Package leaflet: Information for the patient

Bisor 5 mg tablets
Bisor 10 mg 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 your 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. See section 4.

What is in this leaflet

1. What Bisor is and what it is used for

The active substance in Bisor 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. At the same time, the need for oxygen and blood supply to the myocardium decreases.
Bisor is used to treat high blood pressure and angina pectoris.

2. What you need to know before you take Bisor

Do not take Bisor

Do not take Bisor if one of the following conditions applies to you:
- allergy (hypersensitivity) to bisoprolol or to any of the other ingredients (see section 6);
- severe asthma;
- 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 Bisor 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;
- cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure;
- certain heart conditions causing a very slow heart rate or irregular heartbeat (second or third degree AV-block, sinoatrial block, sick sinus syndrome node);
- low blood pressure;

- slow heart rate.

Warnings and precautions
If you have any of the following conditions tell your doctor before taking Bisor; he or she may want to take special care (for example give additional treatment or perform more frequent checks):
- diabetes;
- strict fasting;
- long-term desensitizing therapy (eg to prevent hay fever);
- certain heart diseases (such as disturbances in heart rhythm, or Prinzmetal's angina);
- 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 Bisor may make it more likely that you experience an allergic reaction, or such reaction may be more severe;
- anaesthesia (for example for surgery), because Bisor may influence how your body reacts to this situation.

Children and adolescents
Bisor is not recommended for use in children or adolescents.

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

Do not take the following medicines with Bisor without special advice from your doctor:

Some calcium antagonists used to treat high blood pressure, angina pectoris or an irregular heartbeat, such as verapamil and diltiazem.

Certain medicines used to treat high blood pressure such as clonidine, methyldopa, moxonodine, rilmenidine. However, do not stop taking these medicines without checking with your doctor first.

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

Some calcium antagonists of the dihydropyridine type, such as felodipine and amlodipine, which are used to treat high blood pressure and angina pectoris.

Class I antiarrhythmic medicines (such as quinidine, disopyramide, lidocaine, phenytoin, flecainide, propafenone). These medicines are used to treat irregular or abnormal heartbeat.

Class III antiarrhythmic medicines (such as amiodarone). These medicines are used to treat irregular or abnormal heartbeat.

Beta-blockers applied locally (such as timolol eye drops for glaucoma treatment).

Medicines for the nervous system that are used to stimulate the internal organs or to treat glaucoma (parasymptomimetics) or are used in critical situations to treat severe circulatory diseases (sympathomimetics).

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).

Epinephrine, a medicine used to treat acute life-threatening allergic reactions and heart failure.

Any medicine, which can lower blood pressure as a desired or undesired effect (such as antihypertensives, tricyclic antidepressants, barbiturates, phenothiazines).

Mefloquine, used for prevention or treatment of malaria.

Bisor with food, drink and alcohol
Bisor tablets can be taken with or without food and should be swallowed whole with water.
You should not drink alcohol while taking Bisor.

Pregnancy, breast-feeding and fertility

Pregnancy
If you are pregnant or planning to become pregnant, tell your doctor. He or she will decide whether you can take Bisor during pregnancy.

Breast-feeding
It is not known whether bisoprolol passes into human breast milk. Therefore, breastfeeding is not recommended during therapy with Bisor.

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.

Important information about some of the ingredients of Bisor tablets
Bisor tablets contain 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.

3. How to take Bisor

Treatment with bisoprolol must be started at a low dose and increased gradually. In all cases, the dose should be adjusted individually, especially according to heart rate and therapeutic success.

Dosage
For both indications, the recommended dose is one tablet Bisor 5 mg or half a tablet Bisor 10 mg (equivalent to 5 mg bisoprolol) once daily.
If necessary, the dose can be increased to one tablet Bisor 10 mg or two tablets Bisorp 5 mg (equivalent to 10 mg bisoprolol) once daily.

The maximum recommended daily dose is 20 mg once daily.

Duration of therapy
Treatment with Bisor is usually long-term.

Dosage in renal and/or hepatic impairment
No dose adjustment is generally required in patients with mild to moderate renal or hepatic impairment. The daily dose of 10 mg bisoprolol should not be exceeded in patients with severe renal impairment (creatinine clearance < 20ml/min) and in patients with severe hepatic impairment.

Dosage in elderly patients
No dose adjustment is required in these patients.

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

If you take more Bisor than you should
If you have taken more Bisor tablets than you should, tell your doctor immediately. Your doctor will decide what measures are necessary.
Symptoms of an overdose with Bisor may include slowed heart rate (bradycardia), severe difficulty in breathing (bronchospasm), significant lowering of blood pressure, acute heart failure or lowering of blood sugar.

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

If you stop taking Bisor
Never stop taking Bisor, unless on your doctor's advice. Otherwise your condition could become much worse. In particular, in patients with ischemic heart disease, treatment should not be stopped abruptly. If you need to stop treatment, your doctor will recommend a gradual dose reduction.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequency of possible adverse reactions listed below was defined using the following conditional classification:
- *very common:* may affect more than 1 to 10 patients;
- *common:* may affect up to 1 to 10 patients;
- *uncommon:* may affect up to 1 to 100 patients;
- *rare:* may affect up to 1 to 1000 patients;
- *very rare:* may affect up to 1 to 10 000 patients;
- *not known:* the frequency cannot be estimated from the available data.

Common
- tiredness, dizziness, headache: these symptoms occur mainly at the beginning of treatment. They are mild and usually disappear within 1-2 weeks after starting treatment;
- feeling of coldness or numbness in hands or feet;
- low blood pressure;
- stomach or intestine problems such as nausea, vomiting, diarrhoea, or constipation;

Uncommon
- slowing of the heart rate (bradycardia);
- worsening of heart failure;
- feeling weak;
- sleep disturbances;
- depression;
- heart rate disorders;
- breathing problems in patients with asthma or chronic lung disease;
- muscle weakness, muscle cramps.

Rare

- increase in blood fats;
- reduced tear flow;
- hearing problems;
- allergic runny nose;
- increased levels of some liver enzymes (ALAT, ASAT), inflammation of the liver (hepatitis);
- skin reactions similar to allergies, such as itching, redness, rash;
- impaired erection;
- nightmares, hallucinations;
- fainting.

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

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.

Reporting 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 national reporting system of Bulgarian Drug Agency. By reporting side effects you can help provide more information on the safety of this medicine.

Contacts:
Bulgarian Drug Agency
8 Damyan Gruev Str.,
1303 Sofia
Tel.: +35 928903417
website: www.bda.bg

5. How to store Bisor

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated in the carton after EXP. The expiry date refers to the last date of that month.
Do not store above 30°C.
Do not take Bisor tablets if you notice that the tablets have lost their color or show other signs of damage, and talk to your pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bisor contains
- The active substance – bisoprolol fumarate.

Bisor 5 mg: each tablet 5 mg bisoprolol fumarate.
The other ingredients – lactose monohydrate, microcrystalline cellulose [E460], magnesium stearate [E572] and crospovidone [E1202].
Each tablet of 5 mg also contains a yellow colorant (which contains lactose and yellow iron oxide [E172]).

Bisor 10 mg: each tablet 10 mg bisoprolol fumarate.
The other ingredients – lactose monohydrate, microcrystalline cellulose [E460], magnesium stearate [E572] and crospovidone [E1202].

Each tablet of 10 mg also contains beige coloring (which contains lactose and iron oxide - red and yellow [E172]).

What Bisor looks like and content of the pack

Bisor 5 mg tablets
The 5 mg tablets are pale yellow with a mosaic structure, round and biconvex, with a score line.
The tablets can be divided into two equal doses.
The tablets are packed in aluminum (PVC / PVDC) blisters placed in a carton box.

Bisor 10 mg tablets
10 mg tablets are beige with a mosaic structure, round and biconvex, with a score line.
The tablets can be divided into two equal doses.
The tablets are packed in aluminum (PVC / PVDC) blisters placed in a carton box.

Each pack contains 30 tablets.

Marketing Authorisation Holder and Manufacturer
Tchaikapharma High Quality Medicines Inc.
1 G. M. Dimitrov Blvd, Sofia 1172, Bulgaria
Tel. : + 359 2 962 54 54
FAX: + 359 2 9603 703
e-mail: info@tchaikapharma.com

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