

**Package leaflet: Information for the user**

**Bisoprololfumaraat ratiopharm 5 mg, tabletten**  
**Bisoprololfumaraat ratiopharm 10 mg, tabletten**

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 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 Bisoprolol tablets 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 tablets is and what it is used for**

Bisoprolol belongs to a group of medicines called beta-blockers. This medicine is used to treat high blood pressure and recurring angina pectoris. Angina pectoris is a disease in which the cardiac (heart) muscles receive less oxygen than is necessary. This generally occurs during exercise and the most common symptom associated with this condition is chest pain.

**2. What you need to know before you take Bisoprolol tablets**

**Do not take Bisoprolol tablets**

- if you are allergic to bisoprolol or any of the other ingredients of this medicine (listed in section 6)
- if you are in acute heart failure or if you require injection of inotropic drugs (drugs which increase the force of contraction of the heart)
- if you have had cardiogenic shock (where your heart is unable to pump enough blood to your body).
- if you have certain heart conditions causing a very slow heart rate or irregular heartbeat and you have not been fitted with a pacemaker.
- if you have very poor blood circulation or severe Raynaud's Syndrome
- if you have extremely low blood pressure
- if you have a tumour of the adrenal gland (phaeochromocytoma) which is not currently being treated.
- if you suffer from severe asthma or have severe breathing difficulties.
- if you suffer from metabolic acidosis (disorder of the metabolism causing the blood to become acidic)

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Bisoprolol tablets:

- if you suffer from asthma or from any other breathing difficulties.
- if you suffer from diabetes mellitus, as low blood sugar levels may be masked by this medicine.
- if you suffer from an excessive production of thyroid hormones.
- if you have a history of allergies, including any for which you are undergoing desensitising treatment.
- if you are fasting.

- if you suffer from an irregular heart beat.
- if you suffer from circulatory problems (e.g. less severe forms of Raynaud's syndrome resulting in temporary discoloration of the skin and numbness of the fingers and toes or peripheral arterial disease resulting in pain, aching or cramping in your legs when walking).
- if you experience sudden onset of chest pain, or if you already suffer from a mild form of angina.
- if you suffer from phaeochromocytoma (marked by high blood pressure, raised heart rate and headache). This condition should be treated first, prior to taking Bisoprolol Tablets.
- if you suffer from or have suffered from psoriasis (marked by severe skin rashes).

If you go into hospital to have an operation, tell the anaesthetist or other medical staff that you are taking Bisoprolol Tablets.

**If you have a heart condition, treatment must not be stopped abruptly. The dose must be decreased gradually. For best advice, please contact your doctor.**

### **Children and adolescents**

Bisoprolol tablets is not recommended for use in children or adolescents.

### **Other medicines and Bisoprolol tablets**

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

- Verapamil, diltiazem (medicines used in the treatment of angina and high blood pressure).
- Clonidine (a medicine used to treat high blood pressure, ) and other centrally acting antihypertensives, such as methyldopa, guanfacin, moxonidine, rilmenidine and reserpine.
- Any other drugs used for high blood pressure treatment
- Medicines for depression or mental illness (monoamine-oxidase inhibitors, tricyclic antidepressants or phenothiazines).
- Disopyramide, quinidine, lidocaine, phenytoin, flecainide, propafenone or amiodarone (medicines used to treat irregular heartbeat).
- Calcium antagonists or beta-blockers (medicines used in the treatment of angina and high blood pressure including beta-blockers in eye drops).
- Anticholinesterase drugs (including Tacrine) - medicines used in Alzheimer's disease.
- Insulin or other medicines for diabetes.
- Anaesthetics.
- Digitalis glycosides (medicines used in heart failure).
- Non-steroidal anti-inflammatory painkillers (NSAIDs, medicines used to relieve the pain, tenderness, inflammation and stiffness caused by gout, arthritis, and other inflammatory conditions).
- Ergotamine derivatives (medicines for migraine).
- Sympathomimetic agents (medicines used in heart problems or low blood pressure) such as epinephrine, norepinephrine.
- Barbiturates (medicines used in sleep disorders).
- Baclofen (used to treat muscle spasms associated with multiple sclerosis and spinal cord injury).
- Mefloquine (an anti-malarial drug).
- Corticosteroids (medicines used for the treatment of asthma).
- Amifostine (from a class of drugs known as chemoprotectants).

### **Bisoprolol tablets with food, drink and alcohol**

Avoid drinking excessive alcohol, since it may increase the blood pressure-lowering effect of Bisoprolol.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Bisoprolol tablets 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, bisoprolol should not be taken during pregnancy.

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

### **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. Examples of side effects include visual disturbances, drowsiness or dizziness. If you suffer from any of these side effects it is advisable to refrain from driving or using machinery.

### **Bisoprolol tablets contain lactose**

This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **3. How to take Bisoprolol tablets**

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

The tablets should be swallowed with a glass of water and should not be chewed or crushed. Try to take the tablets the same time each day, preferably in the morning, before, with or after breakfast. The tablet can be divided into equal doses.

It is important that you take this medicine for as long as your doctor prescribes them. **Do not** stop taking your medication without consulting with your doctor first.

### **Adults and the elderly:**

The doctor will decide the dose you require and take into account any other medicines you may be taking. In some patients 5 mg per day may be adequate. The usual dose is 10 mg once daily with a maximum recommended dose of 20 mg.

### **Patients with kidney disease:**

Patients with severe kidney disease should not exceed 10 mg of bisoprolol once daily. This dosage may eventually be halved. Please consult your doctor before starting to use this medicine.

### **Patients with liver disease:**

Patients with severe liver disease should not exceed 10 mg of bisoprolol once daily. Please consult your doctor before starting to use this medicine.

### **If you take more Bisoprolol tablets than you should**

Contact your nearest casualty department or tell your doctor/pharmacist immediately. Take this leaflet and any left over tablets with you to show them.

If you have taken too many tablets you may have a slowed heart rate, low blood pressure, severe difficulty in breathing, feeling dizzy, or trembling (due to decreased blood sugar).

### **If you forget to take Bisoprolol tablets**

Try to take your tablets daily as prescribed. However, if you miss a dose, just take it as soon as you remember that day. **Do not take a double dose to make up for a forgotten dose.**

### **If you stop taking Bisoprolol tablets**

**Do not** stop treatment suddenly or change the recommended dose without talking to your doctor first. If you need to stop the treatment, it must be done gradually to avoid side effects.

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

#### **4. Possible side effects**

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

**Stop taking your tablets and seek immediate medical advice if you experience any of the following rare side effects:**

- allergic reaction - itchy skin, rash, swelling of the face, lips, tongue, throat, or difficulty breathing or swallowing

**Other side effects:**

**Common (may affect up to 1 in 10 people):**

- Feeling of coldness or numbness in the extremities (fingers or toes, ears and nose), Raynaud's disease (a condition where the blood supply to the tips of the fingers or toes may become so restricted as to cause tissue damage), worsening of cramp-like pain (intermittent claudication) that occurs in the legs when walking.
- Hypotension
- Tiredness, exhaustion, dizziness, headache (especially at the beginning of therapy, these are generally mild and often disappear within 1-2 weeks).
- Nausea, vomiting, diarrhoea, abdominal pain, constipation.

**Uncommon (may affect up to 1 in 100 people):**

- Muscular weakness, muscular cramps and joint ache.
- Feeling weak
- Slow or irregular heart beat.
- Worsening of heart failure (a condition in which the pumping action of the ventricle of the heart is inadequate).
- Sleep disturbances, depression.
- Patients with asthma or a history of breathing problems may experience difficulty in breathing.
- Light-headedness, especially on suddenly standing up.

**Rare (may affect up to 1 in 1,000 people):**

- Nightmare, hallucinations.
- Low blood sugar levels.
- Increased liver enzymes (you would notice a yellowing of the skin or the whites of your eyes).
- Increased triglycerides (certain lipids in the blood).
- Hepatitis (an inflammation of the liver).
- Inflammatory skin disease (lupus syndrome), which-disappear upon ending of treatment.
- Reduced sexual performance.
- Hearing impairment, runny nose.
- Reduced tear flow (especially if the patient uses contact lenses).
- Fainting.

**Very rare (may affect up to 1 in 10,000 people):**

- This medicine may aggravate psoriasis or induce psoriasis-like rash, hair loss.
- Itchiness or redness of the eye.

#### **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 [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Bisoprolol tablets

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package in order to protect from moisture.

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

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

## 6. Contents of the pack and other information

### What Bisoprolol tablets contain

The active substance is bisoprolol fumarate.

Each tablet contains 5 mg / 10 mg bisoprolol fumarate.

The other ingredients are:

*Bisoprolol 5 mg tablets*

lactose monohydrate, microcrystalline cellulose, magnesium stearate, crospovidone, iron oxide yellow (E172)

*Bisoprolol 10 mg tablets*

lactose monohydrate, microcrystalline cellulose, magnesium stearate, crospovidone, iron oxide yellow (E172), iron oxide red (E172)

### What Bisoprolol tablets looks like and contents of the pack

*Bisoprolol 5 mg tablets* are mottled pale yellow, round, convex, with a breakline and '5' embossed on the right hand side.

*Bisoprolol 10 mg tablets* are mottled beige, round, convex, with a breakline and '1' embossed on the left and '0' embossed on the right.

The following pack sizes are available:

*Bisoprolol 5 mg tablets*: 20, 28, 30, 50, 56, 60, 98, 100x1 (unit dose) or 100 tablets.

*Bisoprolol 10 mg tablets*: 20, 28, 30, 50, 56, 60, 84, 90, 98, 100x1 (unit dose) or 100 tablets.

<Not all pack sizes may be marketed.>

### Houder van de vergunning voor het in de handel brengen en fabrikant

*Houder van de vergunning voor het in de handel brengen*

Ratiopharm GmbH

Graf-Arco-Str. 3

89079 Ulm

Duitsland

*Fabrikant*

Merckle GmbH

Ludwig-Merckle Strasse 3

89143 Blaubeuren-Weiler

Duitsland

### In het register ingeschreven onder

RVG 24382 – Bisoprololfumaraat ratiopharm 5 mg, tabletten

RVG 24383 – Bisoprololfumaraat ratiopharm 10 mg, tabletten

**Dit geneesmiddel is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:**

Duitsland:	Bisoprolol AbZ 5/10 mg Tabletten
Finland:	Bisopropolol ratiopharm 5/10 mg tabletti
Nederland:	Bisoprololfumaraat ratiopharm 5/10 mg, tabletten
Oostenrijk:	Bisoprolol "ratiopharm" 5/10 mg - Tabletten
Spanje:	Bisoprolol Teva-ratiopharm 5/10 mg comprimidos EFG
Zweden:	Bisoprolol Teva

Deze bijsluiter is voor het laatst goedgekeurd in december 2024