Package leaflet: information for the user
Bisoprolol fumarate Accord 2.5 mg film-coated tablets
Bisoprolol fumarate Accord 5 mg film-coated tablets
Bisoprolol fumarate Accord 10 mg film-coated tablets
Bisoprolol fumarate

Read the entire 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.
- Do you have any questions? Contact your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect that is not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

Contents of this leaflet

1. What is Bisoprolol fumarate Accord and what is this medicine used for?

The active substance in this medicine is bisoprolol fumarate. Bisoprolol fumarate belongs to the group of medicines called beta-blockers. Beta-blockers protect the heart from excessive activity. This medicine affects the body's response to certain nerve impulses, especially in the heart. As a result, bisoprolol fumarate slows the heart rate and ensures that the heart pumps blood more efficiently throughout the body. Heart failure occurs when the heart muscle is weak and cannot pump enough blood to meet the body's needs. Bisoprolol fumarate Accord 2.5 mg, 5 mg, and 10 mg are used in combination with other medicines to treat stable heart failure.

Bisoprolol fumarate Accord 5 mg and 10 mg are also used for the treatment of high blood pressure (hypertension) and angina pectoris (chest pain caused by blockages in the arteries to the heart muscle).

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?
- You are allergic to any of the substances in this medicine. You can find these substances in section 6.
- You have severe asthma.
- You have severe blood circulation disorders in your limbs (such as Raynaud's syndrome), which can cause your fingers and toes to tingle or become pale or blue.

- You have an untreated pheochromocytoma; this is a rare tumor in the adrenal gland.
- You have metabolic acidosis, a condition where there is too much acid in your blood.

Do not use this medicine if you have any of the following heart conditions:
- You have worsening heart failure and need medicines administered into a vein to strengthen your heart's contraction force.
- You have a slow heart rate.
- You have low blood pressure.
- You have a certain heart condition that causes a very slow or irregular heartbeat.
- You have cardiogenic shock; this is an acute, severe heart condition that causes low blood pressure and blood circulation disorders.

When should you be extra careful with this medicine?
Contact your doctor or pharmacist before using this medicine. They may want to take extra precautions (for example, by providing additional treatment or by conducting more frequent check-ups) if you suffer from any of the following conditions:
- diabetes
- strict fasting (no solid food)
- certain heart conditions such as disturbances of heart rhythm or severe chest pain at rest (Prinzmetal's angina)
- kidney or liver problems
- less severe circulatory disorders in your limbs
- less severe asthma or chronic lung disease
- have (had) a scaly skin rash (psoriasis)
- adrenal gland tumor (pheochromocytoma)
- thyroid disorders

Additionally, you should tell your doctor when you:
- are receiving desensitization therapy (to make the body insensitive to certain substances, for example, to prevent hay fever), because this medicine increases the chance of an allergic reaction, or increases the chance that such a reaction
- will be more severe.
- need to be anesthetized (for example, during surgery), because this medicine can affect your body's response to this situation.

If you have a chronic lung disease or a mild form of asthma, inform your doctor immediately if you experience new breathing difficulties, cough, or wheezing after exercise when using this medicine.

Children and adolescents under 18 years
This medicine is not recommended for use in children or adolescents under 18 years.

Are you using any other medicines?
Are you using any other medicines besides Bisoprolol fumarate Accord, or have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription.

Do not take the following medicines together with this medicine without advice from your doctor:

Contact your doctor or pharmacist if you are using any of the following medicines:
- certain medicines used to treat an irregular or abnormal heartbeat (Class I antiarrhythmics such as quinidine, disopyramide, lidocaine, phenytoin, flecainide, propafenone)
- certain medicines for the treatment of high blood pressure, angina pectoris, or irregular heartbeat (calcium antagonists such as verapamil and diltiazem)
- certain medicines for the treatment of high blood pressure such as clonidine, methyldopa, monoxidine, rilmenidine. However, do not stop using these medicines without consulting your doctor first.

Consult your doctor before starting to use the following medicines together with Bisoprolol Fumarate Accord; your doctor may need to monitor your condition more frequently:
- certain medicines for the treatment of high blood pressure or angina pectoris (calcium antagonists of the dihydropyridine type such as felodipine and amlodipine)
- certain medicines for the treatment of an irregular or abnormal heartbeat (Class III antiarrhythmics such as amiodarone)
- beta-blockers for topical use (such as timolol eye drops for the treatment of increased eye pressure [glaucoma])
- certain medicines for the treatment of Alzheimer's disease or increased eye pressure (glaucoma) (parasympathomimetics such as tacrine or carbachol), or medicines for the treatment of acute heart problems (sympathomimetics such as isoprenaline and dobutamine)
- medicines for the treatment of diabetes, including insulin
- medicines for general anesthesia (for example during surgery)
- digitalis, used for the treatment of heart failure
- non-steroidal anti-inflammatory drugs (NSAIDs), used for the treatment of arthritis, pain, or inflammation (for example ibuprofen or diclofenac)
- any medicine that can lower blood pressure (desired or undesired) such as medicines for high blood pressure (antihypertensives), certain medicines for the treatment of depression (for example tricyclic antidepressants such as imipramine or amitriptyline), certain medicines for the treatment of epilepsy or anesthetics (barbiturates such as phenobarbital), or certain medicines for the treatment of mental disorders characterized by loss of contact with reality (phenothiazines such as levomepromazine).
- mefloquine, used for the prevention or treatment of malaria
- medicines for the treatment of depression called monoamine oxidase inhibitors (except MAO-B inhibitors), such as moclobemide.

Pregnancy and breastfeeding

Pregnancy
There is a risk that using this medicine during pregnancy may be harmful to the baby. Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine. He or she will decide whether you can use this medicine during pregnancy.

Breastfeeding
It is not known whether this medicine passes into breast milk. Therefore, breastfeeding during treatment with this medicine is not recommended.
Bisoprolol fumarate Accord contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, which means it is essentially 'sodium-free'.

Driving and using machines
Your ability to drive and operate machines may be adversely affected depending on how well you tolerate this medicine. Be especially careful at the beginning of the treatment, when the dose is increased or when your medication is changed, and in combination with alcohol.

3.How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.
If you are being treated with this medicine, you should have regular check-ups with your doctor. This is especially important at the start of treatment, when the dose is increased, and when you stop the treatment.

This medicine should be taken in the morning, with or without food. Swallow the tablet(s) whole with some water. Do not chew or crush them. The tablet can be divided into equal doses. If you need to take half a tablet, place it with the score line facing up on a flat surface. Then gently press on both sides of the score line to split the tablet into two equal halves.

Treatment with this medicine is usually for a long time.

Adults:
Chest pain and high blood pressure:
Your doctor will start the treatment with the lowest possible dose (5 mg). Your doctor will monitor you closely at the start of the treatment. Your doctor will increase your dose to achieve the best possible dose for you.

The maximum recommended dosage is 20 mg once a day.

Patients with kidney disease:
Patients with severe kidney disease should not use more than 10 mg bisoprolol fumarate once a day. Contact your doctor before using this medicine.

Patients with liver disease:
Patients with severe liver disease should not use more than 10 mg bisoprolol fumarate once a day. Consult your doctor before using this medication.

Heart failure:
Before starting to use this medicine, you should already be using other heart failure medications, including an ACE inhibitor, a diuretic, and (as an additional option) cardiac glycosides.
Treatment with this medicine should be started with a low dose and the dose should be gradually increased. Your doctor will decide how the dose should be increased. Normally, this is done in the following way:

- 1.25 mg: once a day for one week
- 2.5 mg: once a day for one week
- 3.75 mg: once a day for one week
- 5 mg: once a day for four weeks
- 7.5 mg: once a day for four weeks
- 10 mg: once a day for maintenance treatment (long-term treatment).

The maximum recommended daily dose of Bisoprolol Fumarate Accord is 10 mg.

Depending on how well you tolerate the treatment, your doctor may decide to extend the time between dose increases. If your condition worsens or if you no longer tolerate the medication, it may be necessary to reduce the dose again or to interrupt the treatment. In some patients, a maintenance dose of less than 10 mg may be sufficient. Your doctor will tell you what to do. If you need to stop the treatment completely, your doctor will usually advise you to taper the dose slowly, as your condition may otherwise worsen.

Have you taken too much of this medicine?
If you have taken too much of this medicine, tell your doctor immediately. Your doctor will then determine what needs to be done.
Symptoms of an overdose may include: a slow heartbeat, severe breathing difficulties, dizziness, or tremors (due to low blood sugar levels).

Have you forgotten to take this medicine?
If you have forgotten to take your medication, take it as soon as you notice, unless it is almost time for the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop using this medicine
Never stop the treatment suddenly and never change the recommended dosage without first consulting your doctor. If you need to stop the treatment, it should be done gradually to prevent side effects.

Do you have any other questions about the use of this medicine? Then contact 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, you must contact a doctor immediately if you experience a severe side effect, or if it occurs suddenly or worsens rapidly. The most serious side effects are related to heart function:

- Slower heart rate (may occur in up to 1 in 10 people with chronic heart failure and in up to 1 in 100 people with high blood pressure or angina pectoris)
- Worsening of heart failure (may occur in up to 1 in 10 people with chronic heart failure and in up to 1 in 100 people with high blood pressure or angina pectoris)
- slow or irregular heartbeat (may occur in more than 1 in 10 people with chronic heart failure)

If you feel dizzy or weak, or if you experience breathing difficulties, you should contact your doctor as soon as possible.

The other side effects are listed below in order of how often they occur:

Common (may occur in up to 1 in 10 people):
- Fatigue*, feeling of weakness (in patients with chronic heart failure), dizziness*,
- headache*
- A cold or numb feeling in the hands or feet
- Low blood pressure, especially in patients with heart failure
- Stomach or intestinal complaints such as nausea, vomiting, diarrhea, or constipation

Uncommon (may occur in up to 1 in 100 people):
- Sleep disorders
- Depression
- Dizziness when standing up
- Breathing difficulties in patients with asthma or chronic lung conditions
- Muscle weakness, muscle cramps.

Rare (may occur in up to 1 in 1,000 people):
- Hearing problems
- stuffy nose or runny nose
- reduced tear fluid (which can be a problem if you wear contact lenses)
- Inflammation of the liver, which can cause yellowing of the skin or the whites of the eyes
- changes in blood test results
- allergy-like reactions such as itching, flushing, rash. Seek medical attention immediately if you experience more severe symptoms of an allergic reaction, such as swelling of the face, neck, tongue, mouth, or throat, or breathing difficulties.
- Inability to achieve an erection
- Nightmares, hallucinations
- Fainting

Very rare (may occur in up to 1 in 10,000 people)
- Irritation and redness of the eye (conjunctivitis)
- Hair loss
- Onset or worsening of scaly skin rash (psoriasis): Psoriasis-like rash.

* If you are being treated for high blood pressure or angina, these symptoms may occur especially at the start of treatment or when your dosage is changed. They are usually mild in nature and typically disappear within 1 to 2 weeks.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb. Website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date. It can be found on the blister pack and the box after "EXP". It includes a month and a year. The last day of that month is the expiry date.
- Store below 30°C.
- Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.
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6. Contents of the package and otherinformation

What substances are in this medicine?
The active substance in this medicine is bisoprolol fumarate. Each tablet contains 2.5 mg, 5 mg, or 10 mg of bisoprolol fumarate.

The other substances in this medicine are microcrystalline cellulose, sodium starch glycolate (type A), povidone K-30, colloidal anhydrous silica, magnesium stearate (E470b), hypromellose E-15 (E464), macrogol 400 (E553), titanium dioxide (E171), talc.

What does Bisoprolol fumarate Accord look like and what is in a package?
Bisoprolol fumarate Accord 2.5 mg: white to off-white, round, biconvex film-coated tablets with the imprint 'b' and '1' on either side of the score line and plain on another side with side score.
Bisoprolol fumarate Accord 5 mg: white to off-white, round, biconvex film-coated tablets with the imprint 'b' and '2' on either side of the score line and plain on another side with score line.
Bisoprolol fumarate Accord 10 mg: white to off-white, round, biconvex film-coated tablets with the imprint 'b' and '3' on either side of the score line and plain on another side with score line.

Pack sizes of 20, 28, 30, 50, 56, 60, 90, and 100 tablets per box are registered for all strengths.

Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder:
Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
Netherlands

Manufacturer:
Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50, 95-200 Pabianice, Poland
Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
Netherlands

Accord Healthcare single member
S.A. 64th Km National Road
Athens, Lamia, Schimatari, 32009,
Greece

Registered under:
Bisoprolol fumarate Accord 2.5 mg film-coated tablets: RVG 108798
Bisoprolol fumarate Accord 5 mg film-coated tablets: RVG 108799. Bisoprolol fumarate Accord 10 mg film-coated tablets: RVG 108800.

This medicine is registered in member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

name of the member state	Name of the medicine
Austria	Bisoprolol Accord 2.5mg/5 mg/ 10mg Film-coated tablets
France	Bisoprolol Accord Healthcare 2.5/5/10 mg tablet film-coated scored
Italy	Bisoprolol Accord Healthcare 2.5mg/5mg/10mg tablets coated with film
Portugal	Bisoprolol Accord 5 mg/10 mg tablet coated with film
Netherlands	Bisoprolol fumarate Accord 2.5 mg/5 mg/10 mg film-coated tablets
United Kingdom (NI)	Bisoprolol 2.5mg/5mg/10mg Film-coated Tablet
Bulgaria	Bisoprolol Accord 2.5mg/5 mg/10mg film-coated tablets
Germany	Bisoprolol Accord 2.5mg/5 mg/10mg Film tablets
Estonia	Bisoprolol Accord
Finland	Bisoprolol Accord 2.5mg/5 mg/10mg film-coated tablet
Ireland	Bisoprolol 2.5mg/5 mg/10mg Film-coated tablet

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