Package leaflet: Information for the patient

Bisoprololfumaraat 5 mg, filmomhulde tabletten
Bisoprololfumaraat 10 mg, filmomhulde tabletten
bisoprololfumaraat

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 of the 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 [Nationally completed name] is and what it is used for

[Nationally completed name] belongs to the group of medicinal products that are indicated as beta blockers. They protect the heart from too much activity.

[Nationally completed name] is used to treat:
- high blood pressure
- angina pectoris(heart pain)
- heart failure causing breathlessness on exertion or fluid retention. In this instance, [Nationally completed name] may be given as an additional treatment to other medications for heart failure.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]
- if you are allergic to bisoprolol fumarate or any of the other ingredients of this medicine (listed in section 6).
- if you have a cardiogenic shock, a serious heart condition causing a rapid, weak pulse; low blood pressure; cold, clammy skin; weakness and fainting.
- if you have ever suffered from severe wheezing or severe asthma, as they can affect your breathing.
- if you have a slow heart rate (less than 60 beats per minute). Ask your doctor if you are not sure.
- if you have very low blood pressure.
- if you have severe blood circulation problems (which may cause your fingers and toes to tingle or turn pale or blue).
- if you have certain serious heart rhythm problems.
- if you have heart failure which has just occurred or is not stabilised and is requiring hospital treatment.
- if you have a condition in which there is an accumulation of excessive acid in the body known as metabolic acidosis. Your doctor will be able to advise you.

- if you suffer from a tumour of the adrenal glands known as phaeochromocytoma which is untreated.

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

Warnings and precautions
Talk to your doctor before taking [Nationally completed name]

- if you suffer from wheezing or difficulty breathing (asthma). Bronchodilating therapy should be given concomitantly. A higher dose of beta$_2$-stimulants may be needed.
- if you have diabetes. The tablets can hide the symptoms of low blood sugar (such as accelerated heart beat rate, palpitations or sweating).
- if you are fasting from solid food.
- if you are treated for hypersensitivity (allergic) reactions. [Nationally completed name] may increase the hypersensitivity to the substances you are allergic to and increase the severity of the hypersensitivity reactions. Treatment with adrenalin then may not have the desired result. A higher dose of adrenalin (epinephrine) may be needed.
- with 1st degree heart block (conduction disorder in the heart).
- if you suffer from Prinzmetal's angina which is a type of chest pain caused by spasm of the coronary arteries that supply the heart muscle.
- if you have any problems with the circulation to the extremities of the body such as hands and feet.
- in case of surgery involving an anaesthetic: If you consult a doctor, attend hospital or the dentist for surgery involving anaesthetics, let them know what medicines you are taking.
- in combination with calcium antagonists, such as verapamil and diltiazem. Concomitant use is not recommended, see also section "Other medicines and [Nationally completed name]".
- if you suffer (or have suffered) from psoriasis (a recurrent skin disorder involving scaling and dry skin rash).
- if you suffer from phaeochromocytoma (tumour of the adrenal marrow). Your doctor will need to treat this before prescribing [Nationally completed name] for you.
- if you have a thyroid problem. The tablets can hide symptoms of an overactive thyroid.

There is so far no therapeutic experience of [Nationally completed name] treatment of heart failure in patients with the following diseases and conditions:

- diabetes mellitus treated with insulin (type I).
- severe kidney disease.
- severe liver disease.
- certain heart diseases.
- heart attack within 3 months.

Treatment of heart failure with [Nationally completed name] requires regular medical monitoring. This is absolutely necessary, particularly at the beginning of treatment, and upon stopping treatment.

Treatment with [Nationally completed name] must not be discontinued abruptly unless for compelling reasons.

For patients with hypertenstion and angina pectoris and accompanying heart failure treatment should not be stopped abruptly. The dosage should be diminished slowly by a weekly halving of the dose.

Consult your physician if one of the above warnings is applicable to you, or has been in the past.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines obtained without a prescription. Certain medicines cannot be used at the same time, while other drugs require specific changes (in the dose, for example).

Always tell your doctor if you are using or receiving any of the following medicines in addition to [Nationally completed name]:

- 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).
- sedatives and therapies for psychosis (a mental illness) e.g. barbiturates (also used for epilepsy), phenothiazines (also used for vomiting and nausea).
- medicines for depression e.g. tricyclic antidepressants, MAO-A inhibitors.
- medicines used for anaesthesia during an operation (see also section "Warnings and precautions").
- certain pain killers (for instance acetyl salicylic acid, diclofenac, indomethacin, ibuprofen, naproxen).
- medicines for asthma, blocked nose, or certain eye disorders such as glaucoma (increased pressure in the eye) or dilation (widening) of the pupil.
- certain medicines to treat shock (e. g. adrenaline, dobutamine, noradrenaline).
- mefloquine, a medicine for malaria.
- the antibiotic rifampicin.
- ergotamine derivatives for migraine.

All these drugs as well as [Nationally completed name] may influence the blood pressure and/or heart function.

- insulin or other products for diabetes. The blood glucose reducing effect may be enhanced. Symptoms of low blood glucose level can be masked.

[Nationally completed name] with alcohol
The dizziness and light-headedness that may be caused by [Nationally completed name] can be made worse if you drink alcohol. If this happens to you, you should avoid drinking alcohol.

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. [Nationally completed name] 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
This medicine 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 possiblity of these effects, particularly at the beginning of the treatment, with changes in medication and with use in combination with alcohol.

[Nationally completed name] contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take [Nationally completed name]

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

Your doctor will tell you how many tablets to take. You should take this medicine in the morning, before, with or after breakfast. Swallow the tablet(s) with some water and do not chew or crush them.

Elevated blood pressure/ angina pectoris
Adults
The dose is determined individually.
The recommended starting dose is 5 mg once daily.
The usual dose for adults is once daily 10 mg. Your doctor may decide to increase or decrease the dose.
The maximum dose is once daily 20 mg.

Severe kidney or severe liver function disorders
If you suffer from a **severe kidney or severe liver function disorder** the maximum dose is 10 mg per day.

Elderly
Normally no dosage adjustment is required. Your doctor will start therapy with the lowest possible dose.

Heart failure (reduced pumping strength of the heart)
Before you start using [Nationally completed name], you are already using an ACE-inhibitor, diuretic or heart glycoside (heart/ blood pressure product).

The dose 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 is once daily 10 mg.
The doctor will determine the optimum dose for you amongst others based on possible side effects.

After the very first dose of 1.25 mg the doctor will check your blood pressure, heart rate, heart function disorders.

Liver or kidney function disorders
The doctor will be extra careful with the increasing of the dose.

Elderly
Normally spoken an adjustment of the dose is not needed.

If you notice that the effect of [Nationally completed name] is too strong or not strong enough, please consult your doctor or pharmacist.

Place the tablet on a hard, flat surface with the scored side at the top.

Press with the thumb on the middle of the tablet and the tablet will break into two halves, press with the thumb in the middle of each half and you will have four parts.

Duration of the treatment
[Nationally completed name] will usually be used long-term.

Use in children and adolescents
There is no experience with [Nationally completed name] in children and adolescents, therefore its use is not recommended in children.

If you take more [Nationally completed name] 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, b**reathlessness 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 [Nationally completed name]
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 [Nationally completed name]
Treatment with [Nationally completed name] must not be stopped abruptly. If you suddenly stop taking this medicine your condition may get worse. Instead, it must be reduced gradually over a few weeks as advised by your doctor.

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.

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 (may affect more than 1 in 10 people)
• worsening of heart failure (may affect up to 1 in 10 people)
• slow or irregular heartbeat (may affect up to 1 in 100 people)

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

You should see a doctor straight away if you experience more severe allergic reactions, which may involve face, neck, tongue, mouth or throat swelling, or difficulty breathing.

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

Common: may affect up to 1 in 10 people
- exhaustion. In the treatment of hypertension or angina pectoris this side effect occurs uncommonly.
- dizziness, tiredness and headache (especially at the beginning of therapy in patients with hypertension and angina pectoris; symptoms are generally mild and often disappear within 1–2 weeks)
- feeling of coldness or numbness in the extremities (fingers or toes, ears and nose); more frequent occurrence of a cramp-like pain in the legs when walking

- very low blood pressure (hypotension), particularly in patients with heart failure
- feeling sick (nausea), being sick (vomiting)
- diarrhoea
- constipation

Uncommon: may affect up to1 in 100 people
- exhaustion. In the treatment of heart failure this side effect occurs commonly
- fall in blood pressure on standing up which may cause dizziness, light-headedness or fainting
- sleep disturbances
- depression
- irregular heart beat
- patients with asthma or a history of breathing problems may experience difficulty in breathing
- muscular weakness and muscle cramps

Rare: may affect up to 1 in 1,000 people
- nightmares
- hallucinations (imagining things)
- syncope
- hearing impairment
- inflammation of the lining of the nose, causing a runny nose with irritation
- allergic skin reactions (such as itching, flushed appearance, rash)
- dry eyes from reduced tear flow (which can be very troublesome if you use contact lenses)
- inflammation of the liver (hepatitis), causing abdominal pain, loss of appetite and sometimes jaundice with yellowing of the whites of the eyes and skin, and dark urine
- reduced sexual performance (potency disorder)
- increased levels of blood lipids (triglycerides) and liver enzymes

Very rare: may affect up to 1 in 10,000 people
- aggravation of the skin condition psoriasis or cause a similar dry, scaly rash and hair loss
- itchiness or redness of the eye (conjunctivitis)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 [Nationally completed name]

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

Do not use this medicine after the expiry date which is stated on the packaging after "EXP". The expiry date refers to the last day of that month.
Do not use the medicine packed in bottles after 6 months after first opening the bottle.

Blister:
This medicine does not require any special storage conditions.

Bottle:

This medicine does not require any special storage conditions.

Storage conditions after first opening of the bottle:
Do not store above 25°C.

Do not throw away any medicines via wastewater or houshold 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 [Nationally completed name] contains

- The active substance is bisoprolol fumarate. Each film-coated tablet conatins 5 mg of bisoprolol fumarate.
  Each film-coated tablet conatins 10 mg of bisoprolol fumarate.

5mg film-coated tablets:

- The other ingredients are anhydrous calcium hydrogen phosphate, microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, lactose monohydrate, hypromellose, macrogol 4000, titanium dioxide (E 171), yellow iron oxide (E 172).

10mg film-coated tablets:

- The other ingredients are: The other ingredients are anhydrous calcium hydrogen phosphate, microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, lactose monohydrate, hypromellose, macrogol 4000, titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E 172).

What [Nationally completed name] looks like and contents of the pack

5 mg film-coated tablets:
Yellow coloured, round, scored film-coated tablets with a one-sided embossment „BIS 5".
The tablet can be divided into four equal doses.

10 mg film-coated tablets:
Apricot coloured, round, scored film-coated tablet with a one-sided embossment „BIS 10".
The tablet can be divided into four equal doses.

NL/H/0597-0673:

The film-coated tablets are packed in OPA/Alu/PVC/Alu blisters and inserted in a carton.

Pack sizes:
7, 10, 14, 20, 28, 30, 50, 56, 60, 100, 10x30 film-coated tablets

NL/H/0684:

The film-coated tablets are packed in OPA/Alu/PVC/Alu blisters and inserted in a carton, or are packed in a HDPE tablet bottle with PE cap.

Pack sizes:
Blister: 7, 10, 14, 20, 28, 30, 50, 56, 60, 90, 98, 100, 10x30, 500 film-coated tablets
Bottle: 10, 20, 30, 50, 60, 100, 250, 500 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Houder van de vergunning voor het in de handel brengen
Hexal AG
Industriestrasse 25
83607 Holzkirchen
Duitsland

Fabrikanten
Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
39179 Barleben
Duitsland
LEK S.A.
Ul. Domaniewska 50 C
02-672 Warschau
Polen

Rowa Pharmaceuticals Limited
Newtown, Bantry, Co.Cork
Ierland

Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

LEK S.A.
Ul Podlipie 16 C95010 Strykow
Polen

In het register ingeschreven onder
RVG 33091 (5 mg), RVG 33093 (10 mg).

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

NL/H/0673:

Austria:	Bisoprolol 1A Pharma 5 MG – Filmtabletten Bisoprolol 1A Pharma 10 MG – Filmtabletten
The Netherlands:	BISOPROLOLFUMARAAT 5MG, FILMOMHULDE TABLETTEN BISOPROLOLFUMARAAT 10MG, FILMOMHULDE TABLETTEN

Deze bijsluiter is voor het laatst goedgekeurd in maart 2022