Package leaflet: Information for the user

Bisoprolol Normon 1.25 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 Normon is and what it is used for

The active substance is bisoprolol. Bisoprolol belongs to a group of medicines called beta-blockers. These medicines work by affecting the body's response to some nerve impulses, especially in the heart. As a result, bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body. At the same time, it reduces the amount of blood required by the heart, as well as its use of oxygen. Heart failure occurs when the heart muscle is weak and unable to pump enough blood to supply the body's needs.
Bisoprolol Normon is used to:
- treat high blood pressure (hypertension).
- treat stable chronic angina pectoris.
- treat stable chronic heart failure. It is used in combination with other medicines suitable for this condition (such as ACE-inhibitors, diuretics, and heart glycosides).

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

Do not take Bisoprolol Normon if any of the following conditions applies to you:
- if you are allergic to bisoprolol fumarate or any of the other ingredients of this medicine (listed in section 6),
- severe asthma
- 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
- untreated phaeochromocytoma, which is a rare tumour of the adrenal gland
- metabolic acidosis, which is a condition when there is too much acid in the blood

Do not take Bisoprolol Normon if you have any 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, which is an acute serious heart condition causing low blood pressure and circulatory failure.

- slow heart rate.

Talk to your doctor if you think that one of the conditions listed above applies to you.

Warnings and precautions
Talk to your doctor or pharmacist before taking bisoprolol. If you have any of the following conditions, tell your doctor before taking this medicine; your doctor may want to take special care (for example 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)
– tumour of the adrenal gland (pheochromocytoma)
– thyroid disorder

During treatment
In addition, tell your doctor if you are going to have:
- desensitisation 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.

If you have chronic lung disease or less severe asthma please inform your doctor immediately if you start to experience new difficulties in breathing, cough, wheezing after exercise, etc. when taking bisoprolol.

Other medicines and Bisoprolol Normon
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

<u>Do not take the following medicines with Bisoprolol Normon without special advice from your doctor</u>:
– certain medicines used to treat irregular or abnormal heartbeat (Class I antiarrhythmic medicines such as quinidine, disopyramide, lidocaine, phenytoin, flecainide, or 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, or rilmenidine. However, do not stop taking these medicines without checking with your doctor first.

<u>Check with your doctor before taking the following medicines with Bisoprolol Normon; your doctor may need to check your condition more frequently</u>:
– certain medicines used to treat high blood pressure or angina pectoris (dihydropyridine-type calcium antagonists such as nifedipine, 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 for example 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)
– insulin and other antidiabetic medicines
– anaesthetic agents (for example during surgery)
– digitalis, used to treat heart failure
– non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain, or inflammation (for example, ibuprofen or diclofenac)
– medicines for asthma or used for nasal congestion
– 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
– depression treatment medicines called monoamine oxidase inhibitors (except MAO-B inhibitors) such as moclobemide

Pregnancy and breast-feeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Bisoprolol can be harmful to the pregnancy and/or to the foetus. It may also affect the baby's growth. Therefore, bisoprolol should not be used during pregnancy.

It is unknown if bisoprolol is excreted in the breast milk. Therefore, its use is not recommended during breast-feeding.

Children and adolescents
Bisoprolol Normon is not recommended for use in children and adolescents.

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 the medication is changed, as well as in combination with alcohol.

Bisoprolol Normon contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

Important information for athletes
Athletes are warned that this medicine contains a component that can establish an analytical result of doping control as positive.

3. How to take Bisoprolol Normon

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how many tablets to take. Bisoprolol should be taken in the morning, before, during, or after breakfast.
Take the tablets whole with the aid of a glass of water and do not chew or crush them.

Hypertension and angina pectoris
Adults including elderly patients The maximum recommended dose is 20 mg once a day.

Stable chronic heart failure
Adults including elderly patients
Treatment with bisoprolol should be started with 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 of bisoprolol once daily for a week.
- 2.5 mg of bisoprolol once daily for a week.
- 3.75 mg of bisoprolol once daily for a week.
- 5 mg of bisoprolol once daily for four weeks.
- 7.5 mg of bisoprolol once daily for four weeks.
- 10 mg of bisoprolol once daily for maintenance (on-going) therapy.

The maximum recommended daily dose of bisoprolol is 10 mg.
Depending on how well you tolerate the medicine, the doctor may also extend the time between dose increases. If your condition gets worse or if you no longer tolerate the drug, it may be necessary to lower the dose again or to stop treatment. For some patients, a maintenance dose lower than 10 mg bisoprolol fumarate may be sufficient. Your doctor will tell you what to do.

Use in patients with renal and/or liver insufficiency
No dose adjustment is normally required in patients with mild to moderate impaired renal or hepatic function. In patients with severe renal insufficiency (creatinine clearance <20 ml/min) and in patients with severe hepatic

insufficiency, bisoprolol 10 mg once daily should not be exceeded.

Use in children and adolescents
Bisoprolol is not recommended for use by children and adolescents.

If you take more Bisoprolol Normon than you should
If you have taken more bisoprolol tablets than you should, tell your doctor immediately. Your doctor will decide what measures are necessary.

Symptoms of an overdose may include slowed heart rate, severe difficulty in breathing, feeling dizzy, or trembling (due to decreased blood sugar).

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.

If you forget to take Bisoprolol Normon
Do not take a double dose to make up for a forgotten dose**.** Take the next dose as soon as you remember unless it is time to take the next dose.

If you stop taking Bisoprolol Normon
Treatment with bisoprolol should not be stopped abruptly. Otherwise, your condition could become much worse. Instead, the dose should be reduced gradually over a few weeks as directed by your doctor.

If you have any further questions on 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.

To prevent serious reactions, speak to your 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 (may affect more than 1 in 10 people)
– worsening of heart failure (may affect up to 1 in 10 people)
– slow or irregular heartbeat (may affect up to 1 in 100 people)

If you feel dizzy or weak, or have breathing difficulties please contact your doctor as soon as possible.

Further side effects are listed below:

Uncommon (may affect up to 1 in 100 people):
- Depression.
- Breathing problems in patients with asthma or chronic lung disease

Rare (may affect up to 1 in 1,000 people):
- Inflammation of the liver which can cause yellowing of the skin or whites of the eyes.

Other adverse effects are mentioned below according to their frequency of possible appearance:
Common (may affect up to 1 in 10 people):
- Tiredness*.
- Headache*
- Feeling of coldness or numbness of hands and/or feet.
- Low blood pressure.
- Stomach or intestine problems such as nausea, vomiting, diarrhoea or constipation.

*If treated for high blood pressure or angina pectoris then these symptoms occur especially at the beginning of

treatment. They are generally mild and often disappear within 1 to 2 weeks.

Uncommon (may affect up to 1 in 100 people):
- Sleep disorders.
- Changes in normal heart rhythm.
- Muscle weakness and muscle cramps.
- Dizziness when standing up.

Rare (may affect up to 1 in 1,000 people):
- Hearing problems.
- Allergic runny nose.
- Reduced tear flow
- Certain blood test results for liver function or fat levels differing from normal.
- Allergy-like reactions such as itching, flush, and skin rash.
- Impaired erection
- Nightmares, hallucinations
- Fainting

Very rare (may affect up to 1 in 10,000 people):
- Irritation and redness of the eye (conjunctivitis)
- Loss of hair.
- 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bisoprolol Normon

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 container after EXP. The expiry date refers to the last day of that month.

Store below 30 ºC. Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. If you are not sure, ask your pharmacist how to throw away medicines and containers you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bisoprolol Normon contains
- The active substance is bisoprolol fumarate. Each tablet contains 1.25 mg of bisoprolol as bisoprolol fumarate.
- The other ingredients (excipients) are:
  Anhydrous disodium phosphate, microcrystalline cellulose, maize starch, sodium croscarmellose, colloidal silica, plant based magnesium stearate, hypromellose, talc, macrogol 6000, titanium dioxide (E171).

What Bisoprolol Normon looks like and contents of the pack
Bisoprolol Normon 1.25 mg are white or almost white, round and biconvex film-coated tablets debossed with "B1.25" on one side and they are available in blister type (PVC/Al or PVDC-PE/Al) packages.

Blister containing 20 tablets.

Marketing authorisation holder and manufacturer

Marketing authorisation holder
LABORATORIOS NORMON, S.A.
Ronda de Valdecarrizo, 6 - 28760 Tres Cantos – Madrid (Spain)

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