

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

#### **PrBYSTOLIC®**

#### **nebivolol tablets**

Read this carefully before you start taking **BYSTOLIC** 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 **BYSTOLIC**.

#### **What is BYSTOLIC used for?**

- BYSTOLIC is used to treat high blood pressure (also known as hypertension) in adults.
- It can be used alone or with other medicines.

#### **How does BYSTOLIC work?**

BYSTOLIC belongs to a group of medicines called “beta blockers.”

- It makes your heartbeat more slowly and less forcefully.
- It lowers your blood pressure by relaxing your blood vessels so that your blood flows more easily.

This medicine does not cure your disease but helps to control it.

#### **What are the ingredients in BYSTOLIC?**

Medicinal ingredients: Nebivolol (as nebivolol hydrochloride).

Non-medicinal ingredients: Colloidal silicon dioxide, croscarmellose sodium, D&C Red #27 Lake (10 mg and 20 mg only), FD&C Blue #2 Lake, FD&C Yellow #6 Lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, polysorbate 80, and sodium lauryl sulfate.

#### **BYSTOLIC comes in the following dosage forms:**

Tablets: 2.5 mg (light blue), 5 mg (beige), 10 mg (pinkish-purple) and 20 mg (light blue)

#### **Do not use BYSTOLIC if:**

- You are allergic to nebivolol or any of the other ingredients in BYSTOLIC.
- You have heart failure and you notice that your symptoms are getting worse. For example, you feel more tired, are out of breath more often, or have swelling of the ankles.

- You have severe heart damage and your heart is not able to pump enough blood to meet your body's needs.
- You have a slow or irregular heartbeat.
- You have an abnormal heart rate or rhythm.
- You have a problem with your heart's electrical conduction (that causes you to have chest pain, difficulty breathing, nausea, fatigue and fainting).
- You have severe liver disease.
- You have serious problems with blood flow in your feet and legs (peripheral artery disease).
- You have one of the following rare hereditary diseases:
  - Galactose intolerance
  - Lapp lactase deficiency
  - Glucose-galactose malabsorption
- You are 18 years and younger.

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

- Have asthma or other lung problems (like bronchitis or emphysema).
- Have a history of heart problems.
- Have a history of fainting.
- Have diabetes and take medicine to control your blood sugar or have low blood sugar (hypoglycemia).
- Have a condition called pheochromocytoma (a tumour of the adrenal gland).
- Have thyroid problems.
- Have liver or kidney problems.
- Have had allergic reactions or have allergies.
- Are pregnant or trying to become pregnant.
- Are breastfeeding or planning to breastfeed.
- Are scheduled for surgery and will be given an anesthetic.

**Other warnings you should know about:**

**Do not** stop taking BYSTOLIC suddenly. This could cause chest pain or a heart attack. If your healthcare professional decides that you should stop taking BYSTOLIC, your dose may be reduced so that you need to use less and less before you stop the medication completely.

**Driving and using machines:** BYSTOLIC may cause light-headedness, dizziness or fainting. Before doing tasks that require special attention, wait until you know how you respond to BYSTOLIC.

**Pregnancy:** BYSTOLIC is not usually recommended for use during pregnancy. It may harm an unborn baby. Your healthcare professional will decide if the benefits of taking BYSTOLIC

outweigh the potential risks to your baby. If you discover that you are pregnant while taking BYSTOLIC, tell your healthcare professional **right away**.

**Breastfeeding:** It is not known if BYSTOLIC can pass into breast milk and harm a breastfed baby. You and your healthcare professional should decide if you will take BYSTOLIC or breastfeed. You should not do both.

**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 BYSTOLIC:**

- Medicines used for lowering blood pressure:
  - Angiotensin-Converting Enzyme (ACE) inhibitors (such as lisinopril)
  - Calcium channel blockers (such as verapamil and diltiazem)
  - Clonidine
- Medicines used to treat depression and mood disorders (such as fluoxetine, paroxetine, and venlafaxine)
- Anesthetic medicines used during surgery (such as ether and cyclopropane)
- Medicines used to treat diabetes such as insulin and oral medicines. You could become less aware of the symptoms of low blood sugar.
- Medicines used to treat heartburn and ulcers (such as cimetidine)
- Antidiuretic medicines used to reduce the fluid build-up in your body (such as hydrochlorothiazide, furosemide and spironolactone)
- Sildenafil, used to treat erectile dysfunction or high blood pressure in the lungs
- Medicines used to treat HIV/AIDS
- Medicines used to treat heart rhythm disorders (such as amiodarone, disopyramide, flecainide, propafenone, digoxin)
- Dexamethasone, used to treat inflammation
- Rifampin, used to treat tuberculosis
- Fingolimod, used to treat multiple sclerosis

**How to take BYSTOLIC:**

Take BYSTOLIC:

- Exactly as prescribed
- Everyday
- Once a day, at about the same time each day
- With or without food

**Usual dose:**

Starting daily dose: 5 mg once a day

Maximum daily dose: 20 mg once a day

Your healthcare professional may:

- start you on a different dose or change your dose over time depending on how BYSTOLIC works for you.
- add another medicine like a diuretic (water pill) or an ACE inhibitor for you to take along with BYSTOLIC to treat your high blood pressure.

**Do NOT** stop taking BYSTOLIC or change your dose without consulting your healthcare professional. This can be dangerous.

**Overdose:**

If you think you, or a person you are caring for, have taken too much BYSTOLIC, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you have forgotten to take your dose, carry on and take your next dose at the usual time. **Do NOT** double the dose.

**What are possible side effects from using BYSTOLIC?**

These are not all the possible side effects you may have when taking BYSTOLIC. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Cough
- Diarrhea
- Dizziness
- Dry mouth
- Headache
- Joint and back pain
- Nausea
- Stuffy nose and colds
- Tiredness
- Trouble sleeping

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	
<b>COMMON</b>			
<b>Bradycardia</b> (abnormally slow heartbeat): feeling dizzy or fainting		✓	
<b>Chest pain</b>			✓
<b>UNCOMMON</b>			
<b>Allergic reactions:</b> rash, swelling of the lips, face or neck, difficulty breathing or speaking			✓
<b>Myocardial infarction</b> (heart attack): chest pain, squeezing or pressure, fast or irregular heartbeat, nausea, trouble breathing, sweating			✓
<b>Heart conduction disorders</b> (problems with the electrical system that controls the heart's rate and rhythm): feeling lightheaded, dizzy, or passing out			✓
<b>Hypotension</b> (low blood pressure): dizziness or lightheadedness leading to fainting can occur when changing positions, for example from lying down to standing up		✓	
<b>Irregular heartbeat or heart palpitations</b> (skipped beats)		✓	
<b>Peripheral edema</b> (swelling of the legs or hands caused by fluid retention): swollen or puffy legs or hands, feeling heavy, achy or stiff.		✓	
<b>Memory problems:</b> memory loss, absentmindedness		✓	
<b>Dyspnea</b> (shortness of breath)		✓	
<b>Skin reactions:</b> rash	✓		
<b>Vision problems:</b> double vision, blurred vision, loss of vision, dry eyes	✓		

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

- Store at room temperature (15 to 30 °C).
- Protect from light.
- Keep out of reach and sight of children.

### If you want more information about BYSTOLIC:

- 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: ([www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html](http://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html)); the manufacturer's website [www.abbvie.ca](http://www.abbvie.ca), or by calling 1-888-704-8271.

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