

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

Bisoprolol hemifumarate

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your 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.

In this leaflet:

1. What Bisoprolol Merck is and what it is used for
2. Before you take Bisoprolol Merck
3. How to take Bisoprolol Merck
4. Possible side effects
5. How to store Bisoprolol Merck
6. Further information

1. WHAT BISOPROLOL MERCK IS AND WHAT IT IS USED FOR

The active substance in Bisoprolol Merck is bisoprolol. 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 Merck 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. BEFORE YOU TAKE BISOPROLOL MERCK

Do not take Bisoprolol Merck

Do not take Bisoprolol Merck if one of the following conditions applies to you:

- allergy (hypersensitivity) to bisoprolol or to any of the other ingredients (see section 6 'What Bisoprolol Merck contains')
- severe asthma or severe chronic lung disease
- 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
- untreated phaeochromocytoma, which is a rare tumour of the adrenal gland
- metabolic acidosis, which is a condition when there is too much acid in the blood.

Do not take Bisoprolol Merck if you 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 with Bisoprolol Merck

If you have any of the following conditions tell your doctor before taking Bisoprolol Merck; he or she may want to take special care (for example give additional treatment or perform more frequent checks):

- diabetes
- strict fasting
- certain heart diseases such as disturbances in heart rhythm, or severe chest pain at rest (Prinzmetal's angina)
- kidney or liver problems
- less severe blood circulation problems in your limbs
- less severe asthma or chronic lung disease
- history of a scaly skin rash (psoriasis)
- tumour of the adrenal gland (phaeochromocytoma)
- thyroid disorder.

In addition, tell your doctor if you are going to have:

- desensitization therapy (for example for the prevention of hay fever), because Bisoprolol Merck may make it more likely that you experience an allergic reaction, or such reaction may be more severe
- anaesthesia (for example for surgery), because Bisoprolol Merck may influence how your body reacts to this situation.

Taking other medicines

Please 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 Merck without special advice from your doctor:

- Certain medicines used to treat irregular or abnormal heartbeat (Class I antiarrhythmic medicines such as quinidine, disopyramide, lidocaine, phenytoin; flecainide, propafenone)
- Certain medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (calcium antagonists such as verapamil and diltiazem)
- Certain medicines used to treat high blood pressure such as clonidine, methyldopa, moxonidine, rilmenidine. However, **do not stop taking these medicines** without checking with your doctor first.

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

- Certain medicines used to treat high blood pressure or angina pectoris (dihydropyridine-type calcium antagonists such as felodipine and amlodipine)
- Certain medicines used to treat irregular or abnormal heartbeat (Class III antiarrhythmic medicines such as amiodarone)
- Beta-blockers applied locally (such as timolol eye drops for glaucoma treatment)

- Certain medicines used to treat for example Alzheimer's disease or glaucoma (parasympathomimetics such as tacrine or carbachol) or medicines that are used to treat acute heart problems (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 (tricyclic antidepressants such as imipramine or amitriptyline), certain medicines used to treat epilepsy or during anaesthesia (barbiturates such as phenobarbital), or certain medicines to treat mental illness characterized by a loss of contact with reality (phenothiazines 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

There is a risk that use of Bisoprolol Merck 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 Merck during pregnancy.

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

Driving and using machines

Your ability to drive or use machinery may be affected depending on how well you tolerate the medicine. Please 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 MERCK

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

Treatment with Bisoprolol Merck requires regular monitoring by your doctor. This is particularly necessary at the start of treatment and during dose increase.

Take the tablet with some water in the morning, with or without food. Do not crush or chew the tablet.

Treatment with Bisoprolol Merck is usually long-term.

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 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.

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.

Children

Bisoprolol Merck is not recommended for use in children.

If you take more Bisoprolol Merck than you should

If you have taken more Bisoprolol Merck 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, severe difficulty in breathing feeling dizzy, or trembling (due to decreased blood sugar).

If you forget to take Bisoprolol Merck

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 Merck

Never stop taking Bisoprolol Merck unless on your doctor's advice. 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 Merck can cause side effects, although not everybody gets them.

To prevent serious reactions, speak to a doctor immediately if a side effect is severe, occurred suddenly or gets worse rapidly.

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

- slowing of heart rate (affects more than 1 person in 10)
- worsening of heart failure (affects less than 1 person in 10)
- slow or irregular heartbeat (affects less than 1 person in 100)

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

Further side effects are listed below according to how frequently they may occur:

Common (affects less than 1 person in 10):

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

Uncommon (affects less than 1 person in 100):

- sleep disturbances
- depression
- dizziness when standing up
- breathing problems in patients with asthma or chronic lung disease
- muscle weakness, muscle cramps.

Rare (affects less than 1 person in 1,000):

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

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

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

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

5. HOW TO STORE BISOPROLOL MERCK

- Keep out of the reach and sight of children
- Do not use Bisoprolol Merck 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.

Bisoprolol Merck 1.25 mg film-coated tablets:

Bisoprolol Merck 2.5 mg film-coated tablets:

Bisoprolol Merck 3.75 mg film-coated tablets:

- Do not store above 25°C.

Bisoprolol Merck 5 mg film-coated tablets:

Bisoprolol Merck 7.5 mg film-coated tablets:

Bisoprolol Merck 10 mg film-coated tablets:

- Do not store above 30°C.

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 Merck contains

Bisoprolol Merck 1.25 mg film-coated tablets

- The active substance is bisoprolol hemifumarate. Each film-coated tablet contains 1.25 mg.
- The other ingredients are:

Tablet core: Silica, colloidal anhydrous; magnesium stearate; crospovidone; pregelatinised maize starch; maize starch; microcrystalline cellulose; calcium hydrogen phosphate (anhydrous).

Film coating:; dimethicone; talc; macrogol 400; titanium dioxide (E171); hypromellose.

Bisoprolol Merck 2.5 mg film-coated tablets

- The active substance is bisoprolol hemifumarate. Each film-coated tablet contains 2.5 mg.
- The other ingredients are:

Tablet core: Silica, colloidal anhydrous; magnesium stearate; crospovidone; maize starch; microcrystalline cellulose; calcium hydrogen phosphate (anhydrous).

Film coating:; dimethicone; macrogol 400; titanium dioxide (E171); hypromellose.

Bisoprolol Merck 3.75 mg film-coated tablets

- The active substance is bisoprolol hemifumarate. Each film-coated tablet contains 3.75 mg.
- The other ingredients are:
Tablet core: Silica, colloidal anhydrous; magnesium stearate; crospovidone; maize starch; microcrystalline cellulose; calcium hydrogen phosphate (anhydrous).
Film coating:; Iron oxide yellow (E172); dimethicone; macrogol 400; titanium dioxide (E171); hypromellose.

Bisoprolol Merck 5 mg film-coated tablets

- The active substance is bisoprolol hemifumarate. Each film-coated tablet contains 5 mg.
- The other ingredients are:
Tablet core: Silica, colloidal anhydrous; magnesium stearate; crospovidone; maize starch; microcrystalline cellulose; calcium hydrogen phosphate (anhydrous).
Film coating:; Iron oxide yellow (E172); dimethicone; macrogol 400; titanium dioxide (E171); hypromellose.

Bisoprolol Merck 7.5 mg film-coated tablets

- The active substance is bisoprolol hemifumarate. Each film-coated tablet contains 7.5 mg.
- The other ingredients are:
Tablet core: Silica, colloidal anhydrous; magnesium stearate; crospovidone; maize starch; microcrystalline cellulose; calcium hydrogen phosphate (anhydrous).
Film coating:; Iron oxide yellow (E172); dimethicone; macrogol 400; titanium dioxide (E171); hypromellose.

Bisoprolol Merck 10 mg film-coated tablets

- The active substance is bisoprolol hemifumarate. Each film-coated tablet contains 10 mg.
- The other ingredients are:
Tablet core: Silica, colloidal anhydrous; magnesium stearate; crospovidone; maize starch; microcrystalline cellulose; calcium hydrogen phosphate (anhydrous).
Film coating:; Iron oxide red (E172); Iron oxide yellow (E172); dimethicone; macrogol 400; titanium dioxide (E171); hypromellose.

What Bisoprolol Merck looks like and contents of the pack

Bisoprolol Merck 1.25 mg film-coated tablets are white and round.

Bisoprolol Merck 2.5 mg film-coated tablets are white and heart-shaped with a break-line on both sides.

Bisoprolol Merck 3.75 mg film-coated tablets are off-white and heart-shaped with a break-line on both sides.

Bisoprolol Merck 5 mg film-coated tablets are yellowish-white and heart-shaped with a break-line on both sides.

Bisoprolol Merck 7.5 mg film-coated tablets are pale yellow and heart-shaped with a break-line on both sides.

Bisoprolol Merck 10 mg film-coated tablets are pale orange – light orange and 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.

Marketing Authorisation Holder and Manufacturer

Merck KGaA, Frankfurter Strasse 250, 64293 Darmstadt, Germany

[To be completed nationally]

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

France: Bisoprolol Lipha
Ireland: Gercor

Sweden:

Bisoprolol Merck

This leaflet was last approved in 24 October 2008.