

## **PATIENT MEDICATION INFORMATION**

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

#### **PrMETOPROLOL**

##### **Metoprolol Tartrate Tablets**

#### **PrMETOPROLOL – L**

##### **Metoprolol Tartrate Film-Coated Tablets**

Read this carefully before you start taking **METOPROLOL / METOPROLOL – L** 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 **METOPROLOL / METOPROLOL – L**.

#### **What is METOPROLOL / METOPROLOL – L used for?**

METOPROLOL / METOPROLOL – L is used in adults for the following conditions:

- to treat high blood pressure (mild or moderate hypertension). It can be used alone or with other medicines.
- to treat chest pain (angina pectoris) caused by narrowed heart arteries
- to help prevent another heart attack (myocardial infarction)

#### **How does METOPROLOL / METOPROLOL – L work?**

METOPROLOL / METOPROLOL – L belongs to a group of medicines known as “beta-blockers”. It works by blocking the effects of certain hormones, such as adrenaline. This causes your heart to beat more slowly and with less force.

#### **What are the ingredients in METOPROLOL / METOPROLOL – L?**

Medicinal ingredients: metoprolol tartrate.

Non-medicinal ingredients:

METOPROLOL: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

METOPROLOL – L 50 mg: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D & C Red # 30 Aluminum Lake 30%, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose and polyethylene glycol, Sunset Yellow Aluminum Lake 40% and titanium dioxide.

METOPROLOL – L 100 mg: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl methylcellulose, Indigotine Aluminum Lake 12-14% (Blue #2), lactose monohydrate, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol and titanium dioxide.

**METOPROLOL / METOPROLOL – L comes in the following dosage forms:**

Tablets, 25, 50 and 100 mg

Film-Coated Tablets, 50 and 100 mg

**Do not use METOPROLOL / METOPROLOL – L if:**

- you are allergic to metoprolol tartrate or to any other ingredients in METOPROLOL / METOPROLOL – L.
- you are allergic to other beta-blockers.
- you have the following heart or blood vessel problems:
  - bradycardia (abnormally slow heart beat)
  - sick sinus syndrome (heart's natural pacemaker is unable to create normal heartbeats at the normal rate)
  - second or third degree heart block (a type of irregular heart beat and rhythm)
  - right ventricular failure (right side of the heart is not pumping normal amounts of blood to the lungs)
  - heart failure (heart does not pump blood as well as it should)
  - cardiogenic shock (heart is unable to pump enough blood to the organs of the body)
  - severe peripheral arterial disorder (arteries are narrowed which reduces blood flow to your limbs)
- you are receiving anesthesia and are taking medicines that can affect your heart.
- you have a condition known as pheochromocytoma (a tumour in the adrenal gland) and are not being treated with an alpha-blocker.
- you have had a heart attack and also have any of the following:
  - a heart rate of less than 45 beats per minute
  - second or third degree heart block (a type of irregular heart beat and rhythm)
  - systolic blood pressure less than 100 mmHg
  - moderate to severe heart failure

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

- have Prinzmetal's angina (a type of chest pain)
- have blood vessel problems (e.g., peripheral arterial disorder)
- have problems with your heart or had a heart attack
- have an overactive thyroid gland (hyperthyroidism)
- have high or low levels of sugar in the blood (diabetes), and are receiving insulin or other medicines to control blood sugar
- have problems with your liver or kidneys are at risk for allergic reactions
- have asthma or a history of breathing problems (such as wheezing and shortness of breath)
- are under 18 years old or are elderly.

**Other warnings you should know about:**

**Stopping your medication:** Do not suddenly stop taking METOPROLOL / METOPROLOL – L. This could cause chest pains or a heart attack. If your healthcare professional decides that you should stop taking METOPROLOL / METOPROLOL – L, your dose will be reduced slowly before you stop taking the medicine completely.

**Heart failure** (heart does not pump blood as well as it should): Beta-blockers, such as METOPROLOL / METOPROLOL – L, can slow your heart rate and cause heart failure, and/or low blood pressure. If you already have heart failure taking this medicine can make it worse. If you notice any signs or symptoms of a heart failure tell your healthcare professional right away. They may prescribe additional medication and will closely monitor your health.

**Bradycardia** (abnormally slow heart beat): METOPROLOL / METOPROLOL – L can cause severe sinus bradycardia. Tell your healthcare professional if this occurs. They may reduce your dose of METOPROLOL / METOPROLOL – L. They will tell you how to safely stop your treatment with METOPROLOL / METOPROLOL – L.

**Driving and using machines:** If you experience dizziness, tiredness or blurred vision during your treatment with METOPROLOL / METOPROLOL – L, do not drive, use machinery, or perform other tasks that need full attention until you know how you respond to METOPROLOL / METOPROLOL – L.

**Anesthesia and surgery:** If you are going to have surgery where an anesthetic will be used, tell your healthcare professional that you are taking METOPROLOL / METOPROLOL – L.

**Severe skin reactions:** METOPROLOL / METOPROLOL – L can cause a variety of severe skin reactions such as rashes and severe skin dryness. If you notice any signs and symptoms of a skin reaction, tell your healthcare professional. They will tell you how to safely stop your treatment with METOPROLOL / METOPROLOL – L.

**Pregnancy and breastfeeding:** You should not take METOPROLOL / METOPROLOL – L during pregnancy or if you are breastfeeding. Tell your healthcare professional if you are:

- pregnant,
- able to become pregnant,
- breastfeeding, or
- planning to breastfeed.

**Blood tests and monitoring:** Based on your health history, your healthcare professional may perform blood tests for as long as you are being treated with METOPROLOL / METOPROLOL – L. They may monitor:

- your blood sugar
- how well your heart, liver, kidney and thyroid are working
- how METOPROLOL / METOPROLOL – L is affecting other medications that you are taking.

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

#### **Serious Drug Interactions**

Taking METOPROLOL / METOPROLOL – L with:

- calcium channel blockers (such as verapamil, diltiazem) given as an injection into your vein (intravenously) may increase your risk of cardiac arrest.
- inhaled anesthetics used during surgery may further decrease your heart rate
- digitalis glycosides (such as digoxin), used to treat heart failure, may cause an extremely slow heart rate

**The following may also interact with METOPROLOL / METOPROLOL – L:**

- aldesleukin, a medicine used to treat kidney cancer
- alcohol
- medicines that lower blood pressure (e.g. guanethidine, betanidine, reserpine, alpha-methyldopa, clonidine)
- medicines used to treat irregular heartbeat (e.g. quinidine, tocainide, procainamide, ajmaline, amiodarone, flecainide, disopyramide, propafenone, lidocaine)
- medicines used to treat high blood pressure, such as:
  - calcium channel blockers, such as verapamil and diltiazem, taken by mouth

- hydralazine
- prazosin
- medicines used to treat high blood pressure in the eye (e.g. timolol)
- MAO Inhibitors
- antidepressants (e.g. fluvoxamine, fluoxetine, paroxetine, sertraline, bupropion, clomipramine, desipramine)
- antipsychotics (e.g. chlorpromazine, fluphenazine, haloperidol, thioridazine)
- antiretrovirals (e.g. ritonavir)
- antihistamines used to treat hay fever (e.g. diphenhydramine)
- antimalarials (e.g. hydroxychloroquine or quinine)
- antifungals (e.g. terbinafine)
- dipyridamole, used to reduce the risk of blood clots
- ergot alkaloids, used in prevention and treatment of migraine headaches
- fingolimod, a medicine used to treat multiple sclerosis
- rifampicin (an antibiotic)
- anaesthetics, medicines used during surgery (e.g. lidocaine)
- medicines used to treat chest pain (angina) (e.g. nitroglycerin)
- medicines known as non-steroidal anti-inflammatory agents (NSAIDs) used to reduce pain and swelling
- insulin, or oral medicines used to treat high levels of sugar in the blood (diabetes)
- adrenaline or similar substances (sympathomimetics), which are found in some eye and nose drops, and in some cough medicines or remedies for the common cold (e.g. noradrenaline, isoprenaline, ephedrine, phenylephrine, phenylpropanolamine, and xanthine derivatives)

### **How to take METOPROLOL / METOPROLOL – L:**

Once your healthcare professional has identified the correct dosage for you using the regular metoprolol tartrate tablets, you may be switched to the metoprolol tartrate slow-release tablets. Metoprolol tartrate slow-release tablets are convenient because you only take it once a day.

Take METOPROLOL / METOPROLOL – L:

- exactly as your healthcare professional has told you to
- by swallowing the tablet whole

- in the morning, preferably with or right after a meal

**Do not** change the dose or stop taking METOPROLOL / METOPROLOL – L suddenly without talking to your healthcare professional first. This could cause chest pains or a heart attack. If your healthcare professional decides that you should stop taking A METOPROLOL / METOPROLOL – L, your dose will be reduced slowly before you stop taking the medicine completely.

**Usual dose:**

Your healthcare professional will decide how much METOPROLOL / METOPROLOL – L should take each day depending on your condition.

Depending on how you respond to the treatment, your healthcare professional may change your dose.

**The usual adult maintenance doses are:**

- To treat high blood pressure: 100 to 200 mg daily. Your healthcare professional may add another medicine such as a diuretic (water pill) for you to take along with METOPROLOL / METOPROLOL – L to treat your high blood pressure.
- To treat chest pain (Angina Pectoris): 200 mg daily.
- To help prevent another heart attack: 100 mg twice daily.

**Overdose:**

Some of the effects of an overdose of METOPROLOL / METOPROLOL – L are:

- very low blood pressure
- an abnormally slow heartbeat or an irregular heartbeat
- heart failure or stoppage
- sudden and oppressive chest pain (heart attack)
- breathlessness, difficulty breathing when lying down
- low levels of blood sugar
- cardiogenic shock (heart is unable to pump enough blood to the organs of the body)
- loss of consciousness
- seizures
- nausea and vomiting
- blue discoloration of the lips, tongue, skin
- death

Taking METOPROLOL / METOPROLOL – L with alcohol, medicines that lower blood pressure, quinidine, or medicines that have a calming effect on the body (e.g. barbiturates) may make your signs and symptoms worse.

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

### **Missed Dose:**

If you missed a dose of this medication, take it as soon as you remember. But if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

### **What are possible side effects from using METOPROLOL / METOPROLOL – L?**

These are not all the possible side effects you may have when taking METOPROLOL / METOPROLOL – L. If you have any side effects not listed here, tell your healthcare professional.

Side effects may include:

- fainting
- dizziness
- light-headedness
- a drop in blood pressure from sitting or standing up
- hot flush
- vivid dreams or nightmares
- headache
- weakness
- sleep disturbance
- fatigue and tiredness especially with activity
- a tingling sensation in the extremities (signs of paresthesia)
- anxiety
- lack of energy and feeling tired (lethargy)
- heartburn
- increased passing of gas
- shortness of breath, especially with exercise
- wheezing
- stuffy or runny nose, sneezing, and itchy nose
- skin rashes
- sweating
- itchy skin
- increased sensitivity of the skin to sun
- hair loss

- muscle spasms
- arthritis
- impotence
- decreased sex drive
- ringing in the ears
- dry, itchy or red eyes
- blurred vision
- increased weight
- confusion
- increased levels of triglycerides (fat) in the blood, and decreased levels of cholesterol

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): decreased heart rate that causes you to be dizzy or faint.		√	
<b>Gastrointestinal (GI) problems:</b> constipation, anorexia, abdominal discomfort, indigestion, diarrhea, nausea, or vomiting.		√	
<b>Hypotension</b> (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, or fatigue (may occur when you go from lying or sitting to standing up).		√	
Chest Pain		√	
<b>Asthma or bronchospasm</b> (breathing problems): difficulty breathing and coughing, chest tightness, wheezing or whistling sound when breathing.		√	
<b>Congestive heart failure</b> (heart does not pump blood as well as it should): shortness of breath, fatigue, weakness, swelling in ankles, legs and feet, cough,			√



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	
fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, or reduced ability to exercise.			
<b>UNCOMMON</b>			
<b>Edema:</b> ankle swelling.	√		
Slow or irregular heartbeat (palpitations).		√	
<b>New or Worsening Psoriasis:</b> skin rash (in the form of itchy rash, thickened patches of red/silver skin).	√		
<b>Allergic Reaction:</b> rash, swelling of the lips, face or neck, shortness of breath, difficulty speaking, wheezing, drop in blood pressure, feeling sick to your stomach, vomiting, hives, or rash.			√
<b>Liver problems:</b> yellowing of your skin and eyes (jaundice), right upper stomach area pain, swelling, nausea, vomiting, unusual dark urine, or unusual tiredness.		√	
<b>Peyronie's disease</b> (a condition where scar tissue forms under the skin of the penis): penile pain, shortening of the penis, erection problems, or significant bend to the penis.		√	
<b>Hallucinations:</b> see or hear things that are not there.		√	
<b>Depression</b> (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or		√	

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	
hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive), or thoughts of death or suicide.			
Change in personality and confusion.		√	
<b>Vision changes:</b> blurred vision, loss of vision, or increased sensitivity to light.	√		
<b>Hearing changes:</b> noises, reduced or loss of hearing.	√		
<b>Gangrene:</b> toes or fingers cold to the touch, discoloured and painful.			√
<b>Kidney problems:</b> change in frequency of urination, swelling of extremities, fatigue, skin rash, itching, nausea, vomiting.	√		
<b>Retroperitoneal fibrosis</b> (disorder where there is swelling and scar tissue in back of abdominal cavity): lower back pain, kidney failure (low or no urine produced), high blood pressure, blood clot in the legs.			√
<b>Oculomuco-cutaneous Syndrome</b> (severe skin reaction): red, irritated and watery eyes, skin rash and ear infection.			√
<b>UNKNOWN FREQUENCY</b>			
<b>Heart Block:</b> feeling lightheaded, fainting, dizziness, shortness of breath, nausea or fatigue.			√
<b>Raynaud's phenomenon</b> (episodes of reduced blood flow): cold feeling in fingers and toes (and sometimes nose, lips			√

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	
and ears), prickly or stinging feeling, change in skin colour to white then blue.			
<b>Hepatitis</b> (inflammation of liver): Abdominal pain, fatigue, fever, itchiness, light coloured stool, trouble thinking clearly, yellowing of the skin.			√
<b>Thrombocytopenia</b> (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue, or weakness.			√
<b>Leukopenia</b> (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms.			√

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:

METOPROLOL / METOPROLOL – L: Store at room temperature (15°C to 30°C) and protect from light.

**Keep out of reach and sight of children.**

**If you want more information about METOPROLOL / METOPROLOL – L:**

- 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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); Or by contacting Pro Doc Ltée: <http://www.product.qc.ca>, 1-800-361-8559, [medinfo@prodoc.qc.ca](mailto:medinfo@prodoc.qc.ca).

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