Package leaflet: Information for patient

ZADA PHARMACEUTICALS

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 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.

BLOCOR film coated tablets 5 mg
BLOCOR film coated tablets 10 mg
Bisoprolole

In this leaflet:

1. What BLOCOR is and what it is used for
The active substance in this medicine is Bisoprolol fumarate. Bisoprolol fumarate belongs to group of medicines called beta-blockers.
Beta-blocker protects heart from too much activity. This medicine works by affecting the body's response to some nerve impulses, especially in the heart. As a result, **BLOCOR** 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 need.

Bisoprolol 5 mg and 10 mg tablet are also used to treat high blood pressure (Hypertension) and angina pectoris (Chest pain caused by blockages in the arteries that supply the heart muscle).

2. Before you take BLOCOR
DO NOT take BLOCOR if you:
You are allergic to **BLOCOR** or any of the other ingredients of this medicine (listed in section 6).
- You have severe asthma or sever chronic lung disease.
- You have severe blood circulation problem in limbs (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue.
- You have untreated phaeochromocytoma, which is a rare tumour of the adrenal gland (medulla).
- You have metabolic acidosis, which is a condition when there is too much acid in the blood.
- acute heart failure or heart failure that suddenly becomes worse and/or that may require hospital treatment
- slow heart rate
- Very low blood pressure
- Certain heart condition 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.

Tell your doctor if you are not sure about any of the above.

Take Special Care with BLOCOR
Talk to your doctor or pharmacist before taking this medicine. He or she may want to take special care (for example give additional treatment or perform more frequent checks) if you have any of the following conditions:
- diabetes
- strict fasting (fasting from solid food)
- certain heart disease such as disturbance in heart rhythm or severe chest pain at rest (Prinzmetal's angina)
- kidney or liver disease
- less severe blood circulation problem in your limbs
- less severe asthma or chronic lung disease
- history of a scaly skin rash (psoriasis)
- tumour of the adrenal gland (medulla) (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 fumarate may make it more likely that you experience as allergic reaction or such reaction may be more severe.
- Anesthesia (for example for surgery) because this medicine may influence how your body react to this situation.

If any of these apply to you, talk to your doctor.

Other medicines and BLOCOR
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.
It is particularly important to mention your doctor any of the following drugs as their action may be affected:
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 Bisoprolol fumarate tablets without special advice from your doctor:
- medicines for controlling the blood pressure or medicines for heart problems (such as amiodarone, amlodipine, clonidine, digitalis glycosides, diltiazem, disopyramide, felodipine, flecainide, lidocaine, methyldopa, moxonidine, phenytoin, propafenone, quinidine, rilmenidine, verapamil)
- medicines for depression e.g. imipramine, amitriptyline, moclobemide
- medicines to treat mental illness e.g. phenothiazines such as levomepromazine
- medicines used for anaesthesia during an operation (see also "Take special care with Bisoprolol Tablets")
- medicines used to treat epilepsy e.g. barbiturates such as phenobarbital
- certain pain killers (for instance acetyl salicylic acid, diclofenac, indomethacin, ibuprofen, naproxen)
- medicines for asthma or medicines used for a blocked nose
- medicines used for certain eye disorders such as glaucoma (increased pressure in the eye) or used to widen the pupil of the eye
- certain medicines to treat clinical shock (e. g. adrenaline, dobutamine, noradrenaline)
- mefloquine, a medicine for malaria
- all these drugs as well as bisoprolol may influence the blood pressure and/or heart function.
- rifampicin for the treatment of infections
- medicines to treat severe headaches or migraines (ergotamine derivatives).

Blocor and alcohol
The dizziness and light-headedness that may be caused by Blocor can be made worse if you drink alcohol. If this happens to you, you should avoid drinking alcohol.

Pregnancy and breastfeeding
Ask your doctor or pharmacist for advice before taking any medicinal product.
If you are pregnant or breastfeeding, if you are or might become pregnant, ask your doctor for advice before you take this medicine.
BLOCOR may be harmful to the pregnancy and/or the unborn child. There is an increased possibility of premature birth, miscarriage, low blood sugar level and reduced heart rate of the child. The growth of the baby may also be affected. Therefore, **BLOCOR** should not be taken during pregnancy.

It is not known if bisoprolol fumarate is excreted in the breast milk and therefore it is not recommended while breastfeeding.

Driving and using machines
These tablets may make you feel tired, drowsy or dizzy. If you suffer from these side effects, do not operate vehicles and/or machines.
Be aware of the possibility of these effects particularly at the beginning of the treatment, with changes in medication and with use in combination with alcohol.

3. How to take BLOCOR
Always take **BLOCOR** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
The tablets should be swallowed whole with water.
Your doctor will tell you your correct dosage. You should take **BLOCOR** in the morning, before, with or after breakfast. Swallow the tablet/s with some water and do not chew or crush them.
Chest pain and high blood pressure:
Adults
Your doctor will start the treatment with lowest possible dose (5 mg). Your doctor will monitor you closely at the start of treatment. Your doctor will increase your dose to obtain the best possible dosage for you. The maximum recommended dose is 20 mg once per day.
Patients with severe liver or kidney disease
Patients with severe liver kidney or disease should not exceed 10mg of bisoprolol fumarate once daily.
Elderly
In general adjustment of the dose is not needed. It is recommended to start with lowest possible dose.

Heart failure

Before you start using **BLOCOR** you should already be taking other medicines for heart failure including an ACE-inhibitor, a diuretic and (as an added option) a cardiac glycoside. The dose of Bisoprolol Fumarate will be increased gradually until the dose that is suitable for you has been found:

•1.25 mg once daily for 1 week. If this is well tolerated, the dose may be increased to:
•2.5 mg once daily during the next week. If this is well tolerated, the dose may be increased to:
•3.75 mg once daily during the next week. If this is well tolerated, the dose may be increased to:
•5 mg once daily during the next 4 weeks. If this is well tolerated. the dose may be increased to:
•7.5 mg once daily during the next 4 weeks. If this is well tolerated, the dose may be increased to:
•10 mg once daily as a maintenance dose.

Maximum dose: once daily 10 mg.
The doctor will determine the most suitable dose for you based on your tolerance to bisoprolol and side effects.
Your heart rate and blood pressure will be monitored closely as the dose is increased.
Patients with liver or kidney problems:
Your doctor will take extra care when adjusting the dose of **BLOCOR**.
Elderly
In general adjustment of the dose is not needed.
If you notice that the effect of **BLOCOR** is too strong or not strong enough, please consult your doctor or pharmacist.

Duration of the treatment
Bisoprolol Fumarate will usually be used long-term.

Children and adolescents
There is no experience with the use of **BLOCOR** in children and adolescents, therefore **BLOCOR** is not recommended for use in children.

If you take more BLOCOR than you should
If you have accidentally taken more than the prescribed dose, tell your doctor/pharmacist immediately. Take any remaining tablets or this leaflet with you so the medical staff know exactly what you have taken.
Symptoms of overdose may include dizziness, light-headedness, fatigue, breathlessness and/or wheezing. Also, there may be reduced heart rate, reduced blood pressure, insufficient action of the heart and a low blood glucose level (which may involve feelings of hunger, sweating and palpitations).

If you forget to take BLOCOR
Do not take a double dose to make up for a forgotten dose. Take the normal dose as soon as you remember and then carry on with the usual dose the next day.

If you stop taking BLOCOR
Treatment with **BLOCOR** must not be stopped abruptly. If you suddenly stop taking this medicine your condition may get worse. The dose of bisoprolol must be reduced gradually over a few weeks as advised by your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
To prevent serious reaction, speak to a doctor immediately if a side effect is severe, occurs suddenly or gets worse rapidly. The most serious side effects are related to the heart function:
- Slowing of heart rate (may affect up to 1 in 10 people with chronic heart failure and may affect up to 1 in 100 people with hypertension or angina pectoris)
- Worsening of heart failure (may affect up to 1 in 10 people with chronic heart failure and may affect up to 1 in 100 people with hypertension or angina pectoris)
- Slow or irregular heartbeat (may affect more than 1 in 10 people with chronic heart failure)
- Worsening of symptom of blockage of the main blood vessel to the legs, especially at the start of treatment (Frequency not stated).
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 (may affect up to 1 in 10 people):
- Tiredness*, feeling weak (In patient with chronic heart failure), dizziness*, headache*
- Feeling of coldness or numbness in hands or feet
- Low blood pressure, especially in patient with heart failure.
- Stomach or intestine problem such as nausea, vomiting, diarrhea or constipation.
Uncommon (may affect up to 1 in 100 people):
- Sleep disturbances
- Depression
- Breathing problems in patients with asthma or chronic lung disease
- Muscle weakness, muscle cramps.
- feeling weak (In patient with hypertension or angina pectoris)
Rare (may affect up to 1 in 1,000 people):
- Hearing problems
- Allergic runny nose (Blocked or runny nose
- Reduced tear flow (can be a problem if you wear contact lenses)
- Inflammation of liver which may cause yellowing of the skin or whites of the eyes
- Some blood test for liver function and fat content are different from normal value.
- Allergy-like reactions such as itching, flush, rash
- Impaired erection (Reduced sexual performance
- Nightmares, hallucinations
- Fainting
Very rare (may affect up to 1 in 10,000 people):
- Irritation and redness of eye (conjunctivitis)
- Hair loss
- Appearance or worsening of scaly skin rash (psoriasis): Psoriasis like rash.
* if treated for high blood pressure or angina then these symptom occur especially at beginning of treatment, or if your dosage changes. They are generally mild or 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 effect not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.
If any of the side effects get serious or if any side effect is noticed which is not listed in this leaflet, please tell your doctor or pharmacist.

5.How to store BLOCOR tablets
Keep out of the reach and sight of children.
Do not store above 25°C.
Store in the original package.

Shelf life
3 years.
The expiry date of the drug is indicated on the package.
The expiry date refers to the last day of that month.

6. Further information
Content
BLOCOR 5 mg tablets
Each tablet contains 5 mg bisoprolol fumarate,as an active supstannce.
BLOCOR 10 mg tablets
Each tablet contains 10 mg bisoprolol fumarate,as an active supstannce.

The other ingredients are (tablet core):
Calcium hydrogen phosphate dihydrate, microcrystalline cellulose, copovidone, starch, sodium stearyl fumarate, magnesium stearate, colloidal silicon dioxide

Film coated : Opadry II pink (BLOCOR 5 mg), Opadry II yellow (**BLOCOR** 10 mg), purified water

What BLOCOR looks like and contents of the pack
Cardboard box with 30 (3 x 10) tablets (uniform, rounded, slightly biconvex pink film coated tablets) of 5 mg bisoprolole (as fumarate) in blister.
Cardboard box with 30 (3 x 10) tablets(uniform, rounded, slightly biconvex yellow film coated tablets) of 10 mg bisoprolole (as fumarate) in blister.

The Anatomical Therapeutic Chemical Classification System (ATC) : C07AB07

Manufacturer / Marketing authorisation holder:
ZADA Pharmaceuticals Ltd.
Donji Bistarac
75300 Lukavac
Bosnia and Herzegovina

Classification :

- Prescription only.

Data and number of first authorisation / renewal of the authorisation in BIH :

BLOCOR film coated tablets 30 x 5 mg;
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