

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

### PATIENT MEDICATION INFORMATION

#### **Pr LANSOPRAZOLE** **Lansoprazole Delayed Release Capsules, USP**

Read this carefully before you start taking 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 LANSOPRAZOLE.

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

**If you are taking 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 LANSOPRAZOLE used for?**

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.**

LANSOPRAZOLE is also indicated for the treatment of erosive and non-erosive GERD in children, aged 6 to 17 years.

### **How does LANSOPRAZOLE work?**

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

### **What are the ingredients in LANSOPRAZOLE?**

Medicinal ingredients: lansoprazole

Non-medicinal ingredients: D&C yellow No. 10, FD&C blue No. 1, FD&C red No. 3, gelatin, hydroxypropyl cellulose, hypromellose, macrogol, maize starch, magnesium carbonate, methacrylic acid-ethyl acrylate copolymer, polysorbate 80, silica colloidal anhydrous, sucrose, sugar spheres, talc, titanium dioxide.

### **LANSOPRAZOLE comes in the following dosage forms:**

- capsules: 30 mg.

### **Do not use LANSOPRAZOLE if:**

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

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

- about all **health problems** you have now or have had in the past;
- if you have or develop **severe diarrhea**. This may be a sign of a more serious condition;
- if you have **kidney problems**;
- if you have a **stomach cancer**;
- if you have **liver problems**;
- if you experience any symptoms including palpitations (rapid heartbeat), dizziness, seizures, twitching, spasms, cramps and convulsions. These may be signs of low magnesium levels in the body;
- if you are taking **astemizole<sup>†</sup>, terfenadine<sup>†</sup>, cisapride<sup>†</sup>** (<sup>†</sup>not currently marketed in Canada), **or pimozone**;
- if you are taking other medications (see The following may interact with LANSOPRAZOLE);
- if you are **pregnant, trying to get pregnant, breast-feeding or planning to breast-feed**;
- if you are due to have a specific blood test (Chromogranin A).

### **Other warnings you should know about:**

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

Take 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 LANSOPRAZOLE for a longer period.

Using proton pump inhibitors like 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 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 LANSOPRAZOLE:**

- ampicillin esters
- atazanavir
- nelfinavir
- saquinavir/ ritonavir
- clopidogrel
- digoxin
- iron salts
- ketoconazole
- methotrexate
- sucralfate
- tacrolimus
- theophylline
- warfarin

**How to take LANSOPRAZOLE:**

- Take LANSOPRAZOLE daily:
  - Before breakfast
- If your doctor tells you to take LANSOPRAZOLE twice daily, take:
  - One before breakfast
  - One with another meal
- Do not crush or chew capsules.
- Swallow whole with water.

**Usual dose:**

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

<b>Condition</b>	<b>Adult Dose</b>	<b>Child Dose</b>	<b>How Often</b>	<b>How Long</b>
Duodenal Ulcer	15 mg	--	Once daily before breakfast	2 to 4 weeks, as directed by doctor
Triple Therapy	30 mg 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 of NSAID-Associated Gastric Ulcer	15 mg	--	Once daily before breakfast	Up to 12 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

<b>Condition</b>	<b>Adult Dose</b>	<b>Child Dose</b>	<b>How Often</b>	<b>How Long</b>
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)		<b>6 to 11 years of age</b> weighing: <ul style="list-style-type: none"> <li>• 30 kg or less: 15 mg</li> <li>• over 30 kg: 30 mg</li> </ul> <b>12 to 17 years of age:</b> take adult dose	Once daily before breakfast	Up to 12 weeks, as directed by doctor.

**Overdose:**

If you think you have taken too much LANSOPRAZOLE, contact your 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 LANSOPRAZOLE, call your doctor right away.

**What are possible side effects from using LANSOPRAZOLE?**

Like all medicines, LANSOPRAZOLE can cause side effects. However, most people do not have any side effects at all.

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 lansoprazole are uncommon.

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

### **Treatment in combination with antibiotics**

If you experience symptoms such as severe (bloody or repeated watery) diarrhea, with or without fever, abdominal pain or tenderness, you may have bowel inflammation caused by bacterial infection (*Clostridium difficile*). If this happens, stop taking the drug combination and call your healthcare professional immediately.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON*</b> Abdominal pain		✓	
Severe diarrhea accompanied with blood and/or mucous			✓

\*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, talk to your healthcare professional.

<p><b>Reporting Side Effects</b></p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"><li>• Visiting the Web page on Adverse Reaction Reporting (<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html</a>) for information on how to report online, by mail or by fax; or</li><li>• Calling toll-free at 1-866-234-2345.</li></ul> <p><i>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.</i></p>
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### **Storage:**

Keep LANSOPRAZOLE out of reach and sight of children.

Store at room temperature (15°C - 30°C). Protect from light and moisture. Do not use beyond the expiration date.

**If you want more information about 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>); the manufacturer's website ([www.sivem.ca](http://www.sivem.ca)), or by contacting the sponsor, Sivem Pharmaceuticals ULC, at :1-855-788-3153.

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