1.3.5 Package Leaflet

PACKAGE LEAFLET: INFORMATION FOR THE USER

Bisoprolol fumarate 10 mg, tablets
Active substance: bisoprolol fumarate

Read all of this leaflet carefully before you start taking this medicine.
- 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, do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What is Bisoprolol fumarate 10 mg and what is it used for
2. Before you take Bisoprolol fumarate 10 mg
3. How to take Bisoprolol fumarate 10 mg
4. Possible side effects
5. How to store Bisoprolol fumarate 10 mg
6. Further information

1. What Bisoprolol fumarate 10 mg is and what it is used for

Bisoprolol fumarate belongs to the group of blood pressure lowering medicines.

Bisoprolol fumarate is used for:
- the treatment of high blood pressure
- a certain form of chest pain (chronic stable angina pectoris) caused by the heart muscle receiving less oxygen than required. This usually occurs under stress.

2. Before you take Bisoprolol fumarate 10 mg

Do not take Bisoprolol fumarate 10 mg
- in case of sudden occurrence or worsening of heart failure (insufficient pumping power of the heart) being treated with so called inotropic medicines (medicines that may lighten the effort of the heart).
• if you are in a state of shock caused by a decreased pumping function of the heart, whereby, for instance, symptoms can occur such as very low blood pressure, disorientation, confusion and cold clammy skin.
• if you suffer from irregular heart beat as a result of a certain disturbance in the conduction of the heart (second or third degree AV block without pacemaker, sino-atrial block).
• if you have a very slow heartbeat of less than 60 beats per minute before the start of treatment (bradycardia).
• if you have a heart rhythm disorder (sick-sinus syndrome).
• if you have a very low blood pressure (systolic pressure of less than 100 mm mercury, hypotension).
• if you have a severe lung condition (for example severe asthma).
• if you have a severe blood circulatory impairment of the arms or the legs, a severe form of Reynaud’s syndrome.
• if you have an impaired metabolism (metabolic acidosis), whereby acids accumulate in the blood.
• if you are allergic (hypersensitive) to bisoprolol fumarate or any of the other ingredients of Bisoprolol fumarate 10 mg, (see Section 6, What Bisoprolol fumarate 10 mg contains).

Take special care with Bisoprolol fumarate 10 mg

Check to see if any of these warnings apply to you, or have applied to you in the past. Contact your doctor immediately:
• if you use a medicine against heart rhythm disorders (anti-arrhythmics) simultaneously (see Section 2, Taking other medicines).
• if you use other blood pressure-lowering medicines (centrally acting antihypertensives; for example, clonidine) simultaneously, or if you use medicines against heart rhythm disorders and/or increased blood pressure (calcium antagonists) (see Section 2, Taking other medicines).
• if you suffer from breathlessness as a result of cramps in the muscles of the respiratory tract (bronchospasms), for example in case of asthma-like or bronchitis-like respiratory disorders. You can still use this medicine if you do not have a severe lung disorder (see Section 2, Do not take Bisoprolol fumarate 10 mg), but you will have to make more use of bronchodilators.
• if you use medicines with a stimulating action on a certain part of the nervous system (parasympathicomimetics) simultaneously; for example, tacrine (anti-Alzheimer’s).
• if you have diabetes with strong fluctuations in the blood sugar level. Bisoprolol fumarate can mask the symptoms of low blood sugar. Therefore, the sugar level in the blood must be scrupulously monitored.
• if you have a disorder of the thyroid (hyperthyroidism). Bisoprolol fumarate can mask the symptoms of high levels of thyroid hormones.
• if you do not ingest sufficient nutrients, for example during fasting or if you are on a strict diet.
• if you are undergoing preventative allergy therapy (desensitisation therapy), whereby the body is made insensitive for certain substances (allergens).
• if you have a mild conduction disorder of the heart, which results in heart rhythm disorders (first degree AV-block).
• if you suffer from chest pain, which is caused by local constrictions and spasms (Prinzmetal's angina).
• if you have a mild blood circulation disorder of the arms or legs (Raynaud's syndrome, intermittent claudication).
• if you are being treated for a tumour of the adrenal medulla, that is associated with a sudden strong increase in blood pressure, severe headache, perspiration and an increased heartbeat (pheochromocytoma).
• if you have a recurring skin disorder with a scaly, dry skin rash (psoriasis).

This medicine contains bisoprolol fumarate. This substance may result in a positive test during drug testing.

Taking other medicines
Other medicines may be affected by bisoprolol fumarate. They in turn may affect how well bisoprolol fumarate works.

The following medicines must absolutely not be used in combination with bisoprolol fumarate:
• a certain type of painkiller (flottefenine, see Section 2, Do not take Bisoprolol fumarate 10 mg). There is an increased possibility of reduced blood pressure or shock.
• a certain type of medicine against psychiatric disorders such as psychoses (sultopride, see Section 2, Do not take Bisoprolol fumarate 10 mg). There is an increased possibility of heart rhythm disorders.

Combining the following medicines with bisoprolol fumarate is strongly dissuaded because of an increased risk of side effects:
• medicines against irregular heartbeat and/or high blood pressure (calcium antagonists of the verapamil, bepridil, and diltiazem type). The use of these medicines in combination with bisoprolol fumarate may lead to a reduced heart beat and strong reduction of the blood pressure.
• other blood pressure lowering medicines (centrally acting anti-hypertensives): for example, clonidine, methyldopa, guanfacin, moxonidine and rilmenidine.
You should not discontinue both medicines at once, as this may lead to an abrupt increase in blood pressure.

- a certain type of medicine against depression (MAO-A inhibitors). Your blood pressure may become too low or extremely high.

The medicines mentioned below should be used with caution. Your doctor will decide whether you can use these medicines together with bisoprolol fumarate, because they increase the risk of side effects.

- medicines against irregular heartbeat (anti-arrhythmics): for example, disopyramide, quinidine and amiodarone. The combination with bisoprolol fumarate may lead to weakening of the heart.

- medicines against irregular heartbeat and/or high blood pressure (calcium antagonists of the dihydropyridine type), for example nifedipine. The use of these medicines in combination with bisoprolol fumarate may lead to a strong reduction of the blood pressure.

- medicines with a stimulating action on a certain part of the nervous system (parasympathicomimetics); for example, tacrine and galantamine (anti-Alzheimer's). The use of these medicines in combination with bisoprolol fumarate may lead to a reduced heart beat.

- other medicines (beta-blockers) used for high blood pressure, for certain cardiac disorders or for increased eye pressure (including eye drops). An increase of the blood pressure lowering effect may occur.

- medicines used for the treatment of diabetes; for example, insulin and anti-diabetic medicines in tablet form. Bisoprolol fumarate may increase the blood sugar lowering effect and can mask the symptoms of low blood sugar content.

- medicines used for anaesthesia during an operation (anaesthetics). The working of the heart may get influenced during narcosis. Always inform your doctor if you take bisoprolol fumarate.

- medicines that increase the pumping power of the heart (digitalis glycosides) and that must be administered by placing them under the tongue. The use of these medicines in combination with bisoprolol fumarate may lead to a reduced heart beat.

- medicines used to treat migraine (ergotamine derivatives). Increased disturbance of the blood circulation in the arms and legs may occur.

- medicines with a stimulating action on a certain part of the nervous system (beta-sympathicomimetics); for example, the cardiac medicines isoprenaline and dobutamine. The combination of these medicines with bisoprolol fumarate may reduce the effects of both medicines.

- medicines with a blood pressure lowering side effect such as certain medicines against depression (tricyclic antidepressants), medicines to treat amongst others epilepsy (barbiturates), medicines to treat amongst others mental illness, nausea and vomiting (phenothiazines), and certain medicines used for high blood pressure. An increase of the blood pressure lowering effect may occur.
• a certain medicine that relaxes the muscles (baclofen). An increase of the blood pressure lowering effect may occur.
• a certain group of painkillers with an anti-inflammatory and fever inhibiting effect (NSAID); for example, ibuprofen. A decrease of the blood pressure lowering effect may occur.
• a medicine that decreases the side effects of cancer treatment (amifostine). A decrease of the blood pressure lowering effect may occur.
• a certain medicine for malaria prevention (mefloquine). Increased risk of a reduced heartbeat.
• adrenal cortex hormones that have, amongst others, an anti-inflammatory action (corticosteroids). A decrease of the blood pressure lowering effect may occur.
• iodated contrast products, used for making certain organs and blood vessels visible on a scan. Tell your doctor that you are taking bisoprolol fumarate.

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

Taking Bisoprolol fumarate 10 mg with food and drink
Simultaneous use of alcohol can adversely affect the ability to drive a car or to operate machinery.

Pregnancy and breast-feeding
You are only allowed to use bisoprolol fumarate when absolutely necessary. There is a risk that the development of the foetus will be affected by the use of bisoprolol fumarate. Breast feeding is not recommended when using bisoprolol fumarate.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
The ability to drive and to operate machinery can be adversely affected due to the differences in reaction time after the administration of bisoprolol fumarate. This must be borne in mind when beginning treatment, as well as during a change of dose and when taken in combination with alcohol.
3. How to take Bisoprolol fumarate 10 mg

Always take Bisoprolol fumarate 10 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should preferably be taken in the morning with some fluids (for example water) without chewing.

The following doses generally apply:

**Adults**
The starting dose is as low as possible. The usual dose is 10 mg per day, with a maximum dose of 20 mg per day.

**Use in patients with reduced kidney function**
If you have severe renal impairment, then the dose should not be more than 10 mg per day.

**Use in elderly and patients with reduced liver function**
No dose adjustment is required.

**Use in children and adolescents**
There is no experience with this medicine in children younger than 12 years or adolescents. Therefore, the use of bisoprolol fumarate in children younger than 12 years or adolescents is not recommended.

If you take more Bisoprolol fumarate 10 mg than you should
If you have taken more than prescribed, then immediately contact your doctor. Symptoms that can occur are: decreased heart rate, low blood pressure, lung cramps, heart disorders and low blood sugar level.

Take this information leaflet and any remaining tablets with you to show to the doctor.

If you forget to take Bisoprolol fumarate 10 mg
When you have forgotten to take a dose, skip this dose and take the next tablet at the usual time. Never take a double dose to make up for a forgotten dose.

If you stop taking Bisoprolol fumarate 10 mg
If your doctor decides to stop the treatment with bisoprolol fumarate, then the dose should be gradually decreased.
Stopping suddenly with taking bisoprolol fumarate may result in an increased blood pressure and an irregular heart beat (arrhythmia). You are therefore not allowed to abruptly stop the use of bisoprolol fumarate, but should gradually reduce the dose in consultation with your doctor.

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 fumarate 10 mg can cause side effects, although not everybody gets them. Contact your doctor or pharmacist when one of the side effects described below becomes serious or if you suffer from a side effect not described in this leaflet.

The following undesirable effects have been observed during treatment with bisoprolol with the following frequencies:

'Common' means that more than 1 in 100, but less than 1 in 10 people taking bisoprolol fumarate will experience these side effects.

'Uncommon' means that more than 1 in 1000, but less than 1 in 100 people taking bisoprolol fumarate will experience these side effects.

'Rare' means that 1 in 10,000, but less than 1 in 1,000 people taking bisoprolol fumarate will experience these side effects.

'Very rare' means that less than 1 in 10,000 people taking bisoprolol fumarate will experience these side effects.

Nervous system disorders:

Common: fatigue, exhaustion, dizziness and headache (especially at the beginning of treatment, the headache is usually mild and often disappears within 1 to 2 weeks).

Vascular disorders:

Common: cold or numb fingers and toes (Raynaud's syndrome), deterioration of circulatory disorders in the legs (intermittent claudication).

Uncommon: lowering of the blood pressure when, for instance, standing up quickly from a sitting or lying position, sometimes with associated dizziness (orthostatic hypotension).

Gastrointestinal disorders:

Common: nausea, vomiting, diarrhoea, abdominal pain and constipation.

Psychiatric disorders:

Uncommon: sleeping disturbances, severe depression.

Rare: nightmares, observations of things that do not exist (hallucinations).
Cardiac disorders:

Uncommon: decreased heartbeat (bradycardia), a certain conduction disorder of the heart (AV-conduction disorder), increased heart failure (insufficient pumping power of the heart).

Respiratory disorders:

Uncommon: breathlessness due to cramps in the muscles of the respiratory tract (bronchospasms) such as asthmatic or bronchitis-like respiratory disorders.

Muscle and connective tissue disorders:

Uncommon: muscle weakness and cramps, joint disorders (arthropathy).

Ear disorders:

Rare: decreased hearing.

Skin and subcutaneous tissue disorders:

Rare: rash, itchiness, reddening of the skin (allergic reactions).

Very rare: (deterioration of) a recurring skin condition in association with a scaly, dry skin rash (psoriasis) or a similar rash, loss of hair (alopecia).

Eye disorders:

Rare: reduced lachrymal fluid (important when you use contact lenses).

Very rare: inflammation of the conjunctiva (conjunctivitis).

Hepatic disorders:

Rare: liver infection associated with yellow colouring of the skin or eyes (jaundice).

Metabolism and nutrition disorders:

Rare: low blood sugar level, associated with a feeling of hunger, perspiration, dizziness and palpitations of the heart (hypoglycaemia), elevation of certain fats in the blood (triglycerides).

Reproductive system and breast disorders:

Rare: potency disorders.

Immune system disorders:

Rare: inflammatory reactions of the skin, allergic inflammation of the nasal mucous membrane that is characterised by a blocked nose sneezing and secretion (rhinitis).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
5. How to store Bisoprolol fumarate 10 mg

- Keep out of the reach and sight of children.
- Do not store Bisoprolol fumarate 10 mg above 25°C.
- Store in the original package.
- The tablet container should be kept properly closed.

Do not use Bisoprolol fumarate 10 mg after the expiry date which is stated on the packaging behind 'EXP'. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

Medicines should not be disposed of in waste water or household waste. Ask your pharmacist how to dispose of medicines once they are no longer required. These measures will help to protect the environment.

6. Further information

What Bisoprolol fumarate 10 mg contains
- The active substance is bisoprolol fumarate. One tablet contains 10 mg bisoprolol fumarate corresponding with 8.49 mg bisoprolol.
- The other ingredients are microcrystalline cellulose, calcium hydrogen phosphate, pregelatinised maize starch, crospovidone, colloidal anhydrous silica, magnesium stearate, hypromellose, macrogol 400, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172).

What Bisoprolol fumarate 10 mg looks like and contents of the pack
Bisoprolol fumarate 10 mg is a yellow to orange, round, tablet with a score line on both sides and the inscription "BSL10" on one side.

Bisoprolol fumarate 10 mg is available in boxes of 14, 20, 28, 30, 50, 56, 60 or 100 tablets in blisters (additionally, the blisters can be packed in an aluminium sachet) or in boxes of 50 tablets in hospital packaging (EAV-packaging).
Bisoprolol fumarate 10 mg film-coated tablets are also available in HDPE tablet containers of 30 or 50 tablets.

Not all pack sizes may be marketed.
Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
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