

## PART III: CONSUMER INFORMATION

## Pr LANSOPRAZOLE Lansoprazole Delayed-Release Capsules USP

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

## ABOUT THIS MEDICATION

What the medication is used for:

LANSOPRAZOLE is a medicine that is indicated in the treatment of conditions where the reduction of gastric acid secretion is required, 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 (sGERD)**  
sGERD 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.**

What it does:

LANSOPRAZOLE is a type of medication called a proton pump inhibitor, commonly known as PPI.

There are cells in the lining of your stomach that produce the acid your body uses during digestion. The burning pain from acid reflux disease is caused when this stomach acid backs up, or refluxes, into the esophagus.

LANSOPRAZOLE helps reduce stomach acid production. In doing so, LANSOPRAZOLE helps reduce the amount of acid backing up into your esophagus.

When it should not be used:

You should not take LANSOPRAZOLE if you have an allergy to lansoprazole or to any of the nonmedicinal ingredients in LANSOPRAZOLE (see **What the nonmedicinal ingredients are** below).

What the medicinal ingredient is:

lansoprazole

What the nonmedicinal ingredients are:

magnesium hydroxide, methylcellulose 15 CPS, poloxamer 407 (micro), hydroxypropyl methylcellulose 2910 E5, polyethylene glycol 8000, triethyl citrate, talc (500 mesh) and methacrylic acid copolymer dispersion.

15 mg caps composition:

pink opaque cap: D&C red #28, FD&C blue #1, FD&C red #40, titanium dioxide, gelatin

green opaque body: FD&C green #3, titanium dioxide, gelatin

30 mg caps composition:

pink opaque cap: D&C red #28, FD&C blue #1, FD&C red #40, titanium dioxide, gelatin

black opaque body: FD&C blue #1, FD&C red #40, gelatin

What dosage forms it comes in:

15 mg and 30 mg delayed-release capsules

## WARNINGS AND PRECAUTIONS

## Serious Warnings and Precautions

**The antibiotic clarithromycin should not be used in pregnancy unless advised by your doctor due to potential hazards to the fetus.**

Before you use LANSOPRAZOLE talk to your doctor or pharmacist:

- about all **health problems** you have now or have had in the past;
- about all **other medicines** you are taking, including non-prescription medicines, nutritional supplements, or herbal products;
- if you have or develop **severe diarrhea** as this may be a sign of a more serious condition;
- if you have **kidney problems**;
- if you have a **malignant gastric ulcer**;
- if you have **liver problems**;
- if you experience any **cardiovascular (e.g., heart) or neurological (e.g., brain) symptoms** including palpitations (rapid heartbeat), dizziness, seizures, and tetany (muscle condition with symptoms such as twitching, spasms, cramps and convulsions) as these may be signs of hypomagnesemia (low magnesium levels in the body);
- if you are taking **astemizole†, terfenadine†, cisapride† (†not currently marketed in Canada) or pimizide**;
- if you have any **unusual or allergic reaction** (rash, difficulty breathing) to lansoprazole, the antibiotics clarithromycin\*, amoxicillin\*, or penicillin\*, any of the

## IMPORTANT: PLEASE READ

non-medicinal ingredients in LANSOPRAZOLE (see **What the nonmedicinal ingredients are**), other medicines, foods, dyes, or preservatives. \*Some of these antibiotics may be used in the treatment of *H. pylori* and stomach ulcers during triple therapy;

- if you are **pregnant, trying to get pregnant or are breast-feeding**.

People who take multiple daily doses of proton pump inhibitor medicines for a long period of time (a year or longer) may have an increased risk of fractures of the hip, wrist or spine. You should take LANSOPRAZOLE exactly as prescribed, at the lowest dose possible for your treatment and for the shortest time needed. Talk to your doctor about your risk of bone fracture if you take LANSOPRAZOLE

### INTERACTIONS WITH THIS MEDICATION

**Drugs that may interact with LANSOPRAZOLE include:**

- ampicillin esters
- atazanavir
- digoxin
- iron salts
- ketoconazole
- methotrexate
- sucralfate
- theophylline
- warfarin

### PROPER USE OF THIS MEDICATION

Capsules should be swallowed whole. DO NOT open divide crush or chew the capsules.

#### 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.

LANSOPRAZOLE capsules should be taken daily before breakfast. Where the product may be used twice daily, it should be taken prior to breakfast and another meal. You should not chew or crush LANSOPRAZOLE capsules. LANSOPRAZOLE capsules should be swallowed whole with sufficient water.

#### Overdose:

In case of drug overdose, contact your healthcare professional, hospital emergency department or regional poison control centre, even if there are no symptoms.

#### Missed Dose:

If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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. Talk to your doctor or pharmacist if any of these side effects persist or become bothersome.

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)

Serious side effects from lansoprazole are not common.

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 cause by bacterial infection (*Clostridium difficile*). If this happens, stop taking the drug combination and call your healthcare professional immediately.

### 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 seek immediate emergency medical attention
		Only if severe	In all cases	
Uncommon (occurring between 0.2% and 1% in clinical trials)	Abdominal pain		√	
	Severe diarrhea accompanied with blood and/or mucous			√

*This is not a complete list of side effects. For any unexpected effects while taking LANSOPRAZOLE, contact your doctor or pharmacist.*

### HOW TO STORE IT

Keep LANSOPRAZOLE and all other medicines out of reach of children.

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

**GENERAL ADVICE ABOUT PRESCRIPTION MEDICINES:**

Talk to your doctor or other health care provider if you have any questions about this medicine or your condition. Medicines are sometimes prescribed for purposes other than those listed in a CONSUMER INFORMATION Leaflet. If you have any concerns, about this medicine, ask your doctor. Your doctor or pharmacist can give you information about this medicine that was written for health care professionals. Do not use this medicine for a condition for which it was not prescribed. Do not share this medicine with other people

**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](http://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, ON 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](http://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**

For more information, please contact your doctor, pharmacist or other healthcare professional.

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

This leaflet was prepared by  
Pro Doc Ltée, Laval, Québec, H7L 3W9

Date of Revision: November 27, 2014