Package leaflet: Information for the patient

Bisoprolol Viatris 1.25 mg, 2.5 mg, 3.75 mg, 5 mg, 7.5 mg or 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 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 Viatris is and what it is used for

This medicine contains the active substance bisoprolol fumarate, which belongs to a family of medicines called beta-blockers. Bisoprolol is used in combination with other medicines to treat stable heart failure

Heart failure occurs when the heart muscle is too weak to pump blood around the circulation adequately. This results in breathlessness and swelling.

Bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body.

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

Do not take Bisoprolol Viatris if you:
- are allergic to bisoprolol or any of the other ingredients of this medicine (listed in section 6)
- have severe asthma
- have a slow or irregular heart rate. Ask your doctor if you are not sure
- have very low blood pressure
- have severe blood circulation problems (which may cause your fingers and toes to tingle or turn pale or blue)
- have heart failure that suddenly becomes worse and / or that may require hospital treatment
- have excess acid in the blood, a condition known as metabolic acidosis
- have untreated phaeochromocytoma, a rare tumour of the adrenal gland

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if you:
- have asthma or chronic lung disease
- have diabetes. Bisoprolol can hide the symptoms of low blood sugar
- are fasting from solid food
- have any heart problems
- have any liver or kidney problems
- have any problems with the circulation in your limbs

- are taking verapamil or diltiazem, medicines used to treat heart conditions. Concomitant use is not recommended, see also "Other medicines and Bisoprolol Viatris"
- have (or have had) psoriasis (a recurring skin rash)
- have phaeochromocytoma (a rare tumour of the adrenal gland). Your doctor will need to treat this before prescribing bisoprolol for you
- have a thyroid problem. The tablets can hide symptoms of an overactive thyroid

During Treatment
Talk to your doctor or pharmacist if you:
- are going to be given a general anaesthetic during an operation – tell your doctor that you are taking bisoprolol
- are treated for hypersensitivity (allergic) reactions. Bisoprolol may make your allergy worse or more difficult to treat.
- have chronic lung disease or less severe asthma please inform your doctor immediately if you start to experience new difficulties in breathing, cough, wheezing after exercise, etc. when using bisoprolol.
- worsening of symptoms of blockage of the main blood vessels to the legs, especially at the start of treatment.

Children and adolescents
No information is available on the use of this medicine in children.

Other medicines and Bisoprolol Viatris
Tell your doctor or pharmacist if you are already taking or using any of the following as they may interact with your medicine:
- 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)
- medicines for depression e.g. imipramine, amitriptyline, moclobemide
- medicines to treat mental illness e.g. phenothiazines such as levomepromazine
- medicines used for anaesthesia during an operation (see also "Warnings and precautions")
- medicines used to treat epilepsy e.g. barbiturates such as phenobarbital
- certain pain killers (for instance acetyl salicylic acid, diclofenac, indomethacin, ibuprofen, naproxen)
- medicines for asthma or medicines used for a blocked nose
- medicines used for certain eye disorders such as glaucoma (increased pressure in the eye) or used to widen the pupil of the eye
- certain medicines to treat clinical shock (e.g. adrenaline, dobutamine, noradrenaline)
- mefloquine, a medicine for malaria
- all these drugs as well as bisoprolol may influence the blood pressure and/or heart function

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

Pregnancy, breast-feeding and fertility
Bisoprolol can be harmful to the pregnancy and/or to the child (increased possibility of premature birth, miscarriage, retarded growth, low blood glucose level and reduced heart rate of the child). Therefore **do not** use this medicine during pregnancy.

It is unknown if bisoprolol is excreted in the breast milk. Breast-feeding during the use of this medicine is therefore **not** recommended.

No information is available on the effects of bisoprolol on fertility.

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 use of bisoprolol may sometimes result in dizziness or fatigue (see 'Possible side-effects'). If you suffer from these side effects, **do not** operate vehicles and/or machines. These side-effects are likely to happen at the start of treatment, or with a change in the amount of bisoprolol you take.

Bisoprolol Viatris contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'

5 mg, 7.5 mg and 10 mg tablets only:
Bisoprolol Viatris tablets contain sunset yellow

Sunset yellow (E110) may cause allergic reactions.

3. How to take Bisoprolol Viatris

Before you start using Bisoprolol Viatris, you should already be taking other medicines for heart failure including an ACE-inhibitor, a diuretic and (as an added option) a cardiac glycoside.

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

Adults

Treatment with bisoprolol must be started at a low dose and increased gradually. Your doctor will decide how to increase the dose, and this will normally be done in the following way:

- 1.25 mg bisoprolol once daily for one week
- 2.5 mg bisoprolol once daily for one week
- 3.75 mg bisoprolol once daily for one week
- 5 mg bisoprolol once daily for four weeks
- 7.5 mg bisoprolol once daily for four weeks
- 10 mg bisoprolol once daily for maintenance (on-going) therapy.

The maximum recommended daily dose is 10 mg bisoprolol.

Depending on how well you tolerate the medicine, your doctor may also decide to lengthen the time between dose increases. If your condition gets worse or you no longer tolerate the drug, it may be necessary to reduce the dose again or to interrupt treatment. In some patients a maintenance dose lower than 10 mg bisoprolol may be sufficient.

Your doctor will tell you what to do.

Patients with liver or kidney problems
Your doctor will take extra care when adjusting the dose of Bisoprolol Viatris.

Use in children and adolescents
The use of Bisoprolol is **not** recommended as there is insufficient experience with the use of this medicine in children and adolescents.

Elderly patients
In general an adjustment of the dose is not needed. It is recommended to start with the lowest possible dose.

If you notice that the Bisoprolol dose is too strong or does not work well enough, please consult your doctor or pharmacist.

Route and/or method of administration
- The tablets should be taken in the morning
- Swallow the tablets with a glass of water.
- The tablets should not be chewed.
- The 2.5 mg, 3.75 mg 5 mg, 7.5 mg and 10 mg tablets can be divided into equal doses. The 1.25 mg tablets should not be broken.

If you take more Bisoprolol Viatris than you should
If you take more Bisoprolol Viatris than you should contact your doctor or casualty department **immediately**. Take the container and any remaining tablets with you.

If you forget to take Bisoprolol Viatris
Do not take a double dose to make up for the forgotten dose. Take the next dose on time. If you miss several doses, contact your doctor.

If you stop taking Bisoprolol Viatris
If you suddenly stop taking Bisoprolol Viatris you are likely to suffer from side effects. Your doctor will reduce your dose slowly over 2 weeks.

If you have any further questions on the use of this medicine, please ask your doctor or pharmacist.

4. Possible side effects

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

The following side effects are important and will require immediate action if you experience them. You should stop taking Bisoprolol Viatris and see your doctor immediately if the following symptoms occur:

Very common side effects (affecting more than 1 in 10 people):
- slow heart beat

Common side effects (affecting fewer than 1 in 10 people):
- worsening of heart failure causing increased breathlessness and / or retention of fluid.

Uncommon side effects (affecting fewer than 1 in 100 people):
- worsening of irregular heart beat
- depression
- breathing problems in patients with asthma or chronic lung disease

Rare side effects (affecting fewer than 1 in 1,000 people):
- 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
- Allergic reactions such as itching, redness and skin rash. Severe allergic reactions may involve face, neck, tongue, mouth or throat swelling, or difficulty breathing.

If you feel dizzy or weak or have breathing difficulties please contact your doctor as soon as possible.

The following side-effects have also been reported:

Common side effects (affecting fewer than 1 in 10 people):
- cold hands and/or feet

- numbness of hands and/or feet
- low blood pressure
- feeling sick, vomiting, diarrhoea, constipation
- tiredness
- headache.

Uncommon side effects (affecting fewer than 1 in 100 people):
- sleep disorder
- dizziness when standing up
- muscle weakness, muscle cramps.

Rare side effects (affecting fewer than 1 in 1,000 people):
- changes in blood test results
- reduced tear flow (can be a problem if you wear contact lenses)
- hearing disorders
- blocked, runny nose
- failure to get and maintain an erection (erectile dysfunction)
- nightmare
- hallucination (imagining things)
- fainting.

Very rare side effects (affecting fewer than 1 in 10,000 people):
- inflammation of the eye (conjunctivitis)
- aggravation of the skin condition psoriasis or the appearance of a similar dry, scaly rash
- hair loss.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bisoprolol Viatris

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 the bottle or blister after EXP. The expiry date refers to the last day of that month.

Blister: Store below 30°C. Bottle: This medicinal product does not require any special storage conditions.

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 Viatris film-coated tablets contain:
Each film-coated tablet contains either 1.25 mg, 2.5 mg, 3.75 mg, 5 mg, 7.5 mg or 10 mg of the active ingredient bisoprolol fumarate.

The other ingredients are:
Tablet: Cellulose microcrystalline, butylhydroxyanisole, colloidal anhydrous silica, magnesium stearate, sodium lauril sulfate, croscarmellose sodium (see section 2 ‘Bisoprolol Viatris contains sodium’), iron oxide yellow (E172) (2.5 mg, 3.75 mg, 5 mg and 7.5mg tablets only), iron oxide red (E172) (10 mg tablets only).

Film coat: Titanium dioxide (E171), talc, hypromellose (E464), quinoline yellow (5 mg and 7.5 mg tablets only), iron oxide yellow (E172) (3.75 mg and 10 mg tablets only) indigo carmine (E132) (5 mg tablet only), sunset yellow (E110) (5 mg, 7.5 mg and 10 mg tablets only) (see section 2 "Bisoprolol Viatris contains sunset yellow").

What Bisoprolol Viatris looks like and contents of the pack

Film-coated tablet

1.25 mg tablet: White, oval, biconvex film-coated tablets; 'BL' & '1' engraved on one face of the tablet; 'M' engraved on the other face of the tablet.

2.5 mg tablet: White to off-white, oval, biconvex film-coated tablets with side notches and debossed with "BL & 2" on either side of scoreline on one side and "M" on the other side.

3.75 mg tablet: Cream, oval, biconvex film-coated tablets with side notches; 'BL' & '3' engraved on either side of the scoreline on one face of the tablet; 'M' engraved on the other face of the tablet.

5 mg tablet: Pale yellow, oval, biconvex film-coated tablets with side notches; 'BL' & '4' engraved on either side of the scoreline on one face of the tablet; 'M' engraved on the other face of the tablet.

7.5 mg tablet: Yellow, oval, biconvex film-coated tablets with side notches; 'BL' & '5' engraved on either side of the scoreline on one face of the tablet; 'M' engraved on the other face of the tablet.

10 mg tablet: Pale orange to light orange, oval, biconvex film-coated tablets with side notches; 'BL' & '6' engraved on either side of the scoreline on one face of the tablet; 'M' engraved on the other face of the tablet.

Bisoprolol Viatris Tablets are packed in blister packs containing 10, 20, 28, 30, 50, 56, 84, 98 and 100 film-coated tablets. Bisoprolol Viatris Tablets are packed in bottles containing 10, 28, 30, 50, 56, 84, 98, 100, 500 and 1000 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Viatris Limited
Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland.

Manufacturers:
McDermott Laboratories Ltd,
t/a Gerard Laboratories
35/36 Baldoyle Industrial Estate,
Grange Road, Dublin 13, Ireland

Generics [UK] Ltd, Station Close,
Potters Bar, Hertfordshire, EN6 1TL,
United Kingdom

Mylan Hungary Kft., H-2900, Komárom,
Mylan útca.1, Hungary

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland)
under the following names:

Country	Product Name
Ireland	Bisoprolol Viatris 1.25 mg, 2.5 mg, 3.75 mg, 5 mg, 7.5 mg, 10 mg film-coated tablets
Spain	Bisoprolol COR Viatris 2.5 mg, 5 mg, 10 mg comprimidos recubiertos con película EFG
Sweden	Bisomyl 1.25 mg, 2.5 mg, 5 mg, 10 mg filmdragerade tabletter
United Kingdom (Northern Ireland)	Bisoprolol fumarate 1.25 mg, 2.5 mg, 3.75 mg, 5 mg, 7.5 mg, 10 mg film-coated tablets

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