PACKAGE LEAFLET

Package leaflet: Information for the patient

Bisoprolol fumarate 5 mg, tablets
Bisoprolol fumarate 10 mg, 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Bisoprolol fumarate belongs to a group of medicinal products called beta-blockers. It is used to treat:
- high blood pressure
- angina pectoris (pain in the chest caused by blockages in the arteries leading to the heart).

2. What you need to know before you take Bisoprolol fumarate

Do not take Bisoprolol fumarate:
- if you are **allergic** to bisoprolol fumarate or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from **severe asthma** or from other **severe** breathing difficulties
- if you have **acute heart failure** or are in shock caused by heart problems
- if you suffer with **heart conduction** or **rhythm problems** (2nd or 3rd degree AV-block, sick sinus syndrome or sinoatrial block)
- if you have a **slow heart rate** of less than 60 beats per minute before starting treatment
- if you have **low blood pressure**
- if you suffer from severely **blocked blood vessels**, including **blood circulation problems** (which may cause your fingers and toes to tingle or turn pale or blue)
- if you suffer from **increased acidity of the blood** (metabolic acidosis)
- if you suffer from **untreated phaeochromocytoma** (high blood pressure due to a tumour of the adrenal medulla, a gland located near the kidney)
- if you are already treated with floctafenine (product for pain) or sultopride (product for mental illness). See also "Other medicines and Bisoprolol fumarate".

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Bisoprolol fumarate:

- if you have a **heart weakness**

- if you suffer from **asthma** or any other breathing difficulties
- if you suffer from **diabetes mellitus** (low blood sugar levels may be hidden by this medicinal product)
- if you have an overactive thyroid (symptoms such as increased heart rate, sweating, tremor, anxiety, increased appetite or weight loss may be hidden by this medicinal product)
- if you are on a **strict fasting** diet
- if you are having **treatment** to reduce **allergic reactions**. Bisoprolol fumarate may increase your hypersensitivity to the substances you are allergic to and increase the severity of allergic reactions
- if you suffer from a tight, painful feeling in the chest in periods of rest (**Prinzmetal's angina**). Bisoprolol fumarate may increase the number and the length of attacks
- if you suffer from **treated phaeochromocytoma** (high blood pressure due to a tumour of the adrenal medulla, a gland located near a kidney)
- if you have or have suffered from **psoriasis** (severe skin rashes)
- if you suffer from **blood circulation problems** (in the fingers, toes, arms and legs), including less severe forms of Raynaud's phenomenon and intermittent claudication (a cramp like pain in the calves brought on by exercise or walking). The complaints may be worse, particularly at the beginning of the treatment
- if you suffer from a certain **heart conduction disorder** (so-called 1st degree AV block)

If you are **going to have an anaesthetic,** please tell your doctor or dentist that you are taking Bisoprolol fumarate tablets. It may be necessary to stop taking this medicine up to 48 hours before receiving the anaesthetic.

Children and adolescents
Bisoprolol fumarate tablets are not recommended for use in children due to a lack of data.

Other medicines and Bisoprolol fumarate
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Other medicinal products may be affected by bisoprolol fumarate. They in turn may affect how well bisoprolol fumarate works. Bisoprolol fumarate can interact with:

- medicinal products used for the **treatment of pain** and which exhibit an anti-inflammatory or fever inhibiting effect (NSAIDS) such as floctafenine.
- medicinal products 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).
- medicinal products used for **controlling the blood pressure** or medicinal products 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).
- medicinal products 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).
- medicinal products used for **anaesthesia** during surgery.
- medicinal products used to treat **migraine** (e.g. ergotamine).
- a certain medicinal products that **muscle relaxant** (baclofen).
- a medicinal products that decreases the side effects of **cancer treatment** (amifostine).
- a certain medicinal products 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.
- sympathomimetics that activate both beta- and alpha-adrenoceptors (e.g. norepinephrine, epinephrine)

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

- medicinal products used for the treatment of **diabetes**; for example, insulin and anti-diabetic medicinal products in tablet form.

Bisoprolol fumarate may increase the blood sugar lowering effect and can mask the symptoms of low blood sugar content.

Pregnancy and breast-feeding
Bisoprolol fumarate is not recommended during pregnancy or 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.

Driving and using machines
This medicinal product could have a minor influence on the ability to drive and use machines. Bisoprolol fumarate tablets may make you feel tired and dizzy. Make sure you are not affected before you drive or operate machinery, particularly at the start of treatment, after any change in dose or medicinal product and if taken with alcohol.

Bisoprolol fumarate 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 fumarate

Method of administration
The tablet should be swallowed with a sufficient amount of fluid (e.g. one glass of water) at the **same time each day**. The tablet can be taken with or without food.

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 recommended doses are:
- **Adults:** *Initial dose:* Your doctor will start the treatment with the lowest possible dose. Sometimes 5 mg per day (24 hours) can be sufficient.10mg once daily with a maximum recommended dose of 20mg.
- **Patients with kidney disease:** patients with severe kidney disease should not take more than 10mg once daily. This dosage may eventually be halved and divided into two 5 mg doses
- **Patients with liver disease:** patients with severe liver disease should not take more than 10mg once daily. This dosage may eventually be halved and divided into two 5 mg doses
- **Elderly:** it is recommended to start with the lowest possible dose.
- **Children under 12 years old and adolescents:** Bisoprolol fumarate is not recommended for use in children below 12 years old due to a lack of data.

If you take more Bisoprolol fumarate than you should
If you have accidentally taken more than the prescribed dose, contact your nearest casualty department or tell your doctor or pharmacist at once. Symptoms of overdose are: slowed heart beat, asthma, low blood sugar, reduced blood pressure (possibly causing you to feel faint, dizzy or light-headed) and acute heart failure (fluid retention, breathlessness and tiredness).

If you forget to take Bisoprolol fumarate
If you forget to take a dose, take it as soon as you remember, then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Bisoprolol fumarate
Do not suddenly stop taking Bisoprolol fumarate as this could cause your condition to worsen (an exacerbation of a disorder of the heart may occur or your blood pressure may become high again). Your doctor will reduce the dose gradually or replace it by another medicinal product.

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

Stop treatment and contact a doctor at once if you have symptoms of an allergic reaction such as itchy skin rash, flushing, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing. This is a very serious but rare side effect (occurs in less than 1 in 1000 patients). You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:
- **Common** (may affect up to 1 in 10 people): tiredness, exhaustion, dizziness and headache (especially at the beginning of treatment). These are generally mild and often disappear within 1-2 weeks. Feeling of coldness or numbness in the extremities (Raynaud's disease), increase of existing limping (intermittent claudication), low blood pressure, feeling or being sick, diarrhoea, abdominal pain, constipation.
- **Uncommon** (may affect up to 1 in 100 people): dizziness or fainting when standing up due to low blood pressure, lack of muscle strength, sleep disturbances, depression, slow or irregular heartbeat, worsening of heart failure, muscle weakness and cramps, joint disease. Patients with asthma or a history of breathing problems may experience difficulty in breathing.
- **Rare** (may affect up to 1 in 1,000 people): loss of consciousness, nightmares, hallucinations, hearing impairment, dry eyes (to be considered if you wear contact lenses), reduced sexual performance, inflammation of the lining of the nose caused by an allergy, increased levels of fat (triglycerides) in your blood, low blood sugar levels (hypoglycaemia), increased levels of enzymes in your blood (ALAT, ASAT) which indicate how your liver is functioning), inflammation of the liver causing yellowing of the skin or eyes (hepatitis), the appearance of certain blood cells could cause symptoms of lupus syndrome such as joint swelling, fever, tiredness, hayfever (allergic rhinitis), skin rash, (symptoms usually disappear when treatment is stopped).
- **Very rare** (may affect up to 1 in 10,000 people): conjunctivitis (red, sore, itching or weeping eyes), psoriasis-like rash or worsening of psoriasis, hair loss, shock due to low blood sugar levels.

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 6767836. 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 fumarate

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 carton and blister label after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. 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 fumarate contains

- The active substance is Bisoprolol fumarate. Each tablet Bisoprolol fumarate 5 mg contains 4.24 mg bisoprolol equivalent to 5 mg bisoprolol fumarate. Each tablet Bisoprolol fumarate 10 mg contains 8.49 mg bisoprolol equivalent to 10 mg bisoprolol fumarate.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, magnesium stearate, crospovidone. The 5mg tablet contains a yellow pigment blend 22812 (which contains lactose and iron oxide yellow (E172)). The 10mg tablet contains a beige pigment blend 27215 (which contains lactose and iron oxide yellow and red (E172)).

What Bisoprolol fumarate looks like and contents of the pack
Blisters comprising of PVC/PVdC/aluminium foil, contained within a printed carton box.

The 5mg tablets are mottled pale yellow, round and convex, with 'BI' 'above a breakline with '5' below.
The 10mg tablets are mottled beige, round and convex, with 'BI' above a breakline with '10' below.
The tablets can be divided into equal halves.

Pack sizes: 10, 20, 28, 30, 50, 56, 60 or 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer:
Niche Generics Ltd
Unit 5, 151 Baldoyle Industrial Estate, Dublin 13
Ireland

Actavis Group PTC ehf.
Reykjavikurvegur 76-78
IS-220 Hafnarfjordur
Iceland

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

Ireland	Bisoprolol fumarate 5 mg tablets
	Bisoprolol fumarate 10 mg tablets
United Kingdom:	Bisoprolol 5mg tablets
	Bisoprolol 10mg tablets

This leaflet was last revised in: October 2018