

PART III: CONSUMER INFORMATION

P^rMETOPROLOL-L
Metoprolol Tartrate Tablets, USP

This leaflet is part III of a three-part "Product Monograph" published when METOPROLOL-L was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about METOPROLOL-L. Contact your doctor or pharmacist if you have any questions about the drug.

What dosage forms it comes in:

Tablets: 25 mg, 50 mg and 100 mg

WARNINGS AND PRECAUTIONS

BEFORE you use METOPROLOL-L talk to your doctor or pharmacist if you:

- have heart, liver or kidney disease
- have high or low levels of sugar in the blood (diabetes)
- are at risk for serious allergic reactions
- have chest pain when you are at rest
- have poor blood circulation in your limbs (for example, very cold, pale hands or feet, or pain in your leg muscles when you walk)
- have a tumor of the medulla or of the adrenal glands (pheochromocytoma), you would require an additional treatment to METOPROLOL-L
- have allergy to or an intolerance to lactose
- have an overactive thyroid gland
- have respiratory disease such as asthma, or sometimes get breathlessness and wheezing
- have a severe syndrome named oculomucocutaneous syndrome whose signs include severe conjunctivitis (red, irritated and watery eye), skin rash and ear infection
- are pregnant or intend to become pregnant. METOPROLOL-L should not be used during pregnancy. Your doctor will discuss with you the potential risks of taking METOPROLOL-L during pregnancy
- are breast-feeding. If your doctor decides that you must continue to take METOPROLOL-L you should stop breast-feeding as METOPROLOL-L passes into breast milk
- are under 18 years old.

If you need to undergo an operation where an anesthetic is used, tell your anesthetic professional that you are taking METOPROLOL-L.

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

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including herbal and non-prescription medicines. Some other medicines may interact with METOPROLOL-L. These include:

- medicines used to treat high blood pressure,
- medicines used to treat chest pain (angina) (e.g., nitroglycerin),
- medicines used to treat irregular heartbeat (e.g., amiodarone, propafenone, quinidine, disopyramide, tocainide, procainamide, ajmaline, amiodarone, flecainide, digitalis glycosides such as digoxin, lidocaine),
- anaesthetics, medicines used during surgical operations,
- 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.,

ABOUT THIS MEDICATION

What the medication is used for:

METOPROLOL-L is used alone or in combination with another medicine for the following conditions:

- to treat high blood pressure
- to treat angina (chest pain triggered by exercise)
- to help to protect the heart after a heart attack (myocardial infarction)

What it does:

METOPROLOL-L is a beta-blocker. It helps to control high blood pressure or other heart-related problems.

When it should not be used:

You should not be treated with METOPROLOL-L if you:

- are allergic to metoprolol, to any of the other ingredients in METOPROLOL-L or to another beta-blocker
- have breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of a heart disorder)
- have a slow or irregular heartbeat
- have sudden and oppressive chest pain (sign of heart attack)
- have very poor blood circulation in your limbs (for example, very cold, pale hands or feet, or pain in your leg muscles when you walk)
- have low blood pressure
- have non-treated tumor of the medulla of the adrenal glands (pheochromocytoma)
- have asthma or had history of difficulty breathing with wheezing or coughing
- have severe skin problems
- suffer from severe drop in blood pressure, dizziness, fast heartbeat, rapid and shallow breathing, cold clammy skin (signs of a heart disorder named cardiogenic shock).

What the medicinal ingredient is:

Metoprolol Tartrate.

What the non-medicinal ingredients are:

Colloidal Silicon Dioxide, D&C Red No. 30 Aluminum Lake, D&C Yellow No. 10 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake, Hydroxypropyl Methylcellulose, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Polydextrose, Polyethylene Glycol, Polysorbate 80, Povidone, Sodium Starch Glycolate, Titanium Dioxide, Triethyl Citrate.

noradrenaline, isoprenaline, ephedrine, phenylephrine, phenylpropanolamine, and xanthine derivatives),

- insulin, or medicines used to treat high levels of sugar in the blood (diabetes),
- medicines used to relieve pain or inflammation (non-steroidal anti-inflammatory drugs such as COX-2 inhibitors),
- antibiotics (e.g., rifampicin),
- antivirals (e.g., ritonavir),
- antihistamines used to treat hay fever (e.g., diphenhydramine),
- medicines used to treat malaria (e.g., hydroxychloroquine or quinine),
- antipsychotic medicines (e.g., thioridazine, chlorpromazine, fluphenazine, haloperidol),
- antidepressants (e.g., fluoxetine, paroxetine, fluvoxamine, sertraline, clomipramine, desipramine or bupropion),
- MOA Inhibitors and adrenergic neuron blockers (e.g., reserpine or guanethidine),
- antifungals (e.g., terbinafine),
- ergot alkaloids, used in the prevention and treatment of migraine headaches,
- dipyridamole, used to reduce the risk of blood clots,
- alcohol,
- fingolimod, a medicine used to treat multiple sclerosis,
- aldesleukin, a medicine used to treat kidney cancer, or other medicines that may cause a decrease in blood pressure.

PROPER USE OF THIS MEDICATION

Usual dose:

Follow your doctor’s instructions carefully. Do not exceed the recommended dosage.

Your doctor will tell you exactly how many tablets of METOPROLOL-L to take based on your individual requirements.

High Blood Pressure: the usual maintenance dose is 100-200 mg daily.

Angina: the usual maintenance dose is 200 mg daily.

To Protect the Heart after a Heart Attack: the usual maintenance dose is 100 mg twice daily.

In general, the daily dosage is in the following range: 100 to 200 mg daily, either once daily (in the morning), or divided into two separate doses (one in the morning and one in the evening).

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

METOPROLOL-L tablets should be administered preferably with or following a meal.

Do not change the dose or stop the treatment without talking to your doctor. If you stop taking METOPROLOL-L suddenly, your condition may become worse. Your doctor may want you to reduce the dose gradually before stopping treatment altogether.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Center immediately, even if there are no symptoms.

Some of the effects of an overdose of metoprolol tartrate are: an abnormally slow heartbeat or an irregular heartbeat, very low blood pressure, breathlessness, difficulty breathing when lying down, swelling of the feet, loss of consciousness, blue discoloration of the lips, tongue, skin, seizures, nausea and vomiting, sudden and oppressive chest pain and death.

Missed Dose:

If you forget to take a dose of METOPROLOL-L, take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like other medication, METOPROLOL-L may cause some side effects. These side effects may be minor and temporary. However, some may be serious and need medical attention.

Side effects may include: sleep disturbance, fatigue and tiredness especially with activity, headache, dry mouth, nausea and vomiting, diarrhea or constipation and abdominal pain, numbness, a tingling sensation in the extremities, signs of paresthesia, increased sensitivity of the skin to sun, sweating, hair loss, increased weight, and lower back pain.

Based on your health history, your doctor should take blood tests for as long as you are being treated with METOPROLOL-L.

They may monitor:

- blood sugar
- heart, liver, kidney, and thyroid function
- how METOPROLOL-L is affecting other medications that you are taking.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	
COMMON			
Low Blood Pressure: feeling of light-headedness or fainting especially when getting up from a lying or sitting position		✓	
Chest Pain		✓	
Bronchospasm: difficulty breathing with wheezing or coughing		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	
Heart Failure: shortness of breath, leg swelling and tiredness especially with activity			✓
UNCOMMON			
Edema: ankle swelling	✓		
Slow or irregular heartbeat (palpitations)		✓	
New or Worsening Psoriasis: skin rash (in the form of itchy rash, thickened patches of red/silver skin)	✓		
Allergic Reaction: rash, hives, swelling of the face, throat, lips, difficulty swallowing or breathing			✓
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
Sexuality: Abnormal curvature of the penis	✓		
Change in sex drive	✓		
Change in ability to achieve or maintain an erection	✓		
Hallucinations: see or hear things that are not there		✓	
Depression: feel sad, loss of interest in usual activities changes in sleep and eating patterns		✓	
Change in personality and confusion		✓	
Visual Disturbance: Blurred vision, dry or irritated eyes	✓		
Hearing Disturbance: noises, reduced or loss of hearing	✓		
Paresthesia: Colder than usual hands or feet	✓		
Gangrene: toes or fingers cold to the touch, discoloured and painful			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	
Kidney Disorder: change in frequency of urination, swelling of extremities, fatigue, skin rash, itching, nausea, vomiting	✓		
High Blood Pressure: headaches, vision disorders, nausea and vomiting		✓	
Blood clots: swelling, pain and redness in an arm or leg that can be warm to touch. You may develop sudden chest pain, difficulty breathing and heart palpitations.			✓
Decreased Platelets: bruising, bleeding, fatigue and weakness		✓	
Retroperitoneal fibrosis: lower back pain, kidney failure (low or no urine produced), high blood pressure, blood clot in the legs (See Blood Clots above)			✓
Arthritis: stiff sore joints		✓	
Oculomucocutaneous Syndrome: red, irritated and watery eyes, skin rash and ear infection			✓

This is not a complete list of side effects. For any unexpected effects while taking METOPROLOL-L contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15°C and 30°C. Protect from light and humidity.

Keep all medicines out of the reach and sight of children.

This medicine is prescribed for your specific medical problem and for your own use only. Do not give to other people.

Do not use outdated medicines. Discard them safely out of the reach of children or take them to your pharmacist who will dispose of them for you.

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.

MORE INFORMATION**If you want more information about METOPROLOL-L:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>), or by contacting the sponsor Sivem Pharmaceuticals ULC at: 1-855-788-3153.

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Last revised: March 31, 2021