1.3.1 Package Leaflet

Package leaflet: information for the user

Bisoprolol hemifumarate Genthon 5 mg, film-coated tablets
bisoprolol fumarate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Bisoprolol hemifumarate Genthon 5 mg is and what it is used for

Bisoprolol hemifumarate Genthon 5 mg contains the active substance bisoprolol fumarate. 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.

You must talk to your doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Bisoprolol hemifumarate Genthon 5 mg

Do not take Bisoprolol hemifumarate Genthon 5 mg
- if you are **allergic to bisoprolol fumarate or any of the other ingredients** of this medicine (listed in section 6)
- 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 then 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 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).

Warnings and precautions
Talk to your doctor of pharmacist before taking Bisoprolol hemifumarate Genthon 5 mg

Take special care with Bisoprolol hemifumarate Genthon 5 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 have **heart failure**
- if you use a medicine against **heart rhythm disorders** (anti-arrhythmics) simultaneously (see Section 2, Other medicines and Bisoprolol hemifumarate Genthon 5 mg).
- 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, Other medicines and Bisoprolol hemifumarate Genthon 5 mg).
- 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 hemifumarate Genthon 5 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 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)
- if you go into hospital to have an operation, tell the anaesthetist or other medical staff that you are taking Bisoprolol film-coated tablets.

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

Other medicines and Bisoprolol hemifumarate 5 mg
Tell your doctor or pharmacist if your are taking, have recently taken or might take any 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 sultopride, 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, methyldopa, guanfacin, moxonidine, rilmenidine), anti arrhythmics (e.g. disopyramide, quinidine, amiodarone), digitalis glycosides, sympathicommimetics (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.

Bisoprolol hemifumarate Genthon 5 mg with food, drink and alcohol
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 during pregnancy. 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.

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.

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 hemifumarate Genthon 5 mg

Always take this medicine exactly as your doctor or pharmacist has told you. 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 score line is only there to help you break the tablet if you have difficulty swallowing it whole.

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 or liver function
If you have severe renal impairment or reduced liver function, then the dose should not be more than 5 mg per day.

Use in elderly
No dose adjustment is required.

Use in children and adolescents
There is no experience with this medicine in children and adolescents. Therefore, the use of bisoprolol fumarate in children and adolescents is not recommended.

If you take more Bisoprolol hemifumarate Genthon 5 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 hemifumarate Genthon 5 mg
When you have forgotten to take a dose, skip this dose and take the next tablet at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Bisoprolol hemifumarate Genthon 5 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 hart 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 medicine ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects (may affect up to 1 in 10 people)
dizziness and headache (especially at the beginning of treatment, the headache is usually mild and often disappears within 1 to 2 weeks) • cold or numb fingers and toes (Raynaud's syndrome), deterioration of circulatory disorders in the legs (intermittent claudication), low blood pressure (hypotension), lowering of the blood pressure when, for instance, standing up quickly from a sitting or lying position, sometimes with associated dizziness (orthostatic hypotension) • gastrointestinal complaints such as nausea, vomiting, diarrhoea, abdominal pain and constipation • fatigue (especially at the beginning of the therapy, they are generally mild and often disappear within 1-2 weeks)

Uncommon side effects (may affect up to 1 in 100 people)
sleeping disturbances, severe depression • decreased heartbeat (bradycardia), a certain conduction disorder of the heart (AV-conduction disorder), worsening of pre-existing heart failure (insufficient pumping power of the heart) • breathlessness or wheezing due to narrowing of the airways (bronchospasms) in patients with asthma or bronchitis like respiratory disorders • muscle weakness and cramps, joint disorders (arthropathy) • weakness (asthenia) •

Rare side effects (may affect up to 1 in 1,000 people)
inflammatory reactions of the skin, allergic inflammation of the nasal mucous membrane that is characterised by a blocked nose, sneezing and secretion (rhinitis) • low blood sugar level, associated with a feeling of hunger, perspiration, dizziness and palpitations of the heart (hypoglycaemia) • nightmares, observations of things that do not exist (hallucinations) • ***Rare***: fainting • reduced lachrymal fluid (important when you use contact lenses) • hearing disorders • inflammation of the nasal mucous membrane characterised by a blocked-up nose, sneezing (allergic rhinitis) • liver infection associated with yellow colouring of the skin or eyes (hepatitis) • rash, itchiness, reddening of the skin (allergic reactions) • potency disorders • increased liver enzymes (ALAT, ASAT), elevation of certain fats in the blood (triglycerides)

Very rare side effects (may affect up to 1 in 10,000 people)
very low blood sugar level, which may lead to unconsciousness (hypoglycaemic shock) • inflammation of the conjunctiva (conjunctivitis) • (deterioration of) a recurring skin condition in association with a scaly, dry skin rash (psoriasis) or a similar rash, loss of hair (alopecia)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517

Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bisoprolol hemifumarate Genthon 5 mg

- Keep out of the sight and reach of children.
- Do not store Bisoprolol hemifumarate Genthon 5 mg above 25°C.
- Store in the original package to protect from moisture and light.

Do not use this medicine after the expiry date which is stated on the packaging after '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.

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

6. Contents of the pack and other information

What Bisoprolol hemifumarate Genthon 5 mg contains

- The active substance is bisoprolol fumarate. One film-coated tablet contains 5 mg bisoprolol fumarate corresponding with 4.24 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 hemifumarate Genthon 5 mg looks like and contents of the pack
Bisoprolol hemifumarate Genthon 5 mg is a light pink, round, film-coated tablet with a score line on both sides and the inscription "BSL5" on one side.

Bisoprolol hemifumarate Genthon 5 mg is available in boxes of 14, 20, 28, 30, 50, 56, 60 or 100 film-coated tablets in blisters (additionally, the blisters can be packed in an aluminium sachet) or in boxes of 50 film-coated 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 5 mg, filmomhulde tabletten
Austria	Bisoprolol G.L. 5 mg-Filmtabletten
Ireland	Bisoprolol Hemifumarate Genthon 5mg film-coated tablets

This leaflet was last approved in June 2024