

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 fumarate than you should

If you take more Bisoprolol fumarate 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 fumarate

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 fumarate

If you suddenly stop taking Bisoprolol fumarate 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 fumarate 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 if you have chronic heart failure.

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

- worsening of heart failure if you have hypertension or angina pectoris
- 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):

- worsening of irregular heart beat
- 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)
- nightmares
- 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.

* if treated for high blood pressure or angina then these symptoms occur especially 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. 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 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 fumarate 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 lauryl sulfate, croscarmellose sodium, iron oxide yellow (E172) (2.5 mg, 3.75 mg, 5 mg and 7.5 mg 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 fumarate contains sunset yellow").

What Bisoprolol fumarate 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; 'BL' & '2' engraved on either side of the scoreline on one face of the tablet; 'M' engraved on the other face of the tablet.

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 fumarate tablets are packed in blister packs containing 10, 20, 28, 30, 50, 56, 84, 90, 98 and 100 film-coated tablets. Bisoprolol fumarate tablets are packed in bottles containing 10, 28, 30, 50, 56, 84, 98, 100, 500, 1000 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Mylan,
Potters Bar,
Hertfordshire,
EN6 1TL,
United Kingdom.

Manufacturers:

Mylan UK Healthcare Limited
Building 20,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

McDermott Laboratories (trading as
Gerard Laboratories),
35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13,
Ireland.

Generics [UK] Ltd,
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United Kingdom.

Mylan Hungary Kft.,
Mylan útca 1.,
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Artwork Proof No.	1	Aff. Superseded Code	2367206	New Material Code	75084669	Actual A/W Size	Flat - 312 x 448 mm	
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LABEL CONTROL / BUSINESS DEVELOPMENT / REGULATORY / MARKETING				Prepared By	Checked By	Approved By		
Sign Offs	Digital Signature			Packaging Technical Services		Production	Regulatory Affairs	Quality Assurance
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