

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **BISOPROLOL TABLETS**

Bisoprolol Fumarate Tablets

Read this carefully before you start taking BISOPROLOL TABLETS and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about BISOPROLOL TABLETS.

What is BISOPROLOL TABLETS used for?

BISOPROLOL TABLETS is used to treat hypertension (high blood pressure) and heart failure. It is usually used in combination with other drugs to control blood pressure.

How does BISOPROLOL TABLETS work?

Bisoprolol belongs to the group of drugs called "beta-blockers". BISOPROLOL TABLETS decreases blood pressure and reduces how hard the heart has to work.

BISOPROLOL TABLETS can help to reduce heart failure episodes needing hospitalization and the risk of sudden death.

What are the ingredients in BISOPROLOL TABLETS?

Medicinal ingredients: Bisoprolol fumarate

Non-medicinal ingredients: calcium hydrogen phosphate, colloidal anhydrous silica, croscarmellose sodium, hypromellose, lactose monohydrate, macrogol (polyethylene glycol), maize starch (pregelatinised), magnesium stearate, microcrystalline cellulose, red ferric oxide (10 mg only), titanium dioxide and yellow ferric oxide (5 mg and 10 mg only).

BISOPROLOL TABLETS comes in the following dosage forms:

1.25 mg, 2.5 mg, 5 mg, 10 mg tablets

Do not use BISOPROLOL TABLETS if you:

- are allergic to bisoprolol,-any of the non-medicinal ingredients or to another beta-blocker;
- have severe drops in blood pressure, dizziness, fast heartbeat, rapid and shallow breathing, cold clammy skin (signs of a heart disorder called cardiogenic shock);
- have a slow or irregular heartbeat or have been told you have heart block;
- have heart failure and your symptoms are getting worse. For example you feel more tired, more out of breath or have swollen ankles;
- have low blood pressure;
- have severe asthma or a history of difficulty breathing with wheezing or coughing (chronic obstructive lung disease);
- have leg numbness or weakness or painful cramping your feet and legs after walking or climbing stairs (peripheral arterial occlusive disease);

- have numbness, tingling and color change in fingers and toes when exposed to the cold (Raynaud's syndrome);
- have non-treated tumour of the adrenal gland (phaeochromocytoma);
- have abnormally high levels of acid in the blood (metabolic acidosis);
- have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption, because BISOPROLOL TABLETS contain lactose.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BISOPROLOL TABLETS. Talk about any health conditions or problems you may have, including if you:

- are pregnant or plan to become pregnant;
- are breastfeeding;
- have asthma, difficulty breathing, bronchitis, emphysema, or other lung problems;
- have shortness of breath, fatigue, weakness, swelling in legs, ankles and feet, persistent cough;
- have Prinzmetal angina or variant angina;
- have diabetes;
- have any allergic conditions;
- have psoriasis, a skin disease with thickened patches of red skin, often with silvery scales;
- have hyperthyroidism, an over active thyroid gland;
- have any blood vessel disorder causing poor circulation in the arms and legs;
- have kidney problems;
- have liver problems;
- have phaeochromocytoma, a rare tumour of the adrenal gland;
- visit more than one healthcare professional. Make sure each knows about all the medicines you are taking, including ones you can buy without a prescription, especially diuretics (water pills), cold remedies, nasal decongestants and other heart or blood pressure medication;
- are having surgery. Tell your healthcare professional that you are taking BISOPROLOL TABLETS.

Other warnings you should know about:

Stopping treatment with BISOPROLOL TABLETS

You should keep taking BISOPROLOL TABLETS until your healthcare professional tells you to stop. Your healthcare professional will tell you to slowly stop taking it over a two week period if and when it is time for you to stop.

Blood Tests

Your healthcare professional will order regular blood tests for you while you are taking BISOPROLOL TABLETS. The blood tests will help monitor your blood cells, kidneys and liver.

Driving and using machines

Know how you feel while taking BISOPROLOL TABLETS before you drive or use heavy machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BISOPROLOL TABLETS:

- calcium channel blockers, medicines used to treat high blood pressure and angina such as diltiazem, verapamil and amlodipine;
- clonidine, a medicine used to treat high blood pressure;
- monoamine oxidase inhibitors, medicines used to treat depression such as phenelzine, tranylcypromine;
- anti-arrhythmic drugs used to treat irregular or abnormal heartbeat such as flecainide, amiodarone, disopyramide;
- certain medicines, known as NSAIDs used to treat arthritis, pain or inflammation such as indomethacin or ibuprofen;
- other beta-blockers, including eye drops;
- insulin and oral drugs for diabetes;
- anaesthetic agents used in surgery;
- digoxin, a medicine used to treat heart failure;
- ergot derivatives, medicines commonly used to treat migraines;
- tricyclic antidepressants;
- barbiturates, medicines used to treat epilepsy;
- phenothiazines, a type of medicine used to treat some mental conditions;
- rifampicin, a medicine used to treat tuberculosis;
- mefloquine, a medicine used to treat malaria;
- adrenaline, a medicine used to treat allergic reactions;
- fingolimod, a medicine to treat multiple sclerosis.

How to take BISOPROLOL TABLETS:

Take BISOPROLOL TABLETS exactly as your healthcare professional tells you. Do not miss doses or take extra doses, unless your healthcare professional tells you. If you are not clear about the directions, ask your healthcare professional.

- BISOPROLOL TABLETS is taken once daily.
- BISOPROLOL TABLETS may have been prescribed along with other medications to help control your particular health condition. Make sure you take these medications as prescribed.
- It is important you take BISOPROLOL TABLETS at about the same time every day.
- Do not chew or crush the tablets.

Usual dose:

Treatment of high blood pressure: The usual starting dose is 2.5 mg to 5 mg once daily, with a diuretic or alone. If well tolerated, your healthcare professional will gradually increase your dose

over the next 2 weeks, depending how you respond to the drug. The usual effective dosage range is 2.5 mg to 20 mg once daily. The maximum recommended dose is 20 mg, once daily.

Treatment of heart failure: The usual starting dose is 1.25 mg once daily for one week. If well tolerated, your healthcare professional will gradually increase your dose over the next ten weeks, depending on how you respond to the drug. The usual dose for maintenance therapy is 10 mg once daily. The maximum recommended dose is 10 mg, once daily

Overdose:

If you think you have taken too much BISOPROLOL TABLETS, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed.

What are possible side effects from using BISOPROLOL TABLETS?

These are not all the possible side effects you may feel when taking BISOPROLOL TABLETS. If you experience any side effects not listed here, contact your healthcare professional.

Common side effects:

- headache;
- fatigue, tiredness or exhaustion;
- urinary tract infection;
- rhinitis or sinusitis (inflammation in the nose);
- diarrhea or constipation;
- dizziness;
- joint pain;
- cough;
- insomnia (trouble sleeping), sleep disturbances, nightmares;
- nausea (feeling like vomiting);
- sore throat;
- coldness or numbness in the hands or feet.

These are mild side effects of the medicine, and are short-lived.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			

Allergic Reactions: skin reactions such as rash, itching, worsening of psoriasis			√
Depression		√	
Difficulty breathing: shortness of breath, stuffy nose, wheezing			√
Difficulty hearing	√		
Dizziness or lightheadedness (sometimes with fainting), especially on standing up, which may be due to low blood pressure			√
Hallucinations		√	
Muscular weakness or cramps	√		
Peripheral edema (swelling of the ankles)		√	
Very slow heart beat		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Keep BISOPROLOL TABLETS out of sight and reach of children.
- BISOPROLOL TABLETS should be stored between 15°C and 25°C.
- Do not give BISOPROLOL TABLETS to other patients because it may not be suitable for them.

If you want more information about BISOPROLOL TABLETS:

- Talk to your healthcare professional;
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website

(<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) the manufacturer's website www.sivem.ca, or by calling 1-855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC.

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