

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

### PART III : PATIENT MEDICATION INFORMATION

#### Pr LABETALOL HYDROCHLORIDE INJECTION USP

##### **Labetalol Hydrochloride Injection**

You or your caregiver should read this carefully before you are given Labetalol Hydrochloride Injection USP. 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 Labetalol Hydrochloride Injection USP.

##### **What is Labetalol Hydrochloride Injection USP used for?**

Labetalol Hydrochloride Injection USP is used in the hospital for the emergency treatment of very high blood pressure. It is given to you when your blood pressure needs to be lowered quickly.

##### **How does Labetalol Hydrochloride Injection USP work?**

Labetalol Hydrochloride Injection USP is a fast acting blood pressure lowering medication that belongs to a group of drugs called “beta-blockers”. They work by:

- making your heart beat more slowly and less forcefully, and
- lowering your blood pressure by relaxing your blood vessels so that your blood flows more easily.

##### **What are the ingredients in Labetalol Hydrochloride Injection USP?**

Medicinal ingredient: labetalol hydrochloride

Non-medicinal ingredients: Dextrose anhydrous 45 mg, disodium edetate 0.1 mg; methylparaben 0.08% (w/v) and propylparaben 0.01% (w/v) as preservatives and citric acid monohydrate and/or sodium hydroxide to adjust pH and water for injection.

##### **Labetalol Hydrochloride Injection USP comes in the following dosage forms:**

Solution for Injection: 5 mg/mL.

##### **Labetalol Hydrochloride Injection USP will not be used if you:**

- Are allergic or hypersensitive to labetalol hydrochloride or to any of the other ingredients in Labetalol Hydrochloride Injection USP.
- 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.
- Have severe heart damage and your heart is not able to pump enough blood to meet your body’s needs.
- Have a slow or irregular heartbeat.

- Have a problem with your heart’s electrical conduction (that causes you to have chest pain, difficulty breathing, nausea, fatigue and fainting).
- Have asthma or other lung problems (like bronchitis or emphysema).
- Have serious problems with blood flow in your feet and legs (severe peripheral artery disease).
- Are less than 18 years old.

**To help avoid side effects and ensure proper use, you or your caregiver should talk to your healthcare professional before you are given Labetalol Hydrochloride Injection USP. You or your caregiver should talk about any health conditions or problems you may have, including if you:**

- 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 problems.
- Have had allergic reactions or have allergies.
- Are pregnant or trying to become pregnant. Labetalol Hydrochloride Injection USP is not usually recommended for use during pregnancy. Your doctor will consider the benefit to you versus the risk to your unborn baby.
- Are breastfeeding. You should not breastfeed while using Labetalol Hydrochloride Injection USP.
- Are scheduled for surgery and will be given an anesthetic.
- Develop a skin rash while taking Labetalol Hydrochloride Injection USP.

**You or your caregiver should 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 Labetalol Hydrochloride Injection USP:**

- Drugs used to treat high blood pressure, such as:
  - Diuretics (“water pills”)
  - ACE inhibitors
  - Calcium channel blockers (e.g. diltiazem, verapamil)
- Anesthetic drugs used during surgery (e.g. halothane)
- Drugs used to prevent angina (e.g. nitroglycerin)
- Drugs used to treat heartburn and stomach ulcers (e.g. cimetidine)
- Drugs used to treat depression (e.g. tricyclic antidepressants)
- Drugs used to treat Multiple Sclerosis (e.g. fingolimod)

**How Labetalol Hydrochloride Injection USP is given:**

You should **only** be given Labetalol Hydrochloride Injection USP:

- If you are in a hospital or clinic that has the proper monitoring and support equipment

- By a healthcare professional that has been specifically trained in the use of intravenous anti- hypertensives

**Adult dose:** Your healthcare professional will decide the best dose for you. It will depend on:

- your age
- your weight
- your health
- the severity of your hypertension
- previous therapy and how you respond during treatment
- Labetalol Hydrochloride Injection USP is given to you as an injection. It is injected directly into your vein (intravenously). It may be given to you as a:
  - Repeated intravenous injection, or
  - Slow continuous infusion

#### During treatment

- You should be kept lying on your back during treatment. This is because you may experience a considerable drop in your blood pressure while you are standing.

#### After treatment

- Your doctor will monitor you to see if you can tolerate standing.

#### **For elderly patients and patients with liver problems:**

Smaller doses are generally used in older patients, and those with liver problems.

#### **Overdose:**

If you think you have been given too much Labetalol Hydrochloride Injection USP, tell your healthcare professional, the hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

#### **What are possible side effects from using Labetalol Hydrochloride Injection USP?**

These are not all the possible side effects you may feel when taking Labetalol Hydrochloride Injection USP. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

Side effects may include:

- Dizziness
- Headache
- Nausea/Vomiting
- Tiredness

| 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>   |                                      |              |   |
| <ul style="list-style-type: none"> <li><b>Hypotension (low blood pressure):</b> dizziness or lightheadedness leading to fainting can occur when changing positions, for example from lying down to standing up</li> </ul> |                                      | √            |   |
| <ul style="list-style-type: none"> <li><b>Chest pain</b></li> </ul>   |                                      |              | √   |
| <b>UNCOMMON</b>   |                                      |              |   |
| <ul style="list-style-type: none"> <li><b>Bradycardia:</b> decreased heart rate that causes you to be dizzy or faint</li> </ul>   |                                      | √            |   |
| <ul style="list-style-type: none"> <li><b>Allergic reactions:</b> rash, swelling of the lips, face or neck, difficulty breathing or speaking</li> </ul>   |                                      |              | √   |
| <ul style="list-style-type: none"> <li><b>Congestive heart failure:</b> irregular heartbeat, low heart rate, or other changes in heart symptoms</li> </ul>  |                                      | √            |   |
| <ul style="list-style-type: none"> <li>Narrowing of the airways (<b>bronchospasm</b>) or other lung</li> </ul>  |                                      | √            |   |
| <ul style="list-style-type: none"> <li><b>Liver disorders:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite</li> </ul>   |                                      |              | √   |
| <b>UNKNOWN FREQUENCY</b>  |                                      |              |   |
| <ul style="list-style-type: none"> <li><b>Lupus-like syndrome:</b> joint pain, muscle pain, chest pain when you cough or breathe, breathing difficulties (shortness of breath or labored breathing)</li> </ul>            |                                      | √            |   |

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:

Labetalol Hydrochloride Injection USP will be stored by your healthcare professional, hospital, or clinic.

### If you want more information about Labetalol Hydrochloride Injection USP:

- 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.pfizer.ca](http://www.pfizer.ca) or by calling **1-800-463-6001**.

This leaflet was prepared by:

Pfizer Canada ULC

Kirkland, Québec H9J 2M5

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