

PART III: CONSUMER INFORMATION

PrPREVACID® lansoprazole delayed-release capsule (Manufacturer's standard)

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

ABOUT THIS MEDICATION

What the medication is used for:

PREVACID® 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:

PREVACID® 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.

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

When it should not be used:

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

What the medicinal ingredient is:

lansoprazole

What the important non-medicinal ingredients are:

cellulosic polymers, colloidal silicon dioxide, D & C Red No. 28, FD & C Blue No. 1, FD & C Green No. 3 (15 mg capsules only), FD & C Red No. 40, gelatin, magnesium carbonate, methacrylic acid copolymer, starch, talc, sugar spheres, sucrose, polyethylene glycol, polysorbate 80, and titanium dioxide.

What dosage forms it comes in:

PREVACID® is available in the following dosage forms:

- capsules, 15 mg and 30 mg
- granules for oral suspension, 15 mg and 30 mg
- tablets, 15 mg and 30 mg (PREVACID® FasTab)
- lyophilized powder (30 mg) for injection

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 PREVACID® 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 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 nonmedicinal ingredients in PREVACID[®] (see **What the important 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**.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with PREVACID[®] include:

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

PROPER USE OF THIS MEDICATION

Usual dose:

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

PREVACID[®] 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 PREVACID[®] capsules. PREVACID[®] capsule should be swallowed whole with sufficient water.

If you have difficulty swallowing capsules, capsules can be opened, and the intact granules contained within can be sprinkled on one tablespoon of applesauce and swallowed immediately. The granules should not be chewed or crushed.

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, PREVACID[®] 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.

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.

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 call your doctor or pharmacist
	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 PREVACID[®], contact your doctor or pharmacist.

HOW TO STORE IT

HOW DO I STORE PREVACID[®]?

Keep PREVACID[®] and all other medicines out of reach of children.

Store at room temperature (15° - 25°C / 59° - 77°F) in the original package. 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 on line at:**
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**
 - **Mail to: Canada Vigilance Program**
Health Canada
Postal Locator 0701C
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
<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

This document plus the full Product Monograph, prepared for health professionals can be found at:

<http://www.abbott.ca>

or by contacting the sponsor, Abbott Laboratories, Limited,
Saint-Laurent, Qc H4S 1Z1 at:
1-800-699-9948

This leaflet was prepared by Abbott Laboratories, Limited.

Last revised: November 1, 2010

PART III: CONSUMER INFORMATION

PrPREVACID[®]

lansoprazole granules for delayed-release oral suspension

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ABOUT THIS MEDICATION

What the medication is used for:

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- **Gastric ulcer**
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- **Healing of non-steroidal anti-inflammatory drugs (NSAID)-Associated Gastric Ulcer**
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- **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:

PREVACID[®] 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.

PREVACID[®] helps reduce stomach acid production. In doing so, PREVACID[®] helps reduce the amount of acid backing up into your esophagus.

When it should not be used:

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

What the medicinal ingredient is:

lansoprazole

What the important non-medicinal ingredients are:

Confectioner's sugar, mannitol, docusate sodium, ferric oxide, colloidal silicon dioxide, xanthan gum, croscovidone, citric acid, sodium citrate, magnesium stearate, and artificial strawberry flavor.

What dosage forms it comes in:

PREVACID[®] is available in the following dosage forms:

- capsules, 15 mg and 30 mg
- granules for oral suspension, 15 mg and 30 mg
- tablets, 15 mg and 30 mg (PREVACID[®] FasTab)
- lyophilized powder (30 mg) for injection

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.

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- 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**;
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- if you are taking **astemizole[†], terfenadine[†], cisapride[†]** ([†] not

- currently marketed in Canada), or **pimozide**;
- if you have any **unusual** or **allergic reaction** (rash, difficulty breathing) to lansoprazole, the antibiotics clarithromycin*, amoxicillin*, or penicillin*, any of the nonmedicinal ingredients in PREVACID® (see **What the important 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**.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with PREVACID® include:

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

PROPER USE OF THIS MEDICATION

Usual dose:

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

PREVACID® should be taken daily before breakfast. Where the product may be used twice daily, it should be taken prior to breakfast and another meal.

Directions for use:

- Empty sachet contents into a container that contains 2 tablespoons of **WATER**.
- DO NOT USE OTHER LIQUIDS OR FOODS.**
- Stir well, and drink immediately.
- DO NOT CRUSH OR CHEW THE GRANULES.**
- If any material remains after drinking, add more water, stir, and drink immediately.
- THIS PRODUCT SHOULD NOT BE GIVEN THROUGH ENTERAL ADMINISTRATION TUBES.**

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, PREVACID® can cause side effects. However, most people do not have any side effects at all.

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		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			✓

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HOW TO STORE IT**HOW DO I STORE PREVACID®?**

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- **Complete a Canada Vigilance Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789**
 - **Mail to: Canada Vigilance Program**
Health Canada
Postal Locator 0701C
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
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