

Package leaflet: Information for the user

Bisoprolol 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.

What is in this leaflet:

1. What Bisoprolol is and what it is used for.
2. What you need to know before you take Bisoprolol Tablets.
3. How to take Bisoprolol Tablets.
4. Possible side effects.
5. How to store Bisoprolol Tablets.
6. Contents of the pack and other information.

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

Bisoprolol belongs to a family of medicines called beta-blockers. Beta-blockers protect the heart against too much activity.

Bisoprolol is used to treat:

- high blood pressure (hypertension)
- angina pectoris (chest pain caused by blockages in the arteries that supply the heart muscle).

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

Do not take Bisoprolol Tablets if you:

- are allergic to bisoprolol or any of the other ingredients of this medicine (listed in section 6)
- have severe asthma or severe chronic lung disease
- have a slow or irregular heart rate (less than 60 beats per minute). 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
- are treated for hypersensitivity (allergic) reactions. Bisoprolol may make your allergy worse or more difficult to treat.
- have any heart problems
- have any liver or kidney problems
- have any problems with the circulation in your limbs

- are going to be given a general anaesthetic during an operation – tell your doctor that you are taking bisoprolol
- are taking verapamil or diltiazem, medicines used to treat heart conditions. Concomitant use is not recommended, see also “Other medicines and Bisoprolol”
- 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.

Children and adolescents

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

Other medicines and Bisoprolol Tablets

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 “Warning 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.
- rifampicin for the treatment of infections
- medicines to treat severe headaches or migraines (ergotamine derivatives).

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

Bisoprolol Tablets with food and drink

Bisoprolol Tablets should be taken in the morning and can be taken with food. They should be swallowed with liquid and should not be chewed.

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 medicinal product during pregnancy.

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

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 Tablets contain:

5 mg, and 10 mg tablet:

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.

5 mg tablet only:

Tartrazine (E102) - May cause allergic reactions.

10 mg tablet only:

Sunset Yellow (E110) - May cause allergic reactions.

3. How to take Bisoprolol Tablets

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

Adults

Your doctor will start the treatment with the lowest possible dose (5 mg). Your doctor will monitor you closely at the start of treatment. Your doctor will increase your dose to obtain the best possible dosage for you.

The maximum recommended dose is 20 mg once per day.

Patients with kidney disease

Patients with severe kidney disease should not exceed 10 mg of bisoprolol once daily. Please consult your doctor before starting to use this medicine.

Patients with liver disease

Patients with severe liver disease should not exceed 10 mg of bisoprolol once daily. Please consult your doctor before starting to use this medicine.

Use in children and adolescents

The use of Bisoprolol **is not** recommended as there is insufficient experience with the use of this medicinal product 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

- Swallow the tablets with a glass of water.
- The tablets should not be chewed.
- The tablets can be divided into equal doses.

If you take more Bisoprolol Tablets than you should

If you take more Bisoprolol Tablets 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 Tablets

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 Tablets

If you suddenly stop taking Bisoprolol Tablets 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 tablets and see your doctor immediately if the following symptoms occur:

Uncommon side effects (affecting fewer than 1 in 100 people):

- worsening of heart failure causing increased breathlessness and /or retention of fluid.

Frequency cannot be estimated from available data:

- worsening of symptoms of blockage of the main blood vessels to the legs, especially at the start of treatment.

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*
- dizziness*
- headache*.

Uncommon side effects (affecting fewer than 1 in 100 people)

- slow heart beat
- worsening of irregular heart beat
- sleep disorders
- depression
- breathing problems in patients with asthma or chronic lung disease
- muscle weakness, muscle cramps
- feeling weak.

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
- 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
- hypersensitivity reactions such as itching, redness and skin rash
- reduced sexual performance
- nightmares
- hallucinations

- 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.

* these symptoms are especially occur at the beginning of treatment, or if your dosage changes. They are generally mild and often disappear within 1 to 2 weeks.

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 HPRAs 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 tablets

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. Store in the original packaging in order to protect from moisture.

Bottle: Store below 30°C. Store in the original packaging in order to protect from moisture. Use within 100 days of opening. Once open keep bottle tightly closed. 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 film-coated tablets contain:

Each film-coated tablet contains either 5 mg or 10 mg of the active ingredient bisoprolol fumarate.

The other ingredients are: Tablet: Cellulose microcrystalline, lactose anhydrous, colloidal anhydrous silica, magnesium stearate, sodium lauryl sulfate, croscarmellose sodium, iron oxide yellow (E172) (5 mg tablets only), iron oxide red (E172) (10 mg tablets only). Film coat: Titanium dioxide (E171), polydextrose (E1200), hypromellose (E464), macrogol, iron oxide yellow (E172) (10 mg tablets only), tartrazine (E102) (5 mg tablets only), indigo carmine (E132) (5 mg tablet only), sunset yellow (E110) (10 mg tablet only).

What Bisoprolol Tablets looks like and contents of the pack

Film-coated 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.

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 Tablets are packed in blister packs containing 14, 28, 30, 50, 56, 60, 84, 98, 100 and 500 film-coated tablets. Bisoprolol Tablets are packed in bottles containing 14, 28, 30, 50, 56, 60, 84, 98, 100 and 500 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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

Manufacturers:

McDermott Laboratories Limited 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 medicinal product is authorised in the Member States of the EEA
under the following names:**

Country	Product Name
Bulgaria	Gisogen 5 mg and 10 mg film-coated tablets
Denmark	Bisoprolol Mylan 5 mg and 10 mg filmovertrukte tabletter
Finland	Bisoprolol Mylan 5 mg and 10 mg film-coated tablets
Iceland	Bisoprolol Mylan 5 mg and 10 mg film-coated tablets
Ireland	Bisoprolol 5 mg and 10 mg film-coated tablets
Portugal	Bisoprolol Mylan 5 mg and 10 mg film-coated tablets
Spain	Bisoprolol Mylan Pharmaceuticals 5 mg comprimidos recubiertos EFG and Bisoprolol Mylan Pharmaceuticals 10 mg comprimidos recubiertos EFG
Sweden	Bisoprolol Mylan 5 mg and 10 mg film-coated tablets
United Kingdom	Bisoprolol fumarate 5 mg film-coated tablets and Bisoprolol fumarate 10 mg film-coated tablets

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