

## PATIENT MEDICATION INFORMATION

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

#### Pr **PRO-ATENOLOL** **Atenolol Tablets**

Read this carefully before you start taking **PRO-ATENOLOL** 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 **PRO-ATENOLOL**.

#### **Serious Warnings and Precautions**

**Stopping your treatment:** You should follow your healthcare professional's instructions on how to reduce and stop your dose carefully and safely. If you have chest pain (angina) and then suddenly stop taking PRO-ATENOLOL, you can experience serious side effects. This can include heart attacks, irregular heartbeats, or worsening of your chest pain.

To reduce your chances of developing these effects:

- You should talk to your healthcare professional before stopping or lowering your dose of PRO-ATENOLOL.
- Your healthcare professional will monitor your health as you gradually reduce and/or stop your dose. However, if you notice any unusual symptoms tell your healthcare professional right away. They may temporarily prescribe another dose to prevent these symptoms.

See the **Serious side effects and what to do about them** table, below, for more information on these and other serious side effects.

#### **What is PRO-ATENOLOL used for?**

PRO-ATENOLOL is used in adults:

- to treat high blood pressure (also known as hypertension). It can be used alone or with other medicines.
- to prevent chest pain (also known as angina).

#### **How does PRO-ATENOLOL work?**

PRO-ATENOLOL 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 PRO-ATENOLOL?**

Medicinal ingredient: atenolol.

Non-medicinal ingredients: colloidal silicon dioxide, heavy magnesium carbonate, hydroxypropyl methylcellulose, magnesium stearate, maize starch, polyethylene glycol 6000, purified talc, sodium lauryl sulphate, sodium starch glycolate, and titanium dioxide.

#### **PRO-ATENOLOL comes in the following dosage forms:**

Tablets: 25 mg of atenolol.

#### **Do not use PRO-ATENOLOL if:**

- you have the following heart or blood vessel problems:
  - bradycardia (abnormally slow heart beat).
  - second or third degree heart block (a type of irregular heart beat and rhythm).
  - sick sinus syndrome (heart's natural pacemaker is unable to create normal heartbeats at the normal rate).
  - 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).
- right ventricular failure (right side of the heart is not pumping normal amounts of blood to the lungs).
- you have low blood pressure.
- 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).
- you have a condition known as metabolic acidosis (abnormal levels of acid in the body).
- you are allergic to atenolol or to any other ingredients in PRO-ATENOLOL.

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

- have Prinzmetal's angina (a type of chest pain).
- have first degree heart block (a type of irregular heart beat and rhythm).
- have lung problems (e.g., bronchospastic disease).
- have blood vessels problems (e.g., peripheral arterial disorder).
- have kidney problems.
- have thyroid problems (e.g., thyrotoxicosis).
- are planning to get surgery or are taking medicines known as anaesthetics that are used to prevent pain during surgery. In this case, let that particular anaesthetist know that you are taking PRO-ATENOLOL before your surgery.
- have diabetes (body can't produce insulin or can't properly use insulin) and are taking medicine to control your blood sugar.
- have hypoglycemia (low blood sugar) and are taking medicines for hypoglycemia.
- have asthma or a history of problems related to asthma.
- are on hemodialysis (a treatment that filters wastes and extra fluid from your blood).
- have allergies or have had allergic reactions.
- are elderly.

**Other warnings you should know about:**

Taking PRO-ATENOLOL can cause the following side effects:

- **Heart failure** (heart does not pump blood as well as it should): Beta blockers, such as PRO-ATENOLOL, can slow your heart rate and cause heart failure. 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): PRO-ATENOL can cause severe sinus bradycardia. Tell your healthcare professional if this occurs. They may reduce your dose of PRO-ATENOLOL. They will tell you how to safely stop your treatment with PRO-ATENOLOL.
- **Severe skin reactions:** PRO-ATENOLOL can cause a variety of 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 PRO-ATENOLOL.
- **Breathing problems:** Beta blockers, such as PRO-ATENOLOL, can affect your breathing. If this occurs, tell your healthcare professional. They will tell you how to safely stop your treatment with PRO-ATENOLOL.

See the **Serious side effects and what to do about them** table, below, for more information on these and other serious side effects.

**Pregnancy and breastfeeding:** Taking atenolol while pregnant or breastfeeding can cause your baby to develop unwanted effects (e.g., hypoglycemia and/or bradycardia). There are specific risks for you and your unborn baby that you must discuss with your healthcare professional. Tell your healthcare professional if

you are:

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

**Driving and using machines:** PRO-ATENOLOL can cause dizziness and fatigue. Before you drive or do tasks that require special attention, wait until you know how you respond to PRO-ATENOLOL.

**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 PRO-ATENOLOL:**

- medicines used to lower blood pressure:
  - other beta blockers (e.g., carvedilol and bisoprolol);
  - alpha-2 adrenergic agonist (e.g., clonidine);
  - catecholamine-depleting medicines (e.g., reserpine and guanethidine); or
  - calcium channel blockers (e.g., dihydropyridines such as nifedipine).
- medicines known as digitalis glycosides used to treat heart failure (e.g., digoxin).
- medicines known as non-steroidal anti-inflammatory agents (NSAIDs) used to reduce pain and swelling (e.g., aspirin, indomethacin, and ibuprofen).
- medicines known as anaesthetics used to prevent pain during surgery.
- fingolimod, a medicine used to treat multiple sclerosis (MS).
- medicines used to treat abnormal heart rhythms (e.g., disopyramide and amiodarone).

**How to take PRO-ATENOLOL:**

- Take PRO-ATENOLOL:
  - exactly as prescribed by your healthcare professional.
  - by swallowing the tablet whole with water.
  - at the same time each day.
- **Do not** stop or reduce your dose of PRO-ATENOLOL suddenly without first talking with your healthcare professional. This could cause chest pain or a heart attack. If your healthcare professional decides that you should stop taking PRO-ATENOLOL, your dose may be reduced so that you need to use it less and less before you stop the medication completely.
- If you think that the effect of PRO-ATENOLOL is too strong or too weak, talk to your healthcare professional as soon as possible.

**Usual dose:**

Your healthcare professional will decide how much PRO-ATENOLOL you should take each day depending on your condition. They may add another medicine such as a diuretic (water pill) and/or a vasodilator for you to take along with PRO-ATENOLOL to treat your high blood pressure.

The usual recommended adult doses are:

- **High blood pressure:** Two to four 25 mg tablets (50 mg to 100 mg) once a day.
- **Chest pain:** Two to four 25 mg tablets (50 mg to 100 mg) once a day. The dose may be increased up to eight 25 mg tablets (200 mg) once a day.

**Overdose:**

If you think you, or a person you are caring for, have taken too much PRO-ATENOLOL, contact a healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

Do not take a double dose to make up for a missed dose. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. If you are unsure what to do, ask your healthcare professional.

**What are possible side effects from using PRO-ATENOLOL?**

These are not all the possible side effects you may feel when taking PRO-ATENOLOL. If you experience any side effects not listed here, contact your healthcare professional.

The side effects of PRO-ATENOLOL may include:

- **Very common (may affect more than 1 in 10 people)**
  - dry mouth.
- **Common (may affect up to 1 in 10 people)**
  - vertigo.
- **Uncommon (may affect up to 1 in 100 people)**
  - cold fingers and toes;
  - burning or prickling sensation in the hands, arms, legs, or feet;
  - drowsiness;
  - flushes;
  - hair loss or thinning (alopecia);
  - impotence;
  - insomnia;
  - lack of energy;
  - leg pain;
  - loss of coordination;
  - mood changes;
  - nervousness;
  - nosebleeds;
  - ringing in the ears;
  - sweating;
  - vivid dreams.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>COMMON</b>			
<b>Bradycardia</b> (abnormally slow heartbeat): decreased heart rate that causes you to be dizzy or faint.		<b>X</b>	
<b>Gastrointestinal (GI) problems:</b> constipation, anorexia, abdominal discomfort, indigestion, diarrhea, nausea, or vomiting.		<b>X</b>	
<b>UNCOMMON</b>			
<b>Allergic reactions:</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>X</b>
<b>Heart block:</b> feeling lightheaded, fainting, dizziness, shortness of breath, nausea, or fatigue.			<b>X</b>

<b>Heart problems</b> (including heart failure): irregular heartbeat, heart palpitations, shortness of breath, fatigue, weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, or reduced ability to exercise.		X	
<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).		X	
<b>Severe skin reactions:</b> rash, dermatitis, itching, hives, red patches of skin, dry cracked skin that may bleed, itching, burning, or soreness.	X		
<b>Vision changes:</b> blurred vision, loss of vision, or increased sensitivity to light.	X		
<b>Mental state changes:</b> memory loss, psychoses, or seeing or hearing things that are not there (hallucinations).		X	
<b>Breathing problems</b> (including bronchospasm, when there is a sudden narrowing of the airway): difficulty breathing, wheezing, or coughing.		X	
<b>Thrombocytopenia</b> (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue, or weakness.		X	
<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 hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive), or thoughts of death or suicide.		X	
<b>RARE</b>			
<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.		X	
<b>UNKNOWN FREQUENCY</b>			
<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, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, or reduced ability to exercise.			X
<b>Lupus</b> (an autoimmune disease that occurs when your body's immune system attacks your own tissues and organs, including your joints, skin, kidneys, blood cells, heart and lungs): fatigue, fever, joint pain, stiffness and swelling, rash on		X	

the face that covers the cheeks and the bridge of the nose or rashes elsewhere on the body, skin lesions, shortness of breath, chest pain, dry eyes, headaches, confusion, or memory loss.			
<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.		X	

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 healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

- Store PRO-ATENOLOL at room temperature between 15°C to 30°C. Protect from light and moisture.
- Do not take your tablets after the expiry date on the container.
- Keep out of reach and sight of children.

### If you want more information about PRO-ATENOLOL:

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

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