

PART III: CONSUMER INFORMATION

PANTOPRAZOLE MAGNESIUM
Pantoprazole enteric-coated tablets
 (as pantoprazole magnesium)

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

ABOUT THIS MEDICATION

What the medication is used for:

PANTOPRAZOLE MAGNESIUM is used to treat acid-related stomach problems such as stomach ulcers (also known as gastric ulcers), duodenal ulcers (including ulcers that are associated with a bacterium called *Helicobacter pylori*), reflux esophagitis (a severe form of heartburn), and symptoms of gastro-esophageal reflux disease (heartburn and acid regurgitation).

What it does:

PANTOPRAZOLE MAGNESIUM works by reducing the amount of acid made in your stomach.

When it should not be used:

You should not take PANTOPRAZOLE MAGNESIUM if you think you might be allergic to any of the ingredients (see "What the non-medicinal ingredients are").

What the medicinal ingredient is:

pantoprazole magnesium

What the non-medicinal ingredients are:

Anhydrous Sodium Carbonate, Mannitol, Crospovidone, Povidone, Calcium Stearate, Hypromellose, Titanium Dioxide, Ferric Oxide, Propylene Glycol, Poly (ethylacrylate, methacrylic acid), Triethyl Citrate

What dosage forms it comes in:

Enteric-coated* tablet, 40 mg pantoprazole (as pantoprazole magnesium)

(*coated to prevent breakdown in the stomach)

WARNINGS AND PRECAUTIONS

BEFORE you use PANTOPRAZOLE MAGNESIUM you should tell your doctor:

- about all health problems you have now or have had in the past.
- about all other medicines you take, including ones you can get without a prescription.
- if you are taking HIV protease inhibitors such as atazanavir sulphate (Reyataz[®]) or nelfinavir (Viracept[®]) advise your doctor as they may interact with PANTOPRAZOLE MAGNESIUM
- if you are allergic to pantoprazole or to the "non-medicinal" ingredients which are present in PANTOPRAZOLE MAGNESIUM.
- if you are pregnant, plan to become pregnant or are breastfeeding. Excretion into human milk has been reported, discuss this with your doctor.
- if you have a history of liver disease.
- if you have any kidney problems.
- if you suffer unexplained weight loss, recurrent vomiting or vomiting blood, dark stools, fatigue (anemia) or difficulty in swallowing.
- if you have severe and/or persistent diarrhea, because products which reduce stomach acid have been associated with a small increase in infectious diarrhea.
- 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).

Under rare circumstances, supervised by your doctor, proton pump inhibitors might be used for long periods. You should take PANTOPRAZOLE MAGNESIUM 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 PANTOPRAZOLE MAGNESIUM.

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.

The safety and efficacy of PANTOPRAZOLE MAGNESIUM has not been established in children.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with PANTOPRAZOLE MAGNESIUM: Talk to your doctor or pharmacist if you are taking warfarin. Warfarin may interact with PANTOPRAZOLE MAGNESIUM. PANTOPRAZOLE MAGNESIUM may interact with atazanavir sulphate (Reyataz®), nelfinavir (Viracept®) and methotrexate.

Laboratory test interactions with PANTOPRAZOLE MAGNESIUM:

Talk to your doctor if you are to take a tetrahydrocannabinol (THC/Cannabis) urine screening test, as PANTOPRAZOLE MAGNESIUM can provide a false positive result.

PROPER USE OF THIS MEDICATION

Your doctor will have explained why you need to be treated with PANTOPRAZOLE MAGNESIUM and will have told you what dose to take. Follow your doctor’s directions carefully as they may be different from the information provided in this leaflet.

Usual adult dose:

Your doctor has recommended you take PANTOPRAZOLE MAGNESIUM T tablets for a specific number of weeks. Keep taking PANTOPRAZOLE MAGNESIUM until you have finished all your tablets, as recommended by your doctor. Do not stop even when you start to feel better. If you stop taking PANTOPRAZOLE MAGNESIUM too soon, your symptoms may return.

PANTOPRAZOLE MAGNESIUM should be taken in the morning, with or without food. It is generally recommended to take PANTOPRAZOLE MAGNESIUM before breakfast. Swallow the tablet(s) whole, with water. Do not crush or chew the tablet(s).

PANTOPRAZOLE MAGNESIUM may be used in combination with two antibiotics to treat ulcers associated with *Helicobacter pylori*. Doses of PANTOPRAZOLE MAGNESIUM and each of the antibiotics should be taken twice a day, or as prescribed by your doctor.

Overdose:

In case of drug overdose, contact a healthcare professional (e.g. doctor), hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take one dose of PANTOPRAZOLE MAGNESIUM, take a tablet as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed tablet at all. Never double-up on a dose to make up for the one you have missed, just go back to your regular schedule.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, PANTOPRAZOLE MAGNESIUM may cause side effects in some people. When side effects have been reported, they have been generally mild and did not last a long time. Headache, diarrhea, and nausea are the most common side effects; less often rash, itchiness and dizziness can occur. If any of these become troublesome, consult your doctor. If you experience any unusual or unexpected symptoms while using PANTOPRAZOLE MAGNESIUM, consult your doctor.

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 (watery or bloody) diarrhea, fever, abdominal pain or tenderness, you may have *Clostridium difficile* colitis (bowel inflammation). If this happens, stop taking these drugs and call your healthcare professional immediately.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Stop taking drug and call your doctor or pharmacist
<i>Rare</i>	Disturbances in vision*	√
<i>Isolated cases</i>	Liver damage (symptoms include yellowing of the skin and eyes)	√
<i>Isolated cases</i>	Severe skin reactions such as, Stevens-Johnson-Syndrome, Erythema multiforme, Exfoliative dermatitis, Toxic epidermal necrolysis, Photosensitivity	√
<i>Isolated cases</i>	Muscle wasting	√

*most cases reported are not serious

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

HOW TO STORE IT

Keep your tablets at room temperature (15 to 30°C) and in a safe place, where children cannot see or reach them.

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
- 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 0701D
Ottawa, Ontario
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.

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.aspripharma.com> or by contacting the sponsor, Aspri Pharma Canada Inc., at: 1-855-868-8440

This leaflet was prepared by Aspri Pharma Canada Inc.

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