less than 1 out of 10,000 people):

- Eye irritation and reddening (conjunctivitis).
- Hair loss.
- Occurrence or worsening of squamous skin rash (psoriasis); rash similar to psoriasis.

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, tell to your doctor or pharmacist. 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 printed on the package. Expiry date refers to the last day of the indicated month.

Medicinal products should not be poured down the drain or thrown into the rubbish. Ask your pharmacist how to dispose of medicinal products you do not need. This will help to protect the environment.

6. Contents of the pack and other information

Composition of Bisoprolol NORMON

The active substance is bisoprolol (I.N.N.) hemifumarate. Each tablet of Bisoprolol NORMON contains 2.5 mg of bisoprolol hemifumarate.

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

Product appearance and contents of the package

Bisoprolol NORMON 2.5 mg film- coated tablets is presented in the form of white or almost white, round and scored film-coated tablets. Each package contains 28 or 500 tablets.

Not all pack sizes are marketed in all countries.

Marketing authorization holder and manufacturer

LABORATORIOS NORMON, S.A.

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This patient information leaflet was last revised in July 2014