

PART III: CONSUMER INFORMATION**Pr**LOPRESOR[®]**Pr**LOPRESOR[®] SR**Pr**LOPRESOR[®] ampoules**(metoprolol tartrate)**

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

This information applies to LOPRESOR[®], LOPRESOR[®] SR and LOPRESOR[®] ampoules. To facilitate reading, only LOPRESOR[®] is mentioned (unless the information for each product is different).

ABOUT THIS MEDICATION**What the medication is used for:**

LOPRESOR[®] 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:

LOPRESOR[®] 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 LOPRESOR[®] if you:

- are allergic to metoprolol, to any of the other ingredients in LOPRESOR[®] 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 nonmedicinal ingredients are:

LOPRESOR[®] tablets contain: carnauba wax, cellulose compounds, lactose, magnesium stearate, polyethylene glycol, povidone, silicon dioxide, sodium carboxymethyl starch, talc.

LOPRESOR[®] SR tablets contain: castor oil compounds, carnauba wax, cellulose compounds, iron oxides, magnesium stearate, phosphates polysorbate, talc, titanium dioxide.

LOPRESOR[®] ampoules contain: sodium chloride

What dosage forms it comes in:

LOPRESOR[®] Tablets 50 mg and 100 mg

LOPRESOR[®] SR Tablets 100 mg and 200 mg

LOPRESOR[®] Ampoule 1mg/mL

WARNINGS AND PRECAUTIONS**BEFORE you use LOPRESOR[®] 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 LOPRESOR[®]
- have allergy to or an intolerance to lactose. This applies only to LOPRESOR[®]
- 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. LOPRESOR[®] should not be used during pregnancy. Your doctor will

discuss with you the potential risks of taking LOPRESOR* during pregnancy

- are breast feeding. If your doctor decides that you must continue to take LOPRESOR® you should stop breast-feeding as LOPRESOR* 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 LOPRESOR®.

Driving and using machines: If you experience dizziness, tiredness or blurred vision during your treatment with LOPRESOR®, do not drive, use machinery, or perform other tasks that need full attention until you know how you respond to LOPRESOR®. 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 LOPRESOR®. 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, disopyramidetocainide, procainamide, ajmalineamiodarone, 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. 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 LOPRESOR® 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.

LOPRESOR® SR tablets are intended for maintenance dosing. Once your doctor has identified the correct dosage for you using the regular LOPRESOR* tablets, you may be switched to the LOPRESOR® SR tablets. LOPRESOR® SR tablets are convenient because you only take one pill a day. LOPRESOR® SR tablets should be taken in the morning.

LOPRESOR® and LOPRESOR® SR tablets should be swallowed whole without being chewed, preferably with or following a meal.

LOPRESOR® ampoule is used for the emergency treatment of heart attacks. It is only used by an experienced health care provider under circumstances where resuscitation and monitoring equipment is available.

Do not change the dose or stop the treatment without talking to your doctor. If you stop taking LOPRESOR® 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 Centre immediately, even if there are no symptoms.

Some of the effects of an overdose of LOPRESOR® 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 LOPRESOR®, 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 medications, LOPRESOR® 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 LOPRESOR®. They may monitor:

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and immediately seek assistance
	Only if severe	In all cases	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist	Stop taking drug and
Common	Low Blood Pressure: feeling of lightheadedness or fainting especially when getting up from a lying or sitting position	√
	Chest Pain	√
	Broncho-spasm: difficulty breathing with wheezing or coughing	√
	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)	√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and
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		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and
Change in personality and confusion			√
Visual Disturbance: blurred vision, dry or irritated eyes	√		
Hearing Disturbance: noises, reduced or loss of hearing	√		
Parasthesia: Colder than usual hands or feet	√		
Gangrene; toes or fingers cold to the touch, discoloured and painful			√
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		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and
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 LOPRESOR® contact your doctor or pharmacist.

HOW TO STORE IT

Store LOPRESOR® tablets between 2-30 °C. Protect from heat, light and humidity.

Store LOPRESOR® ampoules between 2-30 °C. Protect from heat and light.

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 SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.novartis.ca>

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc, at: 1-800-363-8883

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