

Consumer Medicine Information

BOSVATE

Bisoprolol fumarate

Bosvate 2.5 mg, 5 mg, 10 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start using Bosvate Tablets.

This leaflet answers some common questions about Bosvate Tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Bosvate Tablets against the benefits they expect it will have for you.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Bosvate is used for

The active substance in this medicine is bisoprolol fumarate. Bisoprolol fumarate belongs to a group of medicines called beta-blockers. These medicines work by affecting the body's response to some nerve impulses, especially in the heart. As a result, bisoprolol 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 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).
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Before you use Bosvate

When you must not use it

Do not take Bosvate Tablets if one of the following conditions applies to you:

- allergic (hypersensitive) to bisoprolol fumarate or any of the other ingredients of bisoprolol fumarate tablets.
- severe asthma or severe chronic lung disease.
- 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.
- untreated phaeochromocytoma, which is a rare tumour of the adrenal gland.
- metabolic acidosis, which is a condition when there is too much acid in the blood.

Do not take Bosvate Tablets 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.

Before you start to use it

Take special care with Bosvate Tablets:

If you have any of the following conditions tell your doctor before taking this medicine; he or she may want to take special care (for example give additional treatment or perform more frequent checks):

- diabetes.
- strict fasting.
- certain heart diseases such as disturbances in heart rhythm, or severe chest pain at rest (Prinzmetal's angina).
- kidney or liver problems.
- less severe blood circulation problems in your limbs.
- less severe asthma or chronic lung disease.
- history of a scaly skin rash (psoriasis).
- tumour of the adrenal gland (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 may make it more likely that you experience an allergic reaction, or such reaction may be more severe.
- anaesthesia (for example for surgery), because this medicine may influence how your body reacts to this situation.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Do not take the following medicines with Bosvate Tablets 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 Bosvate Tablets; your doctor may need to check your condition more frequently:

- Certain medicines used to treat high blood pressure or angina or abnormal heart beat (dihydropyridine-derivative calcium antagonists such as nifedipine).
- 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 irregular or abnormal heartbeat (Class III antiarrhythmic medicines such as amiodarone).
- Beta-blocking agents applied locally (such as timolol eye drops for glaucoma treatment).
- 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).
- Antidiabetic medicines including insulin.
- Anaesthetic agents (for example during surgery).
- Digitalis, used to treat heart failure.
- Non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain or inflammation (for example ibuprofen or diclofenac).
- 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).
- Moxisylate, used for treatment raynauds disease (poor circulation which makes toes and fingers numb and pale).
- Mefloquine, used for prevention or treatment of malaria.
- Depression treatment medicines called monoamine oxidase inhibitors (except MAO-B inhibitors) such as moclobemide.

How to use Bosvate

Always take Bosvate Tablets exactly as your doctor has told you. You should check with your doctor or your pharmacist if you are not sure. Bosvate Tablets should be

taken in the morning, before, with or after breakfast. Swallow the tablet/s whole with some water and do not chew or crush them.

This treatment should be initiated by a specialist in cardiology or internal medicine.

Children under 12 years and adolescents: Bosvate Tablets are not recommended for use in children

Stable chronic 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 fumarate.

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.

Renal or liver disease:

The dosage should be increased very gradually and cautiously in patients with severe kidney or liver problems

While you are using Bosvate

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Bosvate Tablets.

If you forget to take Bosvate Tablets:

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 Bosvate Tablets:

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 product, ask your doctor or pharmacist.

Things to be careful of

Taking Bosvate Tablets with food and drink:

Bosvate Tablets should be taken in the morning, before, with or after breakfast. They should be swallowed whole with liquid and should not be chewed or crushed.

Avoid drinking excessive alcohol, since it may increase the blood pressure-lowering effect of bisoprolol. Avoid drinking alcohol altogether, if it makes you more dizzy or more light-headed than usual.

Pregnancy and breast-feeding:

There is a risk that use of Bosvate Tablets 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 this medicine during pregnancy. It is not known whether bisoprolol passes into human breast milk. Therefore, breastfeeding is not recommended during therapy with Bosvate Tablets.

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.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital. Take this leaflet and any tablets you still have with you. Your doctor will decide what measures are necessary.

Symptoms of an overdose may include slowed heart rate, severe difficulty in breathing feeling dizzy, or trembling (due to decreased blood sugar).

Side Effects

Like all medicines, Bosvate 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 (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 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:

Very common:	affects more than 1 user in 10
Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare:	affects less than 1 user in 10,000

Common (affects less than 1 person in 10):

- 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 (affects less than 1 person in 100):

- sleep disturbances
- depression
- dizziness when standing up
- breathing problems in patients with asthma or chronic lung disease
- muscle weakness, muscle cramps.

Rare (affects less than 1 person in 1,000):

- hearing problems
- allergic runny nose
- reduced tear flow
- inflammation of the liver which can cause yellowing of the skin or 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
- impaired erection
- nightmares, hallucinations.

Very rare (affects less than 1 person in 10,000):

- irritation and redness of the eye (conjunctivitis)

- hair loss
- appearance or worsening of scaly skin rash (psoriasis); psoriasis-like rash.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

After using Bosvate

Storage

Keep out of the reach and sight of children.

Do not use Bosvate Tablets after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light. This medicinal product does not require any special temperature storage conditions.

Disposal

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.

Product description

What it looks like

2.5 mg: White to off white round biconvex tablets with a break line on one side.

5 mg: White to off white round biconvex tablets with a break line on one side.

10 mg: White to off white round biconvex tablets with a break line on one side.

The tablets can be divided into equal halves.

Pack sizes of 30 and 90 tablets. Not all pack sizes may be marketed.

Ingredients

Active ingredient(s):

Each 2.5 mg tablet contains 2.5 mg bisoprolol fumarate.

Each 5 mg tablet contains 5 mg bisoprolol fumarate.

Each 10 mg tablet contains 10 mg bisoprolol fumarate.

Inactive ingredients:

The other ingredients are microcrystalline cellulose, silica colloidal anhydrous, croscarmellose sodium, sodium starch glycolate (type A) and magnesium stearate.

Sponsor Details

Bosvate Tablets are supplied in New Zealand by:

Douglas Pharmaceuticals Limited
PO Box 45 027
Auckland 0651
NEW ZEALAND

ph: (09) 835 0660

Date of Preparation

This leaflet was prepared on 4th October 2011.