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1.3.1 spc-label-pl - common-pl-5mg10mg - 26 (NL/H/0597/004-006/IA/013/G updated PL)		20140226
BISOPROLOL FUMARATE 10 MG; 5 MG FILM-COATED TABLET		721-5610.00 721-5612.00

**Package leaflet: Information for the user**

**[Bisoprolol Sandoz] 5 mg and 10 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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

**What is in this leaflet:**

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

**1. What [Bisoprolol Sandoz] is and what it is used for**

[Bisoprolol Sandoz] belongs to the group of medicinal products that are indicated as beta blockers. They protect the heart from too much activity.

[Bisoprolol Sandoz] is used to treat:

- high blood pressure
- angina pectoris(heart pain)
- heart failure causing breathlessness on exertion or fluid retention. In this instance, [Bisoprolol Sandoz] may be given as an additional treatment to other medications for heart failure.

**2. What you need to know before you take [Bisoprolol Sandoz]**

**Do not take [Bisoprolol Sandoz]**

- if you are allergic to bisoprolol fumarate or any of the other ingredients of this medicine (listed in section 6).
- if you have a cardiogenic shock, a serious heart condition causing a rapid, weak pulse; low blood pressure; cold, clammy skin; weakness and fainting.
- if you have ever suffered from severe wheezing or severe asthma, as they can affect your breathing.
- if you have a slow heart rate (less than 60 beats per minute). Ask your doctor if you are not sure.
- if you have very low blood pressure.
- if you have severe blood circulation problems (which may cause your fingers and toes to tingle or turn pale or blue).
- if you have certain serious heart rhythm problems.
- if you have heart failure which has just occurred or is not stabilised and is requiring hospital treatment.
- if you 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.

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- if 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 before taking [Bisoprolol Sandoz]

- if you suffer from wheezing or difficulty breathing (asthma). Bronchodilating therapy should be given concomitantly. A higher dose of beta<sub>2</sub>-stimulants may be needed.
- if you have diabetes. The tablets can hide the symptoms of low blood sugar (such as accelerated heart beat rate, palpitations or sweating).
- if you are fasting from solid food.
- if you are treated for hypersensitivity (allergic) reactions. [Bisoprolol Sandoz] may increase the hypersensitivity to the substances you are allergic to and increase the severity of the hypersensitivity reactions. Treatment with adrenalin then may not have the desired result. A higher dose of adrenalin (epinephrine) may be needed.
- with 1st degree heart block (conduction disorder in the heart).
- if you suffer from Prinzmetal's angina which is a type of chest pain caused by spasm of the coronary arteries that supply the heart muscle.
- if you have any problems with the circulation to the extremities of the body such as hands and feet.
- in case of surgery involving an anaesthetic: If you consult a doctor, attend hospital or the dentist for surgery involving anaesthetics, let them know what medicines you are taking.
- in combination with calcium antagonists, such as verapamil and diltiazem. Concomitant use is not recommended, see also section "Other medicines and [Bisoprolol Sandoz]".
- if you suffer (or have suffered) from psoriasis (a recurrent skin disorder involving scaling and dry skin rash).
- if you suffer from phaeochromocytoma (tumour of the adrenal marrow). Your doctor will need to treat this before prescribing [Bisoprolol Sandoz] for you.
- if you have a thyroid problem. The tablets can hide symptoms of an overactive thyroid.

There is so far no therapeutic experience of [Bisoprolol Sandoz] treatment of heart failure in patients with the following diseases and conditions:

- diabetes mellitus treated with insulin (type I).
- severe kidney disease.
- severe liver disease.
- certain heart diseases.
- heart attack within 3 months.

Treatment of heart failure with [Bisoprolol Sandoz] requires regular medical monitoring. This is absolutely necessary, particularly at the beginning of treatment, and upon stopping treatment.

Treatment with [Bisoprolol Sandoz] must not be discontinued abruptly unless for compelling reasons.

For patients with hypertension and angina pectoris and accompanying heart failure treatment should not be stopped abruptly. The dosage should be diminished slowly by a weekly halving of the dose.

Consult your physician if one of the above warnings is applicable to you, or has been in the past.

### Other medicines and [Bisoprolol Sandoz]

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines obtained without a prescription. Certain medicines cannot be used at the same time, while other drugs require specific changes (in the dose, for example).

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Always tell your doctor if you are using or receiving any of the following medicines in addition to [Bisoprolol Sandoz]:

- medicines for controlling the blood pressure or medicines for heart problems (such as amiodarone, amlodipine, clonidine, digitalis glycosides, diltiazem, disopyramide, felodipine, flecainide, lidocaine, methyldopa, moxonidine, phenytoin, propafenone, quinidine, rilmenidine, verapamil).
- sedatives and therapies for psychosis (a mental illness) e.g. barbiturates (also used for epilepsy), phenothiazines (also used for vomiting and nausea).
- medicines for depression e.g. tricyclic antidepressants, MAO-A inhibitors.
- medicines used for anaesthesia during an operation (see also section “Warnings and precautions”).
- certain pain killers (for instance acetyl salicylic acid, diclofenac, indomethacin, ibuprofen, naproxen).
- medicines for asthma, blocked nose, or certain eye disorders such as glaucoma (increased pressure in the eye) or dilation (widening) of the pupil.
- certain medicines to treat shock (e. g. adrenaline, dobutamine, noradrenaline).
- mefloquine, a medicine for malaria.
- the antibiotic rifampicin.
- ergotamine derivatives for migraine.

All these drugs as well as [Bisoprolol Sandoz] may influence the blood pressure and/or heart function.

- insulin or other products for diabetes. The blood glucose reducing effect may be enhanced. Symptoms of low blood glucose level can be masked.

#### **[Bisoprolol Sandoz]with alcohol**

The dizziness and light-headedness that may be caused by [Bisoprolol Sandoz] 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 for advice before taking this medicine. [Bisoprolol Sandoz] 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 should not be taken during pregnancy.

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

#### **Driving and using machines**

No studies on the effects on the ability to drive and use machines have been performed.

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.

#### **[Bisoprolol Sandoz] contains 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 [Bisoprolol Sandoz]**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many tablets to take. You should take this medicine in the morning, before, with or after breakfast. Swallow the tablet(s) with some water and do not chew or crush them.

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### **Elevated blood pressure/ angina pectoris**

#### *Adults*

The dose is determined individually.

The recommended starting dose is 5 mg once daily.

The usual dose for adults is once daily 10 mg. Your doctor may decide to increase or decrease the dose.

The maximum dose is once daily 20 mg.

#### *Severe kidney or severe liver function disorders*

If you suffer from a **severe kidney or severe liver function disorder** the maximum dose is 10 mg per day.

#### *Elderly*

Normally no dosage adjustment is required. Your doctor will start therapy with the lowest possible dose.

### **Heart failure (reduced pumping strength of the heart)**

Before you start using [Bisoprolol Sandoz], you are already using an ACE-inhibitor, diuretic or heart glycoside (heart/ blood pressure product).

The dose will be increased gradually until the dose that is suitable for you has been found:

1.25 mg once daily for 1 week. If this is well tolerated, the dose may be increased to:

2.5 mg once daily during the next week. If this is well tolerated, the dose may be increased to:

3.75 mg once daily during the next week. If this is well tolerated, the dose may be increased to:

5 mg once daily during the next 4 weeks. If this is well tolerated, the dose may be increased to:

7.5 mg once daily during the next 4 weeks. If this is well tolerated, the dose may be increased to:

10 mg once daily as a maintenance dose.

Maximum dose is once daily 10 mg.

The doctor will determine the optimum dose for you amongst others based on possible side effects.

After the very first dose of 1.25 mg the doctor will check your blood pressure, heart rate, heart function disorders.

#### *Liver or kidney function disorders*

The doctor will be extra careful with the increasing of the dose.

#### *Elderly*

Normally spoken an adjustment of the dose is not needed.

If you notice that the effect of [Bisoprolol Sandoz] is too strong or not strong enough, please consult your doctor or pharmacist.



Place the tablet on a hard, flat surface with the scored side at the top.

Press with the thumb on the middle of the tablet and the tablet will break into two halves, press with the thumb in the middle of each half and you will have four parts.

#### *Duration of the treatment*

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[Bisoprolol Sandoz] will usually be used long-term.

#### Use in children and adolescents

There is no experience with [Bisoprolol Sandoz] in children and adolescents, therefore its use is not recommended in children.

#### If you take more [Bisoprolol Sandoz] 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 [Bisoprolol Sandoz]

Do not take a double dose to **make up for a forgotten dose**. Take the normal dose as soon as you remember and then carry on with the usual dose the next day.

#### If you stop taking [Bisoprolol Sandoz]

Treatment with [Bisoprolol Sandoz] must not be stopped abruptly. If you suddenly stop taking this medicine your condition may get worse. Instead, it must be reduced gradually over a few weeks as advised 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.

Side effects that could occur are:

Very common, affects more than 1 per 10 users:

- slow heart beat. In the treatment of hypertension or angina pectoris this side effect occurs uncommonly.

Common, affects 1 to 10 per 100 users:

- exhaustion. In the treatment of hypertension or angina pectoris this side effect occurs uncommonly.
- dizziness, tiredness and headache (especially at the beginning of therapy in patients with hypertension and angina pectoris; symptoms 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
- worsening of pre-existing heart failure. In the treatment of hypertension or angina pectoris this side effect occurs uncommonly.
- very low blood pressure (hypotension), particularly in patients with heart failure
- feeling sick (nausea), being sick (vomiting)
- diarrhoea
- constipation

Uncommon, affects 1 to 10 per 1,000 users:

- exhaustion. In the treatment of heart failure this side effect occurs commonly

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- fall in blood pressure on standing up which may cause dizziness, light-headedness or fainting
- sleep disturbances
- depression
- slow heart beat. In the treatment of heart failure this side effect occurs very commonly.
- irregular heart beat
- worsening of pre-existing heart failure. In the treatment of heart failure this side effect occurs commonly.
- patients with asthma or a history of breathing problems may experience difficulty in breathing
- muscular weakness and muscle cramps

Rare, affects 1 to 10 per 10,000 users:

- nightmares
- hallucinations (imagining things)
- syncope
- hearing impairment
- inflammation of the lining of the nose, causing a runny nose with irritation
- allergic reactions (such as 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
- reduced sexual performance (potency disorder)
- increased levels of blood lipids (triglycerides) and liver enzymes

Very rare, affects less than 1 per 10,000 users:

- chest pain
- aggravation of the skin condition psoriasis or cause a similar dry, scaly rash and hair loss
- itchiness or redness of the eye (conjunctivitis)

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

## 5. How to store [Bisoprolol Sandoz]

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 packaging after “EXP”. The first two numbers match the month, the last numbers the year. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What <Bisoprolol Sandoz> contains

The active substance is 5 mg / 10mg bisoprolol fumarate.

The other ingredients are:

calcium hydrogen phosphate, anhydrous

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cellulose, microcrystalline  
maize starch, pregelatinised  
croscarmellose sodium  
silica, colloidal anhydrous  
magnesium stearate  
lactose monohydrate  
hypromellose  
macrogol 4000  
titanium dioxide (E171)  
iron oxide, yellow (E172)

The other ingredients are:

calcium hydrogen phosphate, anhydrous  
cellulose, microcrystalline  
maize starch, pregelatinised  
croscarmellose sodium  
silica, colloidal anhydrous  
magnesium stearate  
lactose monohydrate  
hypromellose  
macrogol 4000  
titanium dioxide (E171)  
iron oxide, yellow (E172)  
iron oxide, red (E172)

### What < Bisoprolol Sandoz > looks like and contents of the pack

- Bisoprolol fumarate 5 mg film-coated tablets are yellow, round film-coated tablets with a cross score (divides the tablet in four) on one side and encoded "BIS 5" on the other side and available in blister packs (OPA-AI-PVC/AI)
- Bisoprolol fumarate 10 mg film-coated tablets are apricot, round, convex film-coated tablets with a cross score (divides the tablet in four) on one side and encoded "BIS 10" on the other side and available in blister packs (OPA-AI-PVC/AI)

Pack sizes:

7, 10, 14, 20, 28, 30, 50, 56, 60, 100, 10x30 film-coated tablets

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder

#### Manufacturer

Salutas Pharma GmbH  
Otto-von-Guericke-Allee 1, 39179 Barleben  
Germany

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Lek S.A.  
Ul. Podlipie 16 C, 95 010 Strykow  
Poland

**This medicinal product is authorised in the Member States of the EEA under the following names**

Ireland: BISOP 5 MG FILM-COATED TABLETS  
BISOP10MGFILM-COATEDTABLETS  
Italy: BISOPROLOLO ALMUS 5 MG COMPRESSE RIVESTITE CON FILM  
BISOPROLOLOALMUS10MGCOMPRESSERIVESTITECONFILM  
The Netherlands: BISOPROLOLFUMARAAT 5 MG, FILMOMHULDE TABLETTE  
BISOPROLOLFUMARAAT10MG,FILMOMHULDETABLETTE

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