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 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 **severe asthma** or other severe **lung conditions** with difficulty to breathe.
• if you have a **severe blood circulatory impairment** of the arms or the legs, a severe form of Raynaud’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).
• if you have an **untreated tumour of the adrenal medulla**, which can be associated with a sudden strong increase in blood pressure, severe headache, perspiration and an increased heartbeat (pheochromocytoma).
• if you use a **certain painkiller** simultaneously (floctafenine).
• if you use a certain **medicine against severe psychiatric disorders**, for example psychoses, simultaneously (sultopride).

**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** or **wheezing** as a result of narrowing of the airways (bronchospasms), for example if you suffer from asthma-like or bronchitis-like lung 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** (parasympathomimetics) 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 of the blood vessels of the heart (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. Bisoprolol can interact with:

• medicines used for the **treatment of pain** and which exhibit an anti-inflammatory or fever inhibiting effect (NSAIDS) such as floctafenine.

• medicines used for the treatment of **psychiatric disorders** (anxiety, psychoses or depression) such as sulthopride, MAO-A inhibitors, tricyclic antidepressants, phenothiazines (also used for vomiting and nausea) and barbiturates (also used for epilepsy).

• medicines used for **controlling the blood pressure** or medicines used for **heart problems** such as calcium antagonists, centrally acting anti-hypertensives (e.g. clonidine, methylldopa, guanfacin, moxonidine, rilmenidine), anti arrhythmics (e.g. disopyramide, quinidine, amiodarone), digitalis glycosides, sympathicomimetics (e.g. isoprenaline, dobutamine, noradrenaline, adrenaline) other beta-blockers (including eye drops which are used for the treatment of increased eye pressure).

• medicines with a stimulating action on a certain part of the **nervous system** (parasympathicomimetics) which, amongst others, are used for the treatment of Alzheimer’s disease (e.g. tacrine).

• medicines used for **anaesthesia** during surgery.
• medicines used to treat migraine (e.g. ergotamine).
• a certain medicine that muscle relaxant (baclofen).
• a medicine that decreases the side effects of cancer treatment (amifostine).
• a certain medicine for malaria prevention (mefloquine).
• adrenal cortex hormones that have, amongst others, an anti-inflammatory action (corticosteroids).
• iodated contrast products, used for making certain organs and blood vessels visible on a scan.

The combination of bisoprolol and any of the drugs listed above, may influence the bloodpressure and/or heart function.

• 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.

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
Do not use this medicine if you are pregnant, unless your doctor has specifically recommended it. 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 your doctor may prescribe a lower dose.

**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).
Rare: low blood pressure

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 or wheezing due to narrowing of the airways (bronchospasms) in patients with asthma 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), increased, liver enzymes (ALAT, ASAT).

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).
Very rare: very low blood sugar level, which may lead to unconsciousness (hypoglycaemic shock).

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.

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).

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

*Marketing Authorisation Holder:*
Genthon BV
Microweg 22
6545 CM Nijmegen
The Netherlands
Manufacturers:
Synthon BV
Microweg 22
6545 CM Nijmegen
The Netherlands

Aliud Pharma GMBH & Co. KG
Gottlieb-Daimler-Str. 19
D-89150 Laichingen
Germany

Synthon Hispania S.L.
Castelló, 1
Polígono las Salinas
08830 Sant Boi de Llobregat
SPAIN

STADA Arzneimittel AG
Stadastraße. 2 - 18
61118 Bad Vilbel,
Germany

G.L. Pharma GmbH
Schloßplatz 1,
A-8502 Lannach
Austria

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

The Netherlands  Bisoprololfumaraat 10 mg, filmomhulde tabletten
Austria    Rivacor 10 mg
Belgium    Bisoprolol hemifumarate Genthon 10 mg
Denmark    Bisoprolol hemifumarat "Genthon",
               filmovertrukne tabletter 10 mg
Germany    Bisoprolol STADA 10 mg Tabletten
Ireland    Bisoprolol Hemifumarate Genthon 10mg film-coated
               tablets
Luxembourg  Bisoprolol hemifumarate-Genthon cpr.enr 10 mg
Spain    Bisoprolol Edigen 10 mg comprimidos recubiertos
Sweden    Bisoprolol Genthon, filmdragerad tablett 10 mg
United Kingdom  Genthon Bisoprolol hemifumarate 10 mg
This leaflet was last approved in {MM/YYYY}.