

BISOHEXAL FILM-COATED TABLET

Bisoprolol fumarate (2.5mg, 5mg)

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What BisoHEXAL is used for

BisoHEXAL is used to treat:

- high blood pressure.
- chest pain caused by blockages in the arteries that supply the heart muscle (angina pectoris).
- chronic stable heart failure (usually used in combination with other medicines).

Ask your doctor if you have any questions about why this medicine was prescribed for you. Your doctor may have prescribed it for another reason.

How BisoHEXAL works

The active substance in BisoHEXAL is bisoprolol fumarate. It belongs to a group of medicines called beta-blockers. It works by affecting the body's response to some nerve impulses, especially in the heart. As a result, it 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. BisoHEXAL can help to reduce the number of heart failure episodes needing hospital admission and also the risk of sudden death. It is used in combination with other medicines suitable for this condition (such as ACE-inhibitors, diuretics, and heart glycosides).

Before you use BisoHEXAL

- When you must not use it

Do not take this medicine if you:

- are allergy (hypersensitivity) to bisoprolol fumarate or any ingredients in this medication.
- have severe asthma or severe chronic obstructive lung disease.

- have 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.
- have untreated phaeochromocytoma, a rare tumour of the adrenal gland.
- have metabolic acidosis, a condition when there is too much acid in the blood.

Do not take BisoHEXAL 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.

If you are not sure whether you should start taking this product, consult your doctor.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

If you have or have had any of the following conditions, tell your doctor before taking BisoHEXAL; your doctor 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.
- chronic lung disease or less severe asthma.
- 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 BisoHEXAL may make it more likely that

you experience an allergic reaction, or such reaction may be more severe.

- anaesthesia (for example for surgery), because BisoHEXAL may influence how your body reacts to this situation.

If you 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 BisoHEXAL.

- 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 BisoHEXAL without special advice from your doctor:

- Certain medicines used to treat irregular or abnormal heartbeat (Class I antiarrhythmic medicines such as quinidine, disopyramide, lidocaine, flecainide, phenytoin, 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, methyl dopa, 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 BisoHEXAL; 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 lactation

There is a risk that use of BisohEXAL 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 BisohEXAL during pregnancy.

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

How to use BisohEXAL

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

Treatment with BisohEXAL requires regular monitoring by your doctor. This is particularly necessary at the start of treatment, during dose increase and when you stop treatment.

- How much to use

Treatment of hypertension or angina pectoris:

The usual dosage is 2 tablets of BisohEXAL 2.5 mg or 1 tablet of BisohEXAL 5 mg (equivalent to 5 mg bisoprolol fumarate) once daily.

If necessary, the dose may be increased to 4 tablets of BisohEXAL 2.5 mg or 2 tablets of

BisohEXAL 5 mg (equivalent to 10 mg bisoprolol fumarate) once daily.

The maximum recommended dose is 20 mg once per day.

Treatment of stable chronic heart failure:

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

The maximum recommended dose is 10 mg once daily.

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 fumarate may be sufficient. Your doctor will tell you what to do.

Elderly: No dose adjustment is required.

Children: BisohEXAL is not recommended for use in children.

- When to use it

Use as directed by your doctor or pharmacist. Swallow the tablets with a glass of water in the morning, with or without food. Do not crush or chew the tablet.

If you need to break the tablet, place the tablet on a hard flat surface with the scored side at the top. Press with your thumb in the middle of the tablet to break into halves or quarters.

- How long to use it

Treatment with BisohEXAL is usually long-term. Never stop taking BisohEXAL unless on your doctor's advice. Otherwise your condition could become much worse.

If you have to stop treatment, your doctor will usually advise you to reduce the dose gradually.

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

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Take the medicine pack with you. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include slowed heart rate, severe difficulty in breathing, feeling dizzy, or trembling (due to decreased blood sugar).

While you are using it

- Things you must do

- Always follow the instructions given to you by your doctor or pharmacist.
- Inform all doctors, dentists and pharmacists who are treating you that you are taking BisohEXAL.
- If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking BisohEXAL.
- If you become pregnant while taking BisohEXAL, tell your doctor immediately.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.
- If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

- Visit your doctor regularly so they can check on your progress. Your doctor may check your eyes, thyroid, lipid and blood glucose levels.

- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Your doctor may think it is not working effectively and change your treatment unnecessarily.

- Things you must not do

- Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

- Do not give this medicine to anyone else, even if they have the same condition as you.

- Do not stop taking BisoHEXAL or change the dosage, without checking with your doctor.

- Things to be careful of

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.

Side effects

Like all medicines, BisoHEXAL 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
- worsening of heart failure
- slow or irregular heartbeat

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

- 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

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

Rare

- 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

- 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of BisoHEXAL

Storage

Store in a cool dry place, below 30°C.

Protect from light.

Keep out of reach of children.

- Disposal

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.

Product Description

- What it looks like

BisoHEXAL 2.5mg Film-coated Tablet:

White coloured, round, snap tab film-coated tablets, divisible into two parts with a one-sided embossment “BIS2.5”.

BisoHEXAL 5mg Film-coated Tablet:

Yellow coloured, round, snap tab film-coated tablets, divisible into four parts with a one-sided embossment “BIS5”.

- Ingredients

- Active ingredient
Bisoprolol fumarate

- Inactive ingredients

Microcrystalline cellulose, calcium hydrogen phosphate, pregelatinised maize starch, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate, Opadry white (film-coating).

BisoHEXAL 5mg Film-coated Tablet also contains Yellow ferric oxide (E172).

- Packing

BisoHEXAL 2.5mg Film-coated Tablet:

Blister pack of 10 tablets packed in 30, 50 and 100 tablets per box.

Blister pack of 25 tablets packed in 100 tablets per box.

BisoHEXAL 5mg Film-coated Tablet:

Blister pack of 10 tablets packed in 30, 50 and 100 tablets per box.

Blister pack of 25 tablets packed in 100 tablets per box.

- MAL Number

BisoHEXAL 2.5mg Film-coated Tablet:

MAL09122028AZ

BisoHEXAL 5mg Film-coated Tablet:

MAL09111737AZ

Manufactured by

LEK S.A.

16 Podlipie Str.,

95-010 Stryków, Poland.

For

Hexal AG

Industriestraße 25,

83607 Holzkirchen, Germany.

Product Registration Holder

IMEKS Pharma Sdn. Bhd.

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