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- 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

Uncommon (may affect up to 1 in 100 people):
- Interference with normal heart rate, slow pulse.
- 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.
- Reduced tear flow (dry eyes).
- 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.
- 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.
- Appearance or worsening of scaly skin rash (psoriasis); psoriasis-like rash.

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE BISOPROLOL FUMARATE TABLETS

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.

Keep out of the sight and reach of children.

Do not use Bisoprolol Tablets after the expiry date which is stated on the pack.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Bisoprolol Fumarate Tablets contains
The active substance is Bisoprolol fumarate (either 5 mg or 10 mg). 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 5 mg tablets have "R5" printed on one side and the 10 mg 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.

Marketing Authorisation Holder
Flamingo Phama (UK) Ltd.
1st Floor, Kirkland House, 11-15 Peterborough Road, Harrow, Middlesex,
HA1 2AX, United Kingdom.

Manufacturer
Flamingo Pharma (UK) Limited,
The Bloc, 38 Springfield Way,Anlaby, Hull, HU10 6RJ, United Kingdom.

If you would like this leaflet in a different format please contact the Marketing authorization holder as listed above.

This leaflet was last revised in 10/2026.

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PL 43461/0052

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Pharmacode Reading Direction

PACKAGE LEAFLET: INFORMATION FOR THE USER

Bisoprolol Fumarate 5 mg and 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 Tablet is and what it is 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 TABLET IS AND WHAT IT IS USED FOR

The active substance in this medicine is Bisoprolol fumarate. Bisoprolol belongs to a group of drugs called beta- blockers (a heart drug). These medicines work by affecting the body`s response to some nerve impulses, especially in the heart. Beta-blockers slow down the heart rate and make 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 needs. Bisoprolol 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).
Bisoprolol tablets are also used to treat high blood pressure (hypertension) and 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 (hypersensitive) to bisoprolol or any of the other ingredients of this medicine (listed in section 6).
- Have severe asthma or breathing problems.
- 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 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.

Do not take bisoprolol if you have one of the following heart problems:
- acute heart failure
- worsening heart failure requiring injection of medicines into a vein, that increase the force of contraction of the heart
- slow heart rate
- low blood pressure
- certain heart conditions 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:
If you have any of the following conditions tell your doctor before taking these tablets; he or she may want to take special care (for example give additional treatment or perform more frequent checks):
- diabetes
- strict fasting
- first degree heart block (a condition in which nerve signals to the heart are disturbed, possibly causing it occasionally to skip a beat, or beat irregularly)
- phaeochromocytoma (tumour of the adrenal gland)
- chronic lung disease or less severe asthma
- Prinzmetal's angina (disturbances in heart rhythm, or severe chest pain at rest)
- kidney or liver problems
- less severe blood circulation problems in your limbs

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• psoriasis – history of a scaly skin rash
• thyroid disorder (bisoprolol can hide symptoms of an overactive thyroid).

In addition, tell your doctor if you are going to have:
• desensitization 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.
• anaesthesia (for example for surgery), because bisoprolol may influence how your body reacts to this situation.

If you have chronic lung disease or less severe asthma please inform your doctor immediately if you start to experience new difficulties in breathing, cough, wheezing after exercise, etc. when using bisoprolol.

Children and Adolescents
Bisoprolol is not recommended for use in children or adolescents.

Other medicines and Bisoprolol Fumarate tablets
Tell your doctor before taking, have recently taken or might take any other medicine.
Do not take the following medicines with bisoprolol 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 bisoprolol; 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 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).
• Monoamine oxidase inhibitors (MAOIs) such as moclobemide – used to treat depression.
• Medicines 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. glibenclamide, gliquidone, gliclazide, 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 arthritis, pain and inflammation (such as ibuprofen or diclofenac).
• Beta-blockers applied locally (such as timolol eye drops for glaucoma treatment).
• Mefloquine, used for prevention or treatment of malaria.
• Digitalis, used to treat heart failure.
• 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 characterized by a loss of contact with reality (phenothiazines such as levomepromazine).

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
Pregnancy
There is a risk that use of bisoprolol during pregnancy may harm the baby. If you are pregnant or planning to become pregnant, tell your doctor. He or she will decide whether you can take Bisoprolol during pregnancy.
Breast-feeding
It is not known whether bisoprolol passes into human breast milk. Therefore, breastfeeding is not recommended during therapy with bisoprolol.

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.

Bisoprolol fumarate tablet is 'sodium-free'
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 Bisoprolol Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Treatment with bisoprolol 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.
Treatment with bisoprolol is usually long-term.

High blood pressure/angina pectoris:
Adults
The dose is determined individually. The recommended starting dose is 5 mg once daily. The usual dose for adults is once daily 10 mg. Your doctor may decide to increase or decrease the dose. The maximum dose is once daily 20 mg.

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

Elderly
Normally no dosage adjustment is required. Your doctor will start therapy with the lowest possible dose.

Heart Failure:
Adults including the elderly
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 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 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.

Children and Adolescents
Bisoprolol Tablets are not recommended for use in children and adolescents.

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 if 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, but do not take two doses at the same time. Take your usual dose the next morning.

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, these tablets can cause side effects, although not everybody gets them.
To prevent serious reactions, speak 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)
• worsening of heart failure (may affect up to 1 in 10 people).
• slow or irregular heartbeat (may affect up to 1 in 100 people)

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):