Package leaflet: Information for the user

Bisoprololfumaraat CF 1,25 mg, filmomhulde tabletten
Bisoprololfumaraat CF 2,5 mg, filmomhulde tabletten
Bisoprololfumaraat CF 3,75 mg, filmomhulde tabletten
Bisoprololfumaraat CF 5 mg, filmomhulde tabletten
Bisoprololfumaraat CF 7,5 mg, filmomhulde tabletten
Bisoprololfumaraat CF 10 mg, filmomhulde 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 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 <Product name> is and what it is used for
2. What you need to know before you take <Product name>
3. How to take <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

1. What <Product name> is and what it is used for

The active substance in <Product name> 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.

- <Product name> is used to treat stable chronic heart failure. It is used in combination with other medicines suitable for this condition (such as ACE-inhibitors, diuretics, and heart glycosides). Heart failure occurs when the heart muscle is weak and unable to pump enough blood to supply the body's needs.

- <Product name> 5 mg and 10 mg are also used to treat high blood pressure (hypertension) and chest pain caused by blockages in the arteries that supply the heart muscle (angina pectoris).

2.What you need to know before you take <Product name>

DO NOT take <Product name> if you
- are allergic to bisoprolol or any of the other ingredients of this medicine (listed in section 6)
- have severe asthma
- 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 a tumour of the adrenal gland (phaeochromocytoma) that is untreated
- have a condition where there is too much acid in the blood (metabolic acidosis)

- have an acute heart failure
- have a worsening heart failure requiring injection of medicines into a vein, that increase the force of your heart contractions
- have a slow heart rate
- have low blood pressure
- have certain heart conditions causing a very slow heart rate or irregular heartbeat
- have an acute serious heart condition causing low blood pressure and circulatory failure (cardiogenic shock)

Warnings and precautions
Talk to your doctor before taking <Product name> if you have any of the following conditions. The doctor may want to give you 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
- mild/moderate blood circulation problems in your limbs
- chronic lung disease or mild/moderate asthma
- a history of psoriasis (a scaly skin rash)
- tumour of the adrenal gland (phaeochromocytoma)
- thyroid disorder

In addition, tell your doctor if you are going to have:
- desensitisation therapy (for example for the prevention of hay fever), because bisoprolol may make it more likely that you experience an allergic reaction, or that such a reaction may be more severe
- anaesthesia (for example for surgery), because bisoprolol may influence how your body reacts to this situation

If you have chronic lung disease or mild/moderate asthma, please inform your doctor immediately if you start to experience new difficulties in breathing, cough, wheezing after exercise, etc. when using <Product name>.

Children and adolescents
<Product name> is not recommended for use in children or adolescents.

Other medicines and <Product name>
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 <Product name> without special advice from your doctor:
- certain medicines used to treat irregular or abnormal heartbeat (class I antiarrhythmic medicines such as quinidine, disopyramide, lidocaine, phenytoin, flecainide, 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, 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 <Product name>; 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 characterised 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 breast-feeding
Pregnancy
There is a risk that use of <Product name> during pregnancy may harm the baby. If you are pregnant or planning to become pregnant, tell your doctor. The doctor will decide whether you can take <Product name> during pregnancy.

Breast-feeding
It is not known whether bisoprolol passes into breast milk. Therefore, breast-feeding is not recommended during therapy with <Product name>.

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.

3. How to take <Product name>

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

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

Take the tablet with some water in the morning, with or without food. Do not crush or chew the tablet in order to avoid damage to the film-coating and thus preventing direct exposure to the bad-tasting bisoprolol – the active substance in <Product name>.
The 2.5 mg, 3.75 mg, 5 mg, 7.5 mg and 10 mg tablet can be divided into two equal doses.

Treatment with <Product name> is usually long-term.

Heart failure

Adults
Treatment with bisoprolol 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 once daily for one week
- 2.5 mg bisoprolol once daily for one week

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

The maximum recommended daily dose for treatment of heart failure is 10 mg bisoprolol.

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 medicine, it may be necessary to reduce the dose again or to interrupt treatment. In some patients a maintenance dose lower than 10 mg bisoprolol may be sufficient.

Your doctor will tell you what to do.

If you have to stop treatment entirely, your doctor will usually advise you to reduce the dose gradually, otherwise your condition may become worse.

Chest pain and high blood pressure

Adults
The recommended starting dose is 5 mg per day. The usual dose is 10 mg once daily. Your doctor will monitor you closely at the start of treatment and increase your dose to obtain the best possible dosage for you.

The maximum recommended dose for treatment of chest pain and high blood pressure is 20 mg once per day.

Patients with severe kidney or liver disease
Patient with severe kidney or liver disease should not exceed 10 mg of <Product name> once daily.
Please consult your doctor before starting to use this medicine.

If you take more <Product name> than you should
If you have taken more <Product name> tablets than you should, tell your doctor immediately. Your doctor will decide what measures are necessary.

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

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

If you stop taking <Product name>
Never stop taking <Product name> unless on your doctor's recommendation; your condition could become much worse.

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.

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

To prevent serious reactions, talk 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 in patients with chronic heart failure, may affect up to 1 in 100 people in patients with chest pain or high blood pressure)
- worsening of heart failure (may affect up to 1 in 10 people in patients with chronic heart failure, may affect up to 1 in 100 people in patients with chest pain or high blood pressure)
- slow or irregular heartbeat (may affect up to 1 in 100 people)

Other side effects:

Common (may affect up to 1 in 10 people):
- feeling weak (in patients with chronic heart failure)
- tiredness, dizziness, headache
- feeling of coldness or numbness in hands or feet
- low blood pressure
- stomach or intestinal problems such as nausea, vomiting, diarrhoea, or constipation

Uncommon (may affect up to 1 in 100 people):
- feeling weak (in patients with chest pain or high blood pressure)
- sleep disturbances
- depression
- dizziness when standing up (orthostatic hypotension)
- breathing problems in patients with asthma or chronic lung disease
- muscle weakness, muscle cramps

Rare (may affect up to 1 in 1 000 people):
- hearing problems
- allergic runny nose
- reduced tear flow
- inflammation of the liver which can cause yellowing of the skin or whites of the eyes (hepatitis)
- abnormal blood test results for liver function or fat levels
- allergy-like reactions such as itching, flush, rash. You should see your doctor straight away if you experience more severe allergic reactions, which may involve face, neck, tongue, mouth or throat swelling, or difficulty breathing.
- impaired erection
- nightmares, hallucinations
- fainting

Very rare (may affect up to 1 in 10 000 people):
- irritation and redness of the eye (conjunctivitis)
- hair loss (alopecia)
- appearance or worsening of psoriasis (scaly skin rash); psoriasis-like rash

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 <Product 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 blister, bottle label and the carton after EXP.
The expiry date refers to the last date of that month.

This medicine does not require any special storage conditions.

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 <Product name> contains

<Product name> 1.25 mg film-coated tablets
- The active substance is bisoprolol fumarate. Each film-coated tablet contains 1.25 mg bisoprolol fumarate.
- The other ingredients are:
  Tablet core: microcrystalline cellulose, calcium hydrogen phosphate, pregelatinised starch, crospovidone, silica, colloidal anhydrous, magnesium stearate
  Film-coating: hypromellose (E464), titanium dioxide (E171), macrogol

<Product name> 2.5 mg film-coated tablets
- The active substance is bisoprolol fumarate. Each film-coated tablet contains 2.5 mg bisoprolol fumarate.
- The other ingredients are:
  Tablet core: microcrystalline cellulose, calcium hydrogen phosphate, pregelatinised starch, crospovidone, silica, colloidal anhydrous, magnesium stearate
  Film-coating: hypromellose (E464), titanium dioxide (E171), macrogol

<Product name> 3.75 mg film-coated tablets
- The active substance is bisoprolol fumarate. Each film-coated tablet contains 3.75 mg bisoprolol fumarate.
- The other ingredients are:
  Tablet core: microcrystalline cellulose, calcium hydrogen phosphate, pregelatinised starch, crospovidone, silica, colloidal anhydrous, magnesium stearate
  Film-coating: hypromellose (E464), titanium dioxide (E171), iron oxide yellow (E172), macrogol

<Product name> 5 mg film-coated tablets
- The active substance is bisoprolol fumarate. Each film-coated tablet contains 5 mg bisoprolol fumarate.
- The other ingredients are:
  Tablet core: microcrystalline cellulose, calcium hydrogen phosphate, pregelatinised starch, crospovidone, silica, colloidal anhydrous, magnesium stearate
  Film-coating: hypromellose (E464), titanium dioxide (E171), iron oxide yellow (E172), macrogol

<Product name> 7.5 mg film-coated tablets
- The active substance is bisoprolol fumarate. Each film-coated tablet contains 7.5 mg bisoprolol fumarate.
- The other ingredients are:
  Tablet core: microcrystalline cellulose, calcium hydrogen phosphate, pregelatinised starch, crospovidone, silica, colloidal anhydrous, magnesium stearate
  Film-coating: hypromellose (E464), titanium dioxide (E171), iron oxide yellow (E172), macrogol, iron oxide red (E172)

<Product name> 10 mg film-coated tablets

- The active substance is bisoprolol fumarate. Each film-coated tablet contains 10 mg bisoprolol fumarate.
- The other ingredients are:
  Tablet core: microcrystalline cellulose, calcium hydrogen phosphate, pregelatinised starch, crospovidone, silica, colloidal anhydrous, magnesium stearate
  Film-coating: hypromellose (E464), titanium dioxide (E171), iron oxide yellow (E172), macrogol, iron oxide red (E172)

What <Product name> looks like and contents of the pack

<Product name> 1.25 mg are white to off white, approx. 5 mm, round shaped, biconvex film coated tablets, debossed with 'C' on one side and '42' on other side.

<Product name> 2.5 mg are white to off white, approx. 7 mm, round shaped, biconvex film coated tablets, debossed with ‘C’ and score line on one side and ‘41’ on other side.
The tablet can be divided into equal doses.

<Product name> 3.75 mg are off white, approx. 8 mm, round shaped, biconvex film coated tablets, debossed with 'C' and score line on one side and '40' on other side.
The tablet can be divided into equal doses.

<Product name> 5 mg are yellowish-white, approximately 8 mm, round shaped, biconvex film coated tablets, debossed with 'C' and score line on one side and '39' on other side.
The tablet can be divided into equal doses.

<Product name> 7.5 mg are pale-yellow, approx. 8 mm, round shaped, biconvex film coated tablets, debossed with 'C' and score line on one side and '38' on other side.
The tablet can be divided into equal doses.

<Product name> 10 mg are pale-orange, approximately 8 mm, round shaped, biconvex film coated tablets, debossed with ‘C’ and score line on one side and ‘37’ on other side.
The tablet can be divided into equal doses.

oPA/Alu/PVC//Alu blisters containing 10, 20, 28, 30, 50, 56, 60, 90, 98 or 100 film-coated tablets or oPA/Alu/PVC//Alu perforated unit dose blisters containing 10 x 1, 20 x 1, 30 x 1, 50 x 1, 90 x 1 or 100 x 1 film-coated tablets.

HDPE bottle (high density polyethylene) with closure containing 30, 100, 250, 500 or 1000 film-coated tablets.

Not all pack sizes may be marketed.

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

Vergunninghouder:
Centrafarm B.V.
Van de Reijtstraat 31-E
4814 NE Breda
Nederland

Fabrikant:
STADA Arzneimittel AG
Stadastrasse 2-18, Dortelweil
61118 Bad Vilbel
Duitsland

Clonmel Healthcare Ltd.
Waterford Road, Gurtnafleur
E91 D768 Clonmel
Co. Tipperary
Ierland

Centrafarm Services B.V.
Van de Reijtstraat 31-E
4814 NE Breda
Nederland

STADA Arzneimittel GmbH
Muthgasse 36/2, Doebling
1190 Wenen
Oostenrijk

In het register ingeschreven onder

RVG 132832 - Bisoprololfumaraat CF 1,25 mg, filmomhulde tabletten
RVG 132846 - Bisoprololfumaraat CF 2,5 mg, filmomhulde tabletten
RVG 132847 - Bisoprololfumaraat CF 3,75 mg, filmomhulde tabletten
RVG 132849 - Bisoprololfumaraat CF 5 mg, filmomhulde tabletten
RVG 132850 - Bisoprololfumaraat CF 7,5 mg, filmomhulde tabletten
RVG 132851 - Bisoprololfumaraat CF 10 mg, filmomhulde tabletten

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

België, Luxemburg	Bisoprolol EG
Denemarken, Finland, IJsland, Noorwegen, Zweden	Cardovia
Duitsland	Bisoprolol STADAPHARM
Frankrijk	BISOPROLOL EG LABO
Ierland	Bisoprolol Clonmel
Nederland	Bisoprololfumaraat CF
Oostenrijk	Bisoprolol Stada
Portugal	Bisoprolol Ciclum Farma
Spanje	Bisoprolol STADAFARMA

Deze bijsluiter is voor het laatst goedgekeurd in april 2025.