

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PRO-LANSOPRAZOLE

Lansoprazole delayed-release capsules, USP

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

Serious Warnings and Precautions

If you are taking PRO-LANSOPRAZOLE and clarithromycin, and you are pregnant or nursing: do not use clarithromycin unless your doctor tells you. This may harm your fetus or infant.

What is PRO-LANSOPRAZOLE used for?

PRO-LANSOPRAZOLE is used to treat conditions where reducing stomach acid production is needed, such as:

- **Duodenal ulcer**
A duodenal ulcer is a sore on the lining of the duodenum, which is the beginning of the small intestine.
- **Gastric ulcer**
A gastric ulcer is a sore on the lining of the stomach.
- **Reflux esophagitis**
A reflux esophagitis is an inflammation of the swallowing tube (esophagus) resulting from regurgitation of gastric contents into the esophagus. Because stomach contents are acidic, this may result in irritation of the esophagus.
- **Healing of non-steroidal anti-inflammatory drugs (NSAID)-Associated Gastric Ulcer**
- **Reduction of risk of NSAID-Associated Gastric Ulcer**
- **Symptomatic gastroesophageal reflux disease (GERD)**
GERD is a disorder that results from stomach acid moving backward from the stomach into the esophagus.
- **Pathological hypersecretory conditions**
Pathological hypersecretory conditions are conditions in which the stomach produces too much acid, which comes up into the esophagus and causes heartburn.
- **Treatment of the bacterial infection caused by *Helicobacter pylori* (*H.pylori*) in combination with other medications (e.g., the antibiotics clarithromycin and amoxicillin) to treat stomach ulcers.**

PRO-LANSOPRAZOLE is also indicated for the treatment of erosive and non-erosive GERD in children, aged 1 to 17 years.

How does PRO-LANSOPRAZOLE work?

PRO-LANSOPRAZOLE is a proton pump inhibitor (PPI). It helps reduce acid production in the stomach.

What are the ingredients in PRO-LANSOPRAZOLE?

Medicinal ingredients: Lansoprazole

Non-medicinal ingredients: Ammonium hydroxide, D&C red #28, FD&C blue #1, FD&C green #3 (15 mg capsules only), FD&C red #40, gelatin, hydroxypropyl methylcellulose, magnesium hydroxide, methacrylic acid copolymer dispersion, methylcellulose, poloxamer, polyethylene glycol, shellac glaze, simethicone, talc, titanium dioxide and triethyl citrate.

PRO-LANSOPRAZOLE comes in the following dosage forms:

Delayed-release capsules: 15 mg and 30 mg

Do not use PRO-LANSOPRAZOLE if:

- you have an allergy to:
 - PRO-LANSOPRAZOLE or
 - any of the nonmedicinal ingredients in PRO-LANSOPRAZOLE (see [What are the ingredients in PRO-LANSOPRAZOLE?](#)).
- you are taking rilpivirine

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

- have or develop **severe diarrhea**. This may be a sign of a more serious condition;
- have **kidney problems**;
- have **stomach cancer**;
- have **liver problems**;
- experience palpitations (rapid heartbeat), dizziness, seizures, twitching, spasms, cramps and convulsions. These may be signs of low magnesium levels in the body;
- are taking **astemizole[†], terfenadine[†], cisapride[†]** ([†]not currently marketed in Canada), **or pimozide**;
- are taking other medications (see [The following may interact with PRO-LANSOPRAZOLE](#));
- are **pregnant, trying to get pregnant, breastfeeding or planning to breastfeed**;
- are due to have a specific blood test (Chromogranin A).

Other warnings you should know about:

Tell your doctor if you experience the following symptoms before taking PRO-LANSOPRAZOLE:

- unexplained weight loss.
- severe or persistent diarrhea.
- repeated vomiting.
- vomiting blood.
- dark stools.
- tiredness (anemia).
- difficulty in swallowing.

PRO-LANSOPRAZOLE may help your acid-related symptoms. However you could still have serious stomach problems. Talk to your doctor if your problems continue.

Take PRO-LANSOPRAZOLE exactly as your doctor tells you. You will use the lowest dose and shortest time suitable for your condition. Talk to your doctor if you have any concerns about your treatment.

Depending on your condition, your doctor may tell you to use PRO-LANSOPRAZOLE for a longer period.

Using proton pump inhibitors like PRO-LANSOPRAZOLE for a long time (every day for a year or longer) may increase risks of broken bones of the hip, wrist or spine. Talk to your doctor about this risk.

Long term use of proton pump inhibitors may also interfere with the absorption of Vitamin B₁₂ from the diet. This may cause a shortage of Vitamin B₁₂ in your body. Talk to your doctor.

Using PRO-LANSOPRAZOLE for a long period of time may cause a growth in your stomach (polyp), especially after one year.

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-LANSOPRAZOLE:

- ampicillin esters
- atazanavir
- nelfinavir
- saquinavir/ ritonavir
- clopidogrel
- digoxin
- iron salts

- ketoconazole
- methotrexate
- sucralfate
- tacrolimus
- theophylline
- warfarin
- fluvoxamine

How to take PRO-LANSOPRAZOLE:

- Take PRO-LANSOPRAZOLE daily:
 - Before breakfast
- If your doctor tells you to take PRO-LANSOPRAZOLE twice daily, take:
 - One before breakfast
 - One with another meal
- Do not crush or chew capsules.
- Swallow whole with water.
- If you can't swallow capsules, then
 - Open capsule.
 - Sprinkle granules on one tablespoon of apple sauce and swallow immediately.
 - Do not crush or chew granules.

Usual dose:

The recommended dose of PRO-LANSOPRAZOLE is not the same for all the indications. Your doctor will tell you exactly which dose is better for your condition.

Condition	Adult Dose	Child Dose	How Often	How Long
Duodenal Ulcer	15 mg	--	Once daily before breakfast	2 to 4 weeks, as directed by doctor
Triple Therapy	30 mg PRO-LANSOPRAZOLE 500 mg clarithromycin 1000 mg amoxicillin	--	Twice daily before breakfast and another meal	7, 10 or 14 days, as directed by doctor
Gastric Ulcer	15 mg	--	Once daily before breakfast	4 to 8 weeks, as directed by doctor
Healing of NSAID-Associated Gastric Ulcer	15 to 30 mg	--	Once daily before breakfast	Up to 8 weeks, as directed by doctor
Reduction of Risk	15 mg	--	Once daily	Up to 12

Condition	Adult Dose	Child Dose	How Often	How Long
of NSAID-Associated Gastric Ulcer			before breakfast	weeks, as directed by doctor
Reflux Esophagitis or Poorly Responsive Reflux Esophagitis Including Patients with Barrett's Esophagus	30 mg	--	Once daily before breakfast	4 to 8 weeks, as directed by doctor
Maintenance Treatment of Healed Reflux Esophagitis	15 mg	--	Once daily before breakfast	As directed by doctor
Treatment and Maintenance of Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome	Starting dose: 60 mg once a day. Dose may be increased by doctor.	--	Once daily before breakfast If dose is more than 120 mg per day: take in divided doses.	As directed by doctor
Gastroesophageal Reflux Disease (GERD)	15 mg	--	Once daily before breakfast	Up to 8 weeks, as directed by doctor. If symptoms do not stop within 4 to 8 weeks, talk to your doctor.
Pediatric GERD (erosive and non-erosive esophagitis)		1 to 11 years of age weighing: <ul style="list-style-type: none"> • 30 kg or less: 15 mg • over 30 kg: 30 mg 12 to 17 years of age: take adult dose	Once daily before breakfast	Up to 12 weeks, as directed by doctor.

Overdose:

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

Missed Dose:

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Just take the next dose at your regular time. Do not take 2 doses at the same time. If you are not sure about dosing, call your doctor. If you take too much PRO-LANSOPRAZOLE, call your doctor right away.

What are possible side effects from using PRO-LANSOPRAZOLE?

Like all medicines, PRO-LANSOPRAZOLE can cause side effects. However, most people do not have any side effects at all. If you experience any side effects not listed here, tell your healthcare professional.

The following side effects have been reported (occurring between 1% and 10% in clinical trials): arthralgia (muscle pain), belching, constipation, diarrhea, dizziness, dry mouth, gas, headache, indigestion, insomnia, nausea, rash, vomiting, weakness.

If the following symptoms appear, consult your physician: bladder infection (pain, burning sensation upon urination) and upper respiratory tract infections (e.g., bronchitis, sinusitis, runny nose, sore throat).

Tell your doctor right away if you have any of these symptoms:

- New or worsening joint pain
- Rash on your cheeks or arms that gets worse in the sun

Serious side effects from PRO-LANSOPRAZOLE are uncommon.

After stopping your medication, your symptoms may get worse and your stomach may increase the acid production.

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	
UNCOMMON*			
Abdominal pain		✓	
Severe diarrhea accompanied with blood and/or mucous			✓

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	
UNKNOWN			
Clostridium difficile colitis (Bowel inflammation): Symptoms include severe (watery or bloody) diarrhea, fever, abdominal pain or tenderness.			✓
Clostridium difficile colitis (Bowel inflammation): If you are currently taking or have recently taken antibiotics and you develop diarrhea, contact your doctor, even if the diarrhea is relatively mild.		✓	
Microscopic colitis (inflammation of the gut): symptoms include chronic watery diarrhea, abdominal pain, cramps or bloating weight loss, nausea, uncontrollable bowel movement, signs of dehydration such as: extreme thirst, less frequent urination, dark-coloured urine, fatigue, dizziness, confusion. The symptoms of microscopic colitis can come and go frequently. If you have watery diarrhea that lasts more than a few days, contact your doctor.	✓		
Severe Cutaneous Adverse Reactions (SCAR) (Severe Skin Reactions): Skin rash which may have blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet). You may also experience fever, chills, body aches,			✓

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	
shortness of breath, or enlarged lymph nodes. These serious skin reactions may need to be treated in a hospital and may be life threatening.			
Tubulointerstitial Nephritis (Kidney Problems): decreases in urination, blood in your urine.		✓	
* Uncommon: occurring between 0.2% and 1% in clinical trials			

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:

Keep PRO-LANSOPRAZOLE out of reach and sight of children.

Store between 15°C to 25°C. Protect from light and moisture. Do not use beyond the expiration date.

If you want more information about PRO-LANSOPRAZOLE:

- 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 : 1-800-361-8559, www.prodoc.qc.ca, medinfo@prodoc.qc.ca.

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