Package leaflet: Information for the user
Bisoprolol 2.5 mg Film-coated Tablet
Bisoprolol 5 mg Film-coated Tablet
Bisoprolol 10 mg Film-coated Tablet
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 fumarate tablet is and what it is used for
2. What you need to know before you take Bisoprolol fumarate tablet
3. How to take Bisoprolol fumarate tablet
4. Possible side effects
5. How to store Bisoprolol fumarate tablet
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1. What Bisoprolol Fumarate tablet 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, Bisoprolol fumarate 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 2.5 mg, 5 mg and 10 mg tablet are used in combination with other medicines to treat stable heart failure.

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. What you need to know before you take Bisoprolol Fumarate tablet

Do not take Bisoprolol fumarate tablet if:
- You are allergic to Bisoprolol fumarate 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.

Warnings and precautions
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.

Other medicines and Bisoprolol fumarate tablet:

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).

Pregnancy, breast-feeding
<u>Pregnancy</u>

There is a risk that Bisoprolol fumarate tablet can harm the baby if it is used during pregnancy. 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. He or she will determine whether you can take Bisoprolol fumarate Tablet during pregnancy.

Breast-feeding
It is not known whether Bisoprolol fumarate passes in to breast milk. Therefore, breastfeeding is not recommended during treatment with Bisoprolol fumarate tablet.

Driving and using machines:
The ability to drive or operate machinery may be affected, depending on how well you tolerate the medicine. Be especially careful at the beginning of the treatment, when the dose is increased or when the medication is changed, and when combined with alcohol.

3. How to take Bisoprolol Fumarate tablet

Always take this medicine exactly as your doctor has told you. Check with your doctor or your pharmacist if you are not sure. Treatment with Bisoprolol fumarate tablet requires regular medical check up. This is particularly important in the initiation of therapy and during dose increase. Bisoprolol fumarate tablet should be taken in the morning, with or without food. Swallow the tablet/s whole with some water and do not chew or crush them. The tablet can be divided into equal doses. Treatment with Bisoprolol fumarate tablet is usually prolonged.

Adult:
Chest pain and high blood pressure:
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.

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

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

Heart failure:
Before you start using bisoprolol fumarate tablet, you should already be taking other medicines for heart failure including any ACE inhibitor, a diuretic and (as an added option) a cardiac glycoside.

Treatment with Bisoprolol fumarate tablet 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 fumarate once daily for a week
- 2.5 mg bisoprolol fumarate once daily for a week
- 3.75 mg bisoprolol fumarate once daily for a week
- 5 mg bisoprolol fumarate once daily for four weeks
- 7.5 mg bisoprolol fumarate once daily for four weeks
- 10 mg bisoprolol fumarate once daily for maintenance (on-going) therapy.

The maximum recommended daily dose of bisoprolol fumarate is 10 mg.

Depending on how well you tolerate the medicine, the doctor may also extend the time between dose increases. If your condition gets worse or if you no longer tolerate the drug, it may be necessary to lower the dose again or to stop treatment. For some patients a maintenance dose lower than 10 mg bisoprolol fumarate may be sufficient. Your doctor will tell you what to do. If you have to stop the treatment entirely, your doctor will usually advice you to reduce the dose gradually, as otherwise your condition may become worse.

Use in children
Bisoprolol fumarate tablet is not recommended for use in children.

Elderly patient
In general adjustment of the dose is not needed. It is recommended to start with lowest possible dose.

If you notice that the bisoprolol dose is too strong or does not work well enough, please consult your doctor or pharmacist.

If you take more Bisoprolol fumarate tablet than you should
If you take too much medicine, or if a child has swallowed the medicine by mistake ask your doctor or hospital for assessing risk and advice. Take this leaflet and any tablet you still have with you. You may feel slow heartbeat, severe breathing difficulties, dizziness or tremor (due to decreased blood sugar).

If you forget to take Bisoprolol fumarate tablet:
If you forget to take a dose, take it as soon as you remember it unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Bisoprolol fumarate tablet:
Do not stop treatment suddenly or change the recommended dose without talking to your doctor first. If you need to stop 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.

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. You can also report side effects directly via the national reporting system (see contact details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

5. How to store Bisoprolol fumarate tablet

- 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 and carton after EXP.:. The expiry date refers to the last day of that month.
- Do not store above 30ºC.
- 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 fumarate tablet contains

The active substance is bisoprolol fumarate. Each tablet contains either 2.5mg, 5mg or 10mg Bisoprolol fumarate.

The other ingredients are Cellulose microcrystalline, Sodium starch glycolate (Type-A), Povidone K-30, Silica colloidal anhydrous, Magnesium stearate(E470b), Hypromellose E-15(E464), Macrogol 400(E553), Titanium dioxide (E171), Talc.

What Bisoprolol fumarate tablet looks like and contents of the pack:
White to off white, round, biconvex, film coated tablets, debossed 'b1' on one side and break line on other side
White to off white, round, biconvex, film coated tablets, debossed 'b2' on one side and break line on other side
White to off white, round, biconvex, film coated tablets, debossed 'b3' on one side and break line on other side

Pack sizes of 20, 28, 30, 50, 56, 60, 90 and 100 tablets per pack are registered for all strengths. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare Limited
Sage House, 319, Pinner Road,
North Harrow, Middlesex
HA1 4HF, United Kingdom

Manufacturer

Accord Healthcare Limited,
Sage house, 319 Pinner road,
North Harrow, Middlesex HA1 4HF,
United Kingdom

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

ACCORD-UK LTD
WHIDDON VALLEY, BARNSTAPLE, EX32 8NS,
United Kingdom

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

Name of the Member State	Name of the medicinal product
Austria	Bisoprolol Accord 2.5mg/5 mg/ 10mg Filmtabletten
France	Bisoprolol Accord Healthcare 2,5/5/10 mg comprimé pelliculé sécable
Italy	Bisoprolol Accord Healthcare 2.5mg/5mg/10mg compresse rivestite con film
Portugal	Bisoprolol Accord 5 mg/10 mg comprimidos revestidos por película
Netherlands	Bisoprololfumaraat Accord 2,5 mg/5 mg/10 mg filmomhulde Tabletten
United kingdom	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 Filmtabletten
Estonia	Bisoprolol Accord
Finland	Bisoprolol Accord 2.5mg/5 mg/10mg kalvopäällysteinen tabletti
Ireland	Bisoprolol 2.5mg/5 mg/10mg Film-coated tablet
Latvia	Bisoprolol Accord 2.5mg/5 mg/10mg apvalkotās tabletes
Poland	Bicardiol
Sweden	Bisoprolol Accord 2.5mg/5 mg/10mg filmdragerad tablet
Slovak Republic	Bisoprolol Accord 2.5mg/5 mg/10mg filmom obalené tablety

This leaflet was last revised in 02/2020.