

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 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 TABLETS

Keep out of sight and reach of children

Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last date of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Bisoprolol tablets contain

The active substance is bisoprolol hemifumarate.

Each Bisoprolol 1.25 mg film-coated tablets contains 1.25 mg of the active substance.

Each Bisoprolol 2.5 mg film-coated tablets contains 2.5 mg of the active substance.

Each Bisoprolol 3.75 mg film-coated tablets contains 3.75 mg of the active substance.

Each Bisoprolol 5 mg film-coated tablets contains 5 mg of the active substance.

Each Bisoprolol 7.5 mg film-coated tablets contains 7.5 mg of the active substance.

Each Bisoprolol 10 mg film-coated tablets contains 10 mg of the active substance.

The other ingredients are:

Tablet core: Microcrystalline cellulose (PH -112), maize starch, crospovidone (type B), colloidal anhydrous silica, magnesium stearate.

Film coating (1.25mg tablets and 2.5mg tablets): Hypromellose, Macrogol 400 and Titanium dioxide (E1 71)

Film coating (3.75mg tablets, 5 mg tablets and 7.5mg tablets): Hypromellose, Macrogol 400, Titanium dioxide (E 171), Ferric oxide yellow E- 172

Film coating (10mg tablets): Hypromellose, Macrogol 400, Titanium dioxide (E171), Ferric oxide yellow E-1 72, Ferric oxide red E-1 72

What Bisoprolol tablets looks like and the contents of the pack

The 1.25 mg tablets are white, round and plain on both sides.

The 2.5 mg tablets are white and heart-shaped with a break-line on both sides.

The 3.75 mg tablets are off-white and heart-shaped with a break-line on both sides.

The 5 mg tablets are white -yellow, heart-shaped with a break-line on both sides.

The 7.5 mg tablets are pale yellow and heart-shaped with a break-line on both sides.

The 10 mg tablets are pale to light orange, heart-shaped with a break-line on both sides.

Each pack contains 20, 28, 30, 50, 56, 60, 90 or 100 tablets.

Not all pack sizes may be marketed.

1.25mg: PL 21880/0127, 2.5mg: PL 21880/0128, 3.75mg: PL 21880/0129, 5mg: PL 21880/0 130, 7.5mg: PL 21880/0 131, 10mg: PL 21880/0 132.

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Marketing Authorisation Holder and Manufacturer:

MEDREICH PLC
Warwick House, Plane Tree Crescent,
Feltham TW13 7HF, UK
E-mail : info@medreich.co.uk

POM

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Bisoprolol 1.25 mg film-coated tablets
Bisoprolol 2.5 mg film-coated tablets
Bisoprolol 3.75 mg film-coated tablets
Bisoprolol 5 mg film-coated tablets
Bisoprolol 7.5 mg film-coated tablets
Bisoprolol 10 mg film-coated tablets

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. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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 IS AND WHAT IT IS USED FOR

Bisoprolol belongs to a group of medicines called beta-blockers. These medicines work by affecting the body's response to some nerve impulses, especially in the heart.

As a result, bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body.

Heart failure occurs when the heart muscle is weak and unable to pump enough blood to supply the body's needs.

Bisoprolol is used to treat stable chronic heart failure. It is used in combination with other medicines suitable for this condition (such as ACE-inhibitors, diuretics, and heart glycosides).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BISOPROLOL TABLETS

Do not take Bisoprolol tablets if you:

- are allergic (hypersensitive) to Bisoprolol or to any of the other ingredients (see section 6 for list of ingredients)
- suffer from severe asthma or severe chronic obstructive lung disease
- suffer from severe blood circulation problems in your limbs (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue
- suffer from untreated pheochromocytoma, which is a rare tumour of the adrenal gland
- suffer from metabolic acidosis, which is a condition when there is too much acid in the blood.
- have one of the following heart problems:
 - acute heart failure
 - worsening heart failure requiring injection of medicines into a vein, that increase the force of contraction of the heart
 - slow heart rate
 - low blood pressure
 - certain heart conditions causing a very slow heart rate or irregular heartbeat
 - cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure.

Take special care and tell your doctor if you:

- suffer from less severe asthma or chronic lung disease
- suffer from diabetes
- are currently, or intend to partake in strict fasting while taking this medicine
- suffer from certain heart diseases such as disturbances in heart rhythm, or severe chest pain at rest (Prinzmetal's angina)
- suffer from kidney or liver problems
- suffer from less severe blood circulation problems in your limbs
- have a history of a scaly skin rash (psoriasis)
- are being treated for tumour of the adrenal gland (pheochromocytoma)
- have thyroid problems
- are going to have desensitization therapy (for example for the prevention of hay fever), because Bisoprolol may make it more likely that you experience an allergic reaction, or such reaction may be more severe
- are going to have anaesthesia (for example for surgery), because Bisoprolol may influence how your body reacts to this situation.

This section is continued overleaf →



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Children and adolescents

Bisoprolol is not recommended for use in children or adolescents

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not take the following medicines with Bisoprolol without special advice from your doctor. However, do not stop taking these medicines without checking with your doctor first:

- medicines used to treat irregular or abnormal heartbeat (called 'Class I antiarrhythmic medicines' such as quinidine, disopyramide, lidocaine, phenytoin; flecainide, propafenone)
- medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (called 'calcium antagonists' such as verapamil and diltiazem)
- medicines used to treat high blood pressure such as donidine, methyldopa, moxonodine, rilmenidine.

Check with your doctor before taking the following medicines with Bisoprolol; your doctor may need to check your condition more frequently:

- medicines used to treat high blood pressure or angina pectoris (called dihydropyridine-type calcium antagonists such as felodipine and amlodipine)
- medicines used to treat irregular or abnormal heartbeat (called Class III antiarrhythmic medicines such as amiodarone)
- Types of beta-blockers are applied locally (such as timolol eye drops for glaucoma treatment)
- medicines used to treat for example Alzheimer's disease or glaucoma (called parasympathomimetics such as tacrine or carbachol) or medicines that are used to treat acute heart problems (called sympathomimetics such as isoprenaline and dobutamine)
- Antidiabetic medicines including insulin
- Anaesthetic agents (for example during surgery)
- Digitalis, used to treat heart failure
- Non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain or inflammation (for example ibuprofen or diclofenac)
- Any medicine, which can lower blood pressure as a desired or undesired effect such as antihypertensives, certain medicines for depression (called tricyclic antidepressants such as imipramine or amitriptyline). certain medicines used to treat epilepsy or during anaesthesia (called barbiturates such as phenobarbital), or certain medicines to treat mental illness characterized by a loss of contact with reality (called phenothiazine such as levomepromazine)
- Mefloquine, used for prevention or treatment of malaria
- Depression treatment medicines called monoamine oxidase inhibitors (except MAO-B inhibitors) such as moclobemide.

Pregnancy and breast-feeding

Pregnancy

There is a risk that use of Bisoprolol during pregnancy may harm the baby. If you are pregnant or planning to become pregnant, tell your doctor. He or she will decide whether you can take Bisoprolol during pregnancy.

Breast-feeding

It is not known whether Bisoprolol passes into human breast milk. Therefore, breastfeeding is not recommended during therapy with Bisoprolol.

Driving and using machines

Your ability to drive or use machinery may be affected depending on how well you tolerate the medicine. Be especially cautious at the start of treatment, when the dose is increased or the medication is changed, as well as in combination with alcohol.

3. HOW TO TAKE BISOPROLOL TABLETS

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

Treatment with this medicine requires regular monitoring by your doctor. This is particularly necessary at the start of treatment and during dose increase and when you stop treatment. Take the tablet with some water in the morning, with or without food. Do not crush or chew the tablet.

The break line tablets can be divided into two equal doses.

Treatment with bisoprolol is usually long-term.

Dosage in adults including the elderly:

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 (half of a 2.5mg tablets) once daily for the first week of treatment
- 2.5 mg Bisoprolol (one 2.5mg tablets) once daily for the second week of treatment
- 3.75 mg Bisoprolol (one and half 2.5mg tablets) once daily for the third week of treatment
- 5 mg Bisoprolol (two 2.5mg or one 5mg tablet) once daily for the fourth, fifth, sixth and seventh weeks of treatment
- 7.5 mg Bisoprolol (three 2.5mg tablets) once daily for the eighth, ninth, tenth and eleventh week of treatment
- 10 mg Bisoprolol (one 10mg tablet) once daily from the twelfth week 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 10mg bisoprolol may be sufficient.

Your doctor will tell you what to do.

If you have to stop treatment entirely, your doctor will usually advise you to reduce the dose gradually, as otherwise your condition may become worse.

If you take more Bisoprolol than you should

If you have taken more tablets than you should, tell your doctor immediately. Your doctor will decide what measures are necessary.

Symptoms of an overdose may include slowed heart rate, dizziness, low blood pressure, severe difficulty in breathing, worsening of heart failure, or trembling (due to decreased blood sugar).

If you forget to take a tablet

Do not take a double dose to make up for a forgotten dose. Take your usual dose the next morning.

If you stop taking Bisoprolol

Never stop taking Bisoprolol unless told to by your doctor. Otherwise your condition could become much worse.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Bisoprolol tablets can cause side effects, although not everybody gets them. Speak to a doctor immediately if a side effect is severe, occurred suddenly or gets worse rapidly.

Serious Side Effects

The most serious side effects are related to the heart function:

- slowing of heart rate (may affect more than 1 in 10 people)
- worsening of heart failure (may affect up to 1 in 10 people)
- slow or irregular heartbeat (may affect up to 1 in 100 people)

If you feel dizzy or weak, or have breathing difficulties contact your doctor, pharmacist or nearest hospital as soon as possible.

Other side effects include:

Common (affects between 1 in 10 and 1 in 100 patients)

- dizziness
- headache
- stomach or intestine problems such as nausea, vomiting, diarrhoea or constipation
- feeling of coldness in the hands or feet
- low blood pressure
- weakness or tiredness

Uncommon (affects between 1 in 100 and 1 in 1,000 patients)

- breathing problems in patients with asthma or a chronic lung disease
- muscular weakness and cramps
- dizziness when standing up
- sleep disturbances
- depression

Rare (affects between 1 in 1,000 and 1 in 10,000 patients)

- certain blood test results for liver function or fat levels differing from normal
- fainting
- reduced tear flow
- hearing problems
- allergic runny nose
- allergic reactions such as itching, redness, flush and rash
- inflammation of the liver which can cause yellowing of the skin or whites of the eyes
- impaired erection
- nightmares
- hallucinations

Very rare (affects less than 1 in 10,000 patients)

- irritation and redness of the eye (conjunctivitis)
- hair loss
- appearance or worsening of scaly skin rash (psoriasis or psoriasis-like rash).

Tell your doctor or your pharmacist if any of the side effects get serious or if you notice any other unwanted or unexpected effects.

You should see a doctor straight away if you experience more severe allergic reactions, which may involve face, neck, tongue, mouth or throat swelling, or difficulty breathing.

This section is continued overleaf →