

Bisoprolol Fumarate 2.5 mg film-coated tablets
Bisoprolol Fumarate 3.75 mg film-coated tablets
Bisoprolol Fumarate 5 mg film-coated tablets
Bisoprolol Fumarate 7.5 mg film-coated tablets
Bisoprolol Fumarate 10 mg film-coated tablets

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 is and what it is used for
2. What you need to know before you take Bisoprolol Fumarate
3. How to take Bisoprolol Fumarate
4. Possible side effects
5. How to store Bisoprolol Fumarate
6. Contents of the pack and other information

1. What Bisoprolol Fumarate is and what it is used for

The active ingredient in this medicine is Bisoprolol fumarate. Bisoprolol fumarate belongs to group of medicines called beta-blockers. Beta-blockers protect the heart against 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 tablets are used in combination with other medicines to treat stable heart failure.
- Bisoprolol 5 mg and 10 mg tablets 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

DO NOT take Bisoprolol Fumarate if you:

- are allergic to bisoprolol fumarate or any of the other ingredients of this medicine (listed in section 6).
- have severe asthma or severe chronic lung disease
- have a slow or irregular heart rate. Ask your doctor if you are not sure
- have very low blood pressure
- have severe blood circulation problems (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue
- have heart failure that suddenly becomes worse and/ or may require hospital treatment
- Cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure.
- have excess acid in the blood, a condition known as metabolic acidosis
- have untreated phaeochromocytoma, a rare tumour of the adrenal gland (medulla)

Tell your doctor if you are not sure about any of the above: your doctor will be able to advise you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bisoprolol Fumarate. 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: if you:

- have asthma or chronic lung disease
- have diabetes.
- are fasting from solid food
- certain heart disease such as disturbance in heart rhythm or severe chest pain at rest (Prinzmetal's angina)
- have any liver or kidney problems
- have any problems with the circulation in your limbs
- have (or have had) psoriasis (a recurring skin rash)
- have phaeochromocytoma (tumour of the adrenal gland). Your doctor will need to treat this before prescribing bisoprolol for you
- have a thyroid problem. The tablets can hide symptoms of an overactive thyroid

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

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.. Certain medicines cannot be used at the same time, while other drugs require specific changes (to the dose, for example).

Do not take the following medicines with Bisoprolol Fumarate 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 "Warnings and precautions")
- 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).

It is also especially important to speak with your doctor if you are taking:

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

Bisoprolol Fumarate with food, drink and alcohol

Bisoprolol Fumarate may be taken with or without food and should be swallowed whole with a drink of water.

Pregnancy, breast-feeding and fertility

Do not take bisoprolol if you are pregnant or may be pregnant. Bisoprolol Fumarate 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.

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

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

Driving and using machines

These tablets 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 possibility of these effects, particularly at the beginning of the treatment, with changes in medication and with use in combination with alcohol.

3. How to take Bisoprolol Fumarate

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or 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 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 you should already be taking other medicines for heart failure including an ACE-inhibitor, a diuretic and (as an added option) a cardiac glycoside.

The dose of Bisoprolol Fumarate will be increased gradually until the dose that is suitable for you has been found:

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:

Adults and elderly: the recommended dose is

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: once daily 10 mg. 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 drug, 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, as otherwise your condition may become worse.

Your heart rate and blood pressure will be monitored closely as the dose is increased.

Patients with liver or kidney problems:

Your doctor will take extra care when adjusting the dose of Bisoprolol Fumarate.

Use in Children:

Bisoprolol Fumarate 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 effect of Bisoprolol Fumarate is too strong or not strong enough, please consult your doctor or pharmacist.

Duration of the treatment

Bisoprolol Fumarate will usually be used long-term.

The tablet can be divided into equal halves

If you take more Bisoprolol Fumarate 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, breathlessness 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 Bisoprolol Fumarate

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 Bisoprolol Fumarate

Treatment with Bisoprolol Fumarate must not be stopped abruptly. If you suddenly stop taking this medicine your condition may get worse. The dose of bisoprolol 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 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 (affect more than 1 patient in 10 in patient with chronic heart failure and affected less than 1 patient in 100 in patient with hypertension or angina pectoris)
- Worsening of heart failure (affects more than 1 patient in 100 in patient with chronic heart failure and affected less than 1 patient in 100 in patient with hypertension or angina pectoris)
- irregular heartbeat (affects less than 1 patient in 100)
- 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, diarrhoea, 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
- Inflammation of the lining of the nose, causing a runny nose with irritation
- Allergic reactions (itching, flushed appearance, rash)
- Dry eyes from reduced tear flow (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)
- change in blood test results
- 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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard.

5. How to store Bisoprolol Fumarate

Keep out of the sight and reach of children.

Store below 25 °C. Store in the original package in order to protect from light.

[HDPE bottle of 500 tablets]

Use within 6 months after first opening the HDPE bottle.

Do not use Bisoprolol Fumarate after the expiry date which is stated on the carton/ bottle after EXP. 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 Fumarate contains

- The active substance is bisoprolol fumarate. Each tablet contains 2.5 mg, 3.75 mg, 5 mg, 7.5 mg or 10 mg bisoprolol fumarate. The other ingredients are: Cellulose microcrystalline, calcium hydrogen phosphate anhydrous, silica colloidal anhydrous, crospovidone (Type A), magnesium stearate. *Tablet coat:* Hypromellose 6cP (E464), Titanium Dioxide (E171), Macrogol 400.

What Bisoprolol Fumarate looks like and contents of the pack

Bisoprolol Fumarate 2.5 mg film-coated tablets are white, circular, biconvex, debossed with 'P' and breakline on one side and '2' on the other side. The tablet can be divided into equal doses.

Bisoprolol Fumarate 3.75 mg film-coated tablets are white, circular, biconvex, debossed with 'P' and breakline on one side and '3' on the other side. The tablet can be divided into equal doses.

Bisoprolol Fumarate 5 mg film-coated tablets are white, circular, biconvex, debossed with 'P' and breakline on one side and '5' on the other side. The tablet can be divided into equal doses.

Bisoprolol Fumarate 7.5 mg film-coated tablets are white, circular, biconvex, debossed with 'P' and breakline on one side and '7' on the other side. The tablet can be divided into equal doses.

Bisoprolol Fumarate 10 mg film-coated tablets are white, circular, biconvex, debossed with 'P' and breakline on one side and '10' on the other side. The tablet can be divided into equal doses.

Bisoprolol Fumarate film-coated tablets are available in cold form Polyamide /Aluminum/PVC -Aluminum blisters and HDPE bottle packs.

Pack sizes:

Blister pack: 20, 28, 30, 50, 90, 100 film-coated tablets

Bottle pack: 30, 500 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Milpharm Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
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Manufacturer

APL Swift Services (Malta) Limited
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This leaflet was last revised in 05/2018.