

## **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:**

- 1. What Bisoprolol NORMON is and what it is used for**
- 2. What you need to know before you take Bisoprolol NORMON**
- 3. How to take Bisoprolol NORMON**
- 4. Possible side effects**
- 5. How to store Bisoprolol NORMON**
- 6. Contents of the pack and other information**

#### **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 for:

- 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**

Bisoprolol NORMON administration is not recommended 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 felodipine 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 timolol eye drops for glaucoma treatment).
- 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.

### **Bisoprolol Normon contains sodium**

This medicine contains less than 23 mg sodium (1 mmol) per tablet, that is to say essentially 'sodium-free'.

## **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 a 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 maximum daily dose 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 modified for this patients.

### **Elderly patients**

There is no need to adjust the dose.

### **Pediatric population**

There is no pediatric experience with bisoprolol, therefore its use is not recommended 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 effects 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 effects 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 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.

Store in the original package in order to protect from moisture.

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 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 may be marketed in all countries.

### **Marketing authorization holder and manufacturer**

LABORATORIOS NORMON, S.A.

Ronda de Valdecarrizo, 6 28760 Tres Cantos, Madrid (SPAIN)

**The text was last reviewed in July 2014**

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Bisoprolol NORMON 5 mg film-coated tablets** Bisoprolol hemifumarate

**Read the package 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 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?**

1. What Bisoprolol NORMON is and what it is used for
2. What you need to know before you start taking Bisoprolol NORMON
3. How to take Bisoprolol NORMON
4. Possible side effects
5. How to store Bisoprolol NORMON
6. Contents of the pack and other information

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

Bisoprolol belongs to a 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 for:

- 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. What you need to know before you start taking 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 pulmonary disease.
- 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 pheochromocytoma, 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 certain heart problems which causes a very slow heart rate or irregular pulse.

- Cardiogenic shock, a severe 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.
- Certain heart diseases as heart rhythm disorders, severe chest pain at rest (Prinzmetal's angina).
- Kidneys and liver diseases.
- Less severe limbs circulatory problems.
- Asthma or less severe 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 your doctor if you are going to have:

- Desensitization treatment (e.g. hay fever prevention), due to Bisoprolol NORMON may be more probable you present allergic reaction, or such reaction may be more severe.
- Anesthesia (e.g. for surgery), due to Bisoprolol NORMON may influence on how your body reacts to this situation.

### **Children and adolescent**

Bisoprolol NORMON administration is not recommended in children nor adolescents.

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

### **Other medicines and Bisoprolol NORMON**

Tell your doctor if you are 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:

- Certain medicines used to treat irregular or abnormal heart beating (Class I antiarrhythmics drugs like quinidine, disopyramide, lidocaine, phenytoin; 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, moxonidine, rilmenidine. However, **don't stop taking these medicines** without previously asking your doctor.

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

- Certain medicines used to treat high blood pressure or angina pectoris (calcium antagonists dihydropyridine type, such as felodipine and amlodipine).
- Certain medicines used to treat irregular or abnormal heart beating (class III antiarrhythmics such as amiodarone).
- Beta-blockers applied locally (such as timolol eye drops for glaucoma treatment).
- Certain medicines used to treat for example Alzheimer disease or glaucoma (parasympathomimetics such as tacrine or carbachol) or medicines to treat acute heart diseases (sympathomimetics such as isoprenaline and dobutamine).
- Antidiabetic medicines including insulin.
- Anesthetics agents (e.g., during surgery).
- Digitalis, used to treat heart failure.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) used to treat arthritis, pain or inflammation (e.g. ibuprofen or diclofenac).
- Epinephrine, used to treat very severe allergic reactions and heart attack.
- Any medicine which can reduce blood pressure as desired or undesired effect, such as antihypertensive, certain medicines for depression (tricyclic antidepressants such as imipramine and amitriptyline), certain medicines used to treat epilepsy or during the anesthesia (barbiturates such as phenobarbital),

or certain medicines for treat mental diseases characterized by a loss of contact with the reality (phenothiazines such as levopromazine).

- Mefloquine, used for the prevention or treatment of malaria.
- Medicines to treat depression called 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. Tell 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.

Breast-feeding is not recommended during treatment with Bisoprolol NORMON because it is not known whether bisoprolol passes into breast milk.

### **Driving and using machinery**

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

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.

### **Bisoprolol Normon contains sodium**

This medicine contains less than 23 mg sodium (1 mmol) per tablet, that is to say essentially 'sodium-free'.

## **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 requires a regular monitoring by your doctor. This is particularly necessary at the beginning of the treatment and during the dose increasing. Take the tablet with some water, with or without food in the morning. Do not crush nor chew the tablet. Bisoprolol NORMON treatment is usually long-term.

### **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 if necessary.

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 to 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. The experience with bisoprolol in dialysis patients is limited, however, until now, not seem to be necessary to adjust the dose.

### **Elderly**

In general, adjustment of the dose is not needed.

### **Pediatric population**

There is no pediatric experience with bisoprolol, therefore its use is not recommended in this 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 at the next morning.

### **If you stop taking Bisoprolol NORMON**

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

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

## **4. Possible side effects**

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

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

### **The most severe 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 up
- 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
- 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).
- Certain unusual blood tests results for the liver function or fat level.
- 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 eyes (conjunctivitis)
- Hair loss
- Appearance or worsening of scaly skin rash (psoriasis); psoriasis-like rash.

If you get any side effects 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 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.

Store in the original package in order to protect from moisture.

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

Medicines should not be disposed of via wastewater or household waste. If you doubt ask your pharmacist how to dispose of medicines no longer required. This will help protect the environment.

## **6. Contents of the pack and other information**

### **Bisoprolol NORMON composition**

The active ingredient is bisoprolol hemifumarate. Each tablet of Bisoprolol NORMON contains 5 mg bisoprolol hemifumarate. The other ingredients are microcrystalline cellulose, maize starch, colloidal silica, hypromellose, anhydrous disodium phosphate, magnesium stearate, croscarmellose sodium, titanium dioxide (E-171), macrogol 6000 and yellow iron oxide (E-172).

### **What Bisoprolol NORMON looks like and contents of the pack**

Bisoprolol NORMON are film-coated tablets, yellow, round, biconvex and scored. It comes in packs of 30 or 60 tablets.

Not all pack sizes may be marketed in all countries.

### **Marketing Authorization Holder and Responsible for Manufacturing**

LABORATORIOS NORMON, S.A.

Ronda de Valdecarrizo, 6-28760 Tres Cantos, Madrid (SPAIN)

**The text was last reviewed in July 2014**

## **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 a 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 for:

- 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 at 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 probable 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 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:

- Certain medicines used to treat irregular or abnormal heart beating (Class I antiarrhythmics drugs like quinidine, disopyramide, lidocaine, phenytoin; 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, moxonidine, rilmenidine.
- However, **don't stop taking these medicines** without previously asking to your doctor.

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

- Certain medicines used to treat high blood pressure or angina pectoris (calcium antagonists of dihydropyridine type such as felodipine and amlodipine).
- Certain medicines used to treat irregular or abnormal heart beating (class III antiarrhythmics such as amiodarone),
- Beta-blockers applied locally (such as timolol eye drops for glaucoma treatment).
- Certain 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 isoprenoline and dobutamine)
- Antidiabetic medicines including insulin
- Anesthetics agents (e.g., during surgery).
- Digitalis, used to treat 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 blood pressure as an expected or not expected effect, such as antihypertensive, certain medicines for depression (tricyclic antydepressants such as imipramine and amitriptiline), certain medicines used to treat the epilepsy or during the anesthesia (barbiturates such as phenobarbital), or certain 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.
  - Breast-feeding is not recommended during treatment with Bisoprolol NORMON because it is not known whether bisoprolol passes into breast milk.

### **Driving and using machinery**

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.

### **Bisoprolol Normon contains sodium**

This medicine contains less than 23 mg sodium (1 mmol) per tablet, that is to say essentially 'sodium-free'.

### **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 in the morning. Do not crush nor chew. Bisoprolol NORMON treatment is usually long-term.

### **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 your doctor's advice it. 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.

Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton . 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 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 may be marketed in all countries.

**Marketing Authorization Holder and Responsible for Manufacturing**

LABORATORIOS NORMON, S.A.

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**The text was last reviewed in July 2014.**