PART III: CONSUMER INFORMATION

PREVACID® FasTab
lansoprazole delayed-release tablet

This leaflet is PART III of a three-part "Product Monograph" published when PREVACID® FasTab 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® FasTab. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
PREVACID® FasTab 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 (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.

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

What it does:
PREVACID® FasTab 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 reflexes, into the esophagus.

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

When it should not be used:
You should not take PREVACID® FasTab if you have an allergy to lansoprazole or to any of the nonmedicinal ingredients in PREVACID® FasTab (see What the important non-medicinal ingredients are).

What the medicinal ingredient is:
lansoprazole

What the important non-medicinal ingredients are:
lactose monohydrate, microcrystalline cellulose, magnesium carbonate, hydroxypropyl cellulose, hydroxypropyl methylcellulose, titanium dioxide, talc, mannitol, methacrylic acid, polyacrylate, polyethylene glycol, glyceryl monostearate, polysorbate 80, triethyl citrate, ferric oxide, citric acid, crospovidone, aspartame*, strawberry flavor and magnesium stearate.

Patients with phenylketonuria: PREVACID® FasTab contains Phenylalanine* (2.5 mg per 15 mg tablet and 5.1 mg per 30 mg tablet).

* from aspartame

What dosage forms it comes in:
- capsules, 15 mg and 30 mg (PREVACID®)
- tablets, 15 mg and 30 mg (PREVACID® FasTab)

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
If taking lansoprazole in combination with clarithromycin, note that 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® FasTab 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 have phenylketonuria. PREVACID® FasTab contains aspartame;

- if you are taking astemizole†, terfenadine†, cisapride† († not currently marketed in Canada), or pimozide;

- if you are taking HIV protease inhibitors (e.g., atazanavir, nelfinavir) as your doctor may recommend that these medications should not be taken at the same time as PREVACID® FasTab;

- 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® FasTab (see What the important non-medicinal 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, breastfeeding or planning to breastfeed.

PREVACID® FasTab may help your acid-related symptoms, but you could still have serious stomach problems. Talk to your doctor.

Under rare circumstances, supervised by your doctor, proton pump inhibitors might be used for long periods.

You should take PREVACID® FasTab exactly as prescribed, at the lowest dose possible for your treatment and for the shortest time needed.

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. Talk to your doctor about your risk of bone fracture if you take PREVACID® FasTab.

Long term use of proton pump inhibitors may prevent normal absorption of Vitamin B12 from the diet and could lead to Vitamin B12 deficiency. Talk to your doctor.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with PREVACID® FasTab include:

- ampicillin esters
- HIV protease inhibitors (e.g., atazanavir, nelfinavir)
- clopidogrel
- digoxin
- iron salts
- ketoconazole
- methotrexate
- sucralfate
- tacrolimus
- theophylline
- warfarin

PROPER USE OF THIS MEDICATION

Usual dose:

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

Duodenal Ulcer: The recommended adult oral dose is 15 mg once daily before breakfast for 2 to 4 weeks.

Triple Therapy: The recommended adult oral dose is 30 mg PREVACID®, 500 mg clarithromycin, and 1000 mg amoxicillin, all given twice daily for 7, 10 or 14 days. Daily doses should be taken before meals.

Gastric Ulcer: The recommended adult oral dose is 15 mg once daily before breakfast for 4 to 8 weeks.

Healing of NSAID-Associated Gastric Ulcer: The recommended adult oral dose is 15 to 30 mg once daily before breakfast for up to 8 weeks.

Reduction of Risk of NSAID-Associated Gastric Ulcer: The recommended adult oral dose is 15 mg once daily before breakfast for up to 12 weeks.

Reflux Esophagitis or Poorly Responsive Reflux Esophagitis Including Patients with Barrett’s Esophagus: The recommended adult oral dose is 30 mg once daily before breakfast for 4 to 8 weeks.

Maintenance Treatment of Healed Reflux Esophagitis: The recommended adult oral dose is 15 mg once daily before breakfast.

Treatment and Maintenance of Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome: The recommended adult oral starting dose is 60 mg once a day. Your doctor may adjust this dose. Daily dosages of greater than 120 mg should be taken in divided doses.

Gastroesophageal Reflux Disease (GERD): The recommended adult oral dose for the treatment of heartburn and other symptoms associated with GERD is 15 mg once daily before breakfast for up to 8 weeks. If significant symptom relief is not obtained within 4 to 8 weeks, talk to your doctor.

Pediatric GERD (erosive and non-erosive esophagitis): The recommended pediatric oral dose for children 1 to 11 years of age is 15 mg (for children weighing 30 kg or less) and 30 mg (for children weighing more than 30 kg) once daily for up to 12 weeks. Your doctor may change your dose. For adolescents of 12 to 17 years, the adult dose can be used.
PREVACID® FasTab should be taken daily before breakfast. Where the product may be used twice daily, it should be taken prior to breakfast and another meal. PREVACID® FasTab tablets are not designed to be swallowed intact or chewed. Place the tablet on your tongue and allow it to disintegrate with or without water until the particles can be swallowed. Typically, the tablet disintegrates in less than 1 minute. **PREVACID® FasTab tablets should not be crushed, chewed, broken or cut.**

Do not chew the granules.

**For adults and children who have difficulty swallowing:**

**Oral Syringe Option**

For administration via oral syringe, PREVACID® FasTab can be administered as follows:

- Place a 15 mg tablet in oral syringe and draw up approximately 4 mL of water, or place a 30 mg tablet in oral syringe and draw up approximately 10 mL of water.
- Shake gently to allow for a quick dispersal.
- After the tablet has dispersed, administer the contents within 15 minutes.
- Refill the syringe with approximately 2 mL (5 mL for the 30 mg tablet) of water, shake gently, and administer any remaining contents.

**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 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 PREVACID® FasTab, call your doctor right away.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, PREVACID® FasTab 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 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**

<table>
<thead>
<tr>
<th>Symptom/effect</th>
<th>Talk with your doctor or pharmacist</th>
<th>Stop taking drug and call your doctor or pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>Only if severe</td>
<td>In all cases</td>
</tr>
<tr>
<td>Severe diarrhea accompanied with blood and/or mucus</td>
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This is not a complete list of side effects. For any unexpected effects while taking PREVACID® FasTab, contact your doctor or pharmacist.

**HOW TO STORE IT**

**HOW DO I STORE PREVACID® FasTab?**

Keep PREVACID® FasTab out of reach and sight of children.

Store at room temperature (15 to 25°C) in the original container. Protect from light and moisture. Do not use beyond the expiration date.
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 0701D
    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

The most recent version of this document plus the full Product Monograph, prepared for health professionals can be found at:

http://www.mylan.ca

or by contacting the distributor, BGP Pharma ULC, Saint-Laurent, Qc  H4S 1Z1 at:
1-844-596-9526

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This leaflet was prepared by BGP Pharma ULC.

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