

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **LOPRESOR SR**[®]

Metoprolol Tartrate Slow-Release Tablets

Read this carefully before you start taking **LOPRESOR SR**[®] 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 **LOPRESOR SR**.

What is LOPRESOR SR used for?

LOPRESOR SR 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 LOPRESOR SR work?

LOPRESOR SR 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 LOPRESOR SR?

Medicinal ingredients: metoprolol tartrate.

Non-medicinal ingredients: carnauba wax, castor oil compounds, cellulose compounds, iron oxides, magnesium stearate, phosphates polysorbate, talc, titanium dioxide.

LOPRESOR SR comes in the following dosage forms:

Slow-release tablets 100 mg and 200 mg

Do not use LOPRESOR SR if:

- you are allergic to metoprolol tartrate or to any other ingredients in LOPRESOR SR.
- 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 LOPRESOR SR. 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 LOPRESOR SR. This could cause chest pains or a heart attack. If your healthcare professional decides that you should stop taking LOPRESOR SR, 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 LOPRESOR SR, 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): LOPRESOR SR can cause severe sinus bradycardia. Tell your healthcare professional if this occurs. They may reduce your dose of LOPRESOR SR. They will tell you how to safely stop your treatment with LOPRESOR SR.

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

Anesthesia and surgery: If you are going to have surgery where an anesthetic will be used, tell your healthcare professional that you are taking LOPRESOR SR.

Severe skin reactions: LOPRESOR SR 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 LOPRESOR SR.

Pregnancy and breastfeeding: You should not take LOPRESOR SR 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 LOPRESOR SR. They may monitor:

- your blood sugar
- how well your heart, liver, kidney and thyroid are working
- how LOPRESOR SR 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 LOPRESOR SR 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 LOPRESOR SR:

- 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 LOPRESOR SR:

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

Take LOPRESOR SR:

- 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 LOPRESOR SR 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 LOPRESOR SR, your dose will be reduced slowly before you stop taking the medicine completely.

Usual dose:

Your healthcare professional will decide how much LOPRESOR SR you 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: 100-200 mg daily. Your healthcare professional may add another medicine such as a diuretic (water pill) for you to take along with LOPRESOR SR 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 LOPRESOR SR 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 LOPRESOR SR 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 LOPRESOR SR, 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 LOPRESOR SR?

These are not all the possible side effects you may have when taking LOPRESOR SR. 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	
COMMON			
Bradycardia (abnormally slow heartbeat): decreased heart rate that causes you to be dizzy or faint.		√	
Gastrointestinal (GI) problems: constipation, anorexia, abdominal discomfort, indigestion, diarrhea, nausea, or vomiting.		√	

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	
Hypotension (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		√	
Asthma or bronchospasm (breathing problems): difficulty breathing and coughing, chest tightness, wheezing or whistling sound when breathing.		√	
Congestive heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue, weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, or reduced ability to exercise.			√
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, 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.			√
Liver problems: yellowing of your skin and eyes (jaundice), right upper stomach area pain, swelling, nausea, vomiting, unusual dark urine, or unusual tiredness.		√	
Peyronie's disease (a condition where scar tissue forms under the skin of the penis): penile pain, shortening of the penis, erection		√	

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	
problems, or significant bend to the penis.			
Hallucinations: see or hear things that are not there.		√	
Depression (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 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.		√	
Vision changes: blurred vision, loss of vision, or increased sensitivity to light.	√		
Hearing changes: noises, reduced or loss of hearing.	√		
Gangrene: toes or fingers cold to the touch, discoloured and painful.			√
Kidney problems: change in frequency of urination, swelling of extremities, fatigue, skin rash, itching, nausea, vomiting.	√		
Retroperitoneal fibrosis (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.			√
Oculomuco-cutaneous Syndrome (severe skin reaction): red, irritated and watery eyes, skin rash and ear infection.			√
UNKNOWN FREQUENCY			

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	
Heart Block: feeling lightheaded, fainting, dizziness, shortness of breath, nausea or fatigue.			√
Raynaud's phenomenon (episodes of reduced blood flow): cold feeling in fingers and toes (and sometimes nose, lips and ears), prickly or stinging feeling, change in skin colour to white then blue.			√
Hepatitis (inflammation of liver): Abdominal pain, fatigue, fever, itchiness, light coloured stool, trouble thinking clearly, yellowing of the skin.			√
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue, or weakness.			√
Leukopenia (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:

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

Keep out of reach and sight of children.

If you want more information about LOPRESOR SR

- 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>); the manufacturer's website (www.novartis.ca), Novartis Pharmaceuticals Canada Inc., or by calling 1-800-363-8883.

This leaflet was prepared by

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