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Package leaflet: Information for the user

Bisoprolol Fumarate 5mg and 10mg 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 Tablets are and what they are used for
2. What you need to know before you take Bisoprolol Fumarate Tablets
3. How to take Bisoprolol Fumarate Tablets
4. Possible side effects
5. How to store Bisoprolol Fumarate Tablets
6. Contents of the pack and other information

1. What Bisoprolol Fumarate Tablets are and what they are used for

These tablets contain bisoprolol fumarate. Bisoprolol belongs to a group of drugs called beta-blockers (a heart drug). Beta-blockers slow the heart rate, causing the heart to beat slowly and make the heart more efficient at pumping blood around the body.
They are used to treat:
- High blood pressure (hypertension)
- Angina pectoris (chest pain).

2. What you need to know before you take Bisoprolol Fumarate Tablets

Do not take Bisoprolol Fumarate Tablets if you:
- are allergic to bisoprolol fumarate or any of the other ingredients of this medicine (listed in section 6). The symptoms of an allergic reaction include itching, nettle rash, wheezing or swelling of the hands, throat, mouth or eyelids
- are suffering from a condition called Cardiogenic Shock – symptoms include low blood pressure, fast pulse, restlessness, thirst and cold, clammy skin
- have severe asthma or breathing problems
- have untreated heart failure (severe ankle swelling and breathlessness)
- have an irregular heart beat or a slow heart rate. Including sick sinus syndrome – a condition that causes abnormal heart rhythm or heart block – where the heart beats very slowly
- suffer from low blood pressure
- 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 severe chronic lung diseases
- have untreated phaeochromocytoma, which is a rare tumour of the adrenal gland
- have metabolic acidosis, which is a condition in which the blood is too acidic
- have wheezing or asthma.

If you think any of the above points apply to you, do not take the tablets. Talk to your doctor first and follow the advice given.

Warnings and precautions
Talk to your doctor before taking Bisoprolol Fumarate Tablets:
- if you suffer from any heart disease, including heart failure and angina (specifically Prinzmetal's angina - an uncommon form of angina pectoris that occurs at rest in cycles, typically at night)
- if you are diabetic
- if you are strict fasting
- if you have heart block, including first, second or third degree heart block or sick sinus syndrome (these are conditions where the nerve signals to the heart are disturbed, possibly causing it to occasionally skip a beat or beat irregularly)
- if you have phaeochromocytoma (a tumour near the kidney)
- if you have ever suffered from asthma, wheezing or breathing problems
- if you have kidney or liver problems
- if you have any problem with the circulation in your limbs
- if you have psoriasis – a condition in which your skin becomes red and dry and pieces of dead skin fall off
- if you are due to undergo an anaesthetic
- if you have a thyroid disorder (Bisoprolol can hide symptoms of an overactive thyroid)
- 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 such reaction may be more severe.

Other medicines and Bisoprolol Fumarate Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist if you are taking:
- certain medicines used to treat high blood pressure and angina (such as verapamil, diltiazem, nifedipine or amlodipine)
- certain medicines used to treat high blood pressure such as clonidine, methyldopa, moxonidine, rilmenidine. However, do not stop taking these medicines without checking with your doctor first
- digoxin – used to treat various heart conditions
- medicines used to treat abnormal heart rhythms (such as disopyramide, quinidine or amiodarone)
- insulin or medicines that you take by mouth for diabetes including sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide). Bisoprolol could increase the risk of severely low blood glucose levels when used with these medicines.
- anaesthetic agents (for example during surgery)
- non-steroidal anti-inflammatory drugs (NSAIDs) – used to treat pain and inflammation (such as ibuprofen or indomethacin)
- beta-blockers applied locally (such as timolol eye drops for glaucoma treatment)
- rifampicin – used to treat tuberculosis (TB)
- medicines such as adrenaline (used to increase heart rate and blood pressure) or ephedrine (found in some cold remedies)
- tricyclic antidepressants used to treat depression e.g. amitriptyline, imipramine, barbiturates, chlorpromazine, levomepromazine and Monoamine-oxidase inhibitors (MAOIs) such as phenelzine
- medicines used to treat mental problem e.g. chlorpromazine
- medicines used to treat insomnia and epilepsy e.g. barbiturates
- moxisylyte, which is used to treat circulatory problems like Raynaud's syndrome
- mefloquine, used for prevention or treatment of malaria.

Bisoprolol Fumarate Tablets with alcohol
Do not drink alcohol whilst taking Bisoprolol as it could cause your blood pressure to fall too low.

Pregnancy and breast-feeding
Do not take this medicine if you are pregnant or breast-feeding. If you are taking it and think that you may be pregnant or are planning a family, consult your doctor. Bisoprolol is not recommended if you are pregnant as it can cause you to give birth prematurely and can cause problems in the baby.

Breast-feeding is not recommended while taking Bisoprolol as it could be passed on to your baby through the milk.

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.
Some of the possible side effects listed in section 4 below could affect you when you are driving. If you feel tired, dizzy or faint, or get any muscle weakness or cramps, you should not drive.

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

3. How to take Bisoprolol Fumarate Tablets

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

Take the tablet with some water in the morning, with or without food. Do not crush or chew the tablet.

Dosage in adults
The usual dose for high blood pressure and angina (chest pain) is 10mg a day. In some patients 5mg a day may be adequate.

Elderly patients may be prescribed a lower dose. The dose should not exceed 20mg in one day. If you have severe liver or kidney problems, your doctor will prescribe a lower dose.

Use in children
Bisoprolol Fumarate Tablets should not be given to children.

If you take more Bisoprolol Fumarate Tablets than you should
An overdose of this medicine may be dangerous. If you take too many tablets, or you (or someone else) swallow a lot of the tablets together, tell your doctor or go to the nearest hospital casualty department immediately.

If you have taken too many tablets you may have a slowed heart rate, severe difficulty in breathing, feeling dizzy, or trembling (due to decreased blood sugar).

If you forget to take Bisoprolol Fumarate Tablets
If you forget to take a dose take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Bisoprolol Fumarate Tablets
Do not stop taking your tablets suddenly unless on your doctor's advice, otherwise your condition could become much worse. If your treatment is to be stopped, your doctor will gradually reduce your dose by halving it each week.

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.

Serious side effects
The most serious side effects are related to the heart function:
- slowing of heart rate (affects more than 1 person in 10)
- worsening of heart failure (affects less than 1 person in 10)
- slow or irregular heartbeat (affects less than 1 person in 100)

If you get any of the side effects shown in the list below STOP TAKING the tablets and seek medical attention:
- sudden attacks of unconsciousness
- allergic reactions such as itching or rash or swelling of the hands, feet, ankles, mouth, throat or face
- shortness of breath or wheezing
- light-headedness
- worsening of heart failure causing increased breathlessness and/or retention of fluid
- if you already have Raynaud's disease (a condition in which the fingers and toes become white, numb and painful in cold weather) or intermittent claudication (pain in the legs while walking) Bisoprolol may make these worse
- inflammation of the liver which can cause the yellowing of the skin or whites of the eyes.

Known side effects are listed below according to how frequently they may occur:
Common (may affect up to 1 in 10 people):
- tiredness, feeling weak, dizziness, headache
- feeling of coldness or numbness in hands or feet
- low blood pressure
- stomach or intestine problems such as nausea, vomiting, diarrhoea, or constipation
- oedema
- sweating.

Uncommon (may affect up to 1 in 100 people):
- interference with normal heart rate, slow pulse
- worsening heart failure
- sleep disturbances (including vivid dreams)
- depression
- breathing problems in patients with asthma or chronic lung disease
- feeling weak, muscle weakness, muscle cramps
- dizziness when standing up.

Rare (may affect up to 1 in 1,000 people):
- hearing problems
- allergic runny nose, sneezing and itching
- reduced tear flow (dry eyes), impaired vision
- inflammation of the liver which can cause yellowing of the skin or the whites of the eyes
- certain blood test results for liver function or fat levels differing from normal
- allergic reactions such as itching, redness and skin rash. 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
- impaired erection
- nightmares, hallucinations, anxiety, psychosis, confusion
- fainting
- muscle and joint ache
- blue fingers and toes
- pins and needles.

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

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bisoprolol Fumarate Tablets

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

Blister packs: Do not store above 25°C. Store your medicine in the original packaging in order to protect from light and moisture. Do not put them into another container as they might get mixed up.

Do not use this medicine after the expiry date which is stated on the pack. 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 dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bisoprolol Fumarate Tablets contains
The active substance is bisoprolol fumarate (either 5mg or 10mg). The other ingredients are mannitol (E421), microcrystalline cellulose (E460), magnesium stearate (E572), hypromellose (E464), croscarmellose sodium, titanium dioxide (E171) and macrogol 6000.

What Bisoprolol Fumarate Tablets look like and contents of the pack
The tablets are round, white, film-coated convex tablets. The 5mg tablets have “R5” printed on one side and the 10mg tablets have “R6” printed on one side. The tablets are available in packs of: 20, 28, 30, 50, 56, 98, 100 and 105 tablets. Not all pack sizes may be marketed.

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