

PART III: CONSUMER INFORMATION

P APO-PANTOPRAZOLE

Pantoprazole Sodium Delayed-Release Tablets USP
20 mg and 40 mg pantoprazole (as pantoprazole sodium)

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

ABOUT THIS MEDICATION

What the medication is used for:

APO-PANTOPRAZOLE is used to treat acid-related stomach problems such as stomach ulcers (also known as gastric ulcers), duodenal ulcers, reflux esophagitis (a severe form of heartburn), symptoms of gastro-esophageal reflux disease (heartburn and acid regurgitation), and the prevention of gastrointestinal damage (such as erosions and/or ulcers in the stomach/duodenum) and symptoms caused by non-steroidal anti-inflammatory drugs [(NSAIDs) medicines commonly used to treat arthritis and certain muscle conditions] when individuals must continue to take NSAIDs and where these individuals are considered to have an increased risk of developing gastrointestinal damage.

What it does:

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

When it should not be used:

You should not take APO-PANTOPRAZOLE 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 sodium

What the non-medicinal ingredients are:

APO-PANTOPRAZOLE 20 mg and 40 mg tablets contains the following non-medicinal ingredients: anhydrous lactose, crospovidone, hydroxypropyl methylcellulose, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, purified water, sodium carbonate anhydrous, talc, titanium dioxide, triethyl citrate and yellow ferric oxide.

What dosage forms it comes in:

enteric-coated tablet, 20 mg and 40 mg pantoprazole

APO-PANTOPRAZOLE meets USP Dissolution Test 2.

WARNINGS AND PRECAUTIONS

Before you use APO-PANTOPRAZOLE talk to your doctor or pharmacist:

- about all health problems you have now or have had in the past, including liver problems;
- about all other medicines you take, including ones you can get without a prescription
- if you are taking atazanavir sulphate (Reyataz) advise your doctor as this may interact with APO-PANTOPRAZOLE.
- if you are allergic to pantoprazole or to the “non-medicinal” ingredients which are present in APO-PANTOPRAZOLE;
- 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 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 hypomagnesaemia (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 APO-PANTOPRAZOLE 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 APO-PANTOPRAZOLE.

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

Talk to your doctor or pharmacist if you are taking warfarin. Warfarin may interact with APO-PANTOPRAZOLE. APO-PANTOPRAZOLE may interact with atazanavir sulphate (Reyataz) and methotrexate.

PROPER USE OF THIS MEDICATION

Usual adult dose:

Your doctor will have explained why you need to be treated with APO-PANTOPRAZOLE 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.

APO-PANTOPRAZOLE should be taken in the morning, with or without food. Swallow the tablet(s) whole, with water. Do not crush or chew the tablet(s).

Overdose:

In case of drug overdose, contact a healthcare practitioner (e.g. doctor), hospital emergency department or regional Poison Control Centre

Missed Dose:

If you forget to take one dose of APO-PANTOPRAZOLE, 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, APO-PANTOPRAZOLE 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 APO-PANTOPRAZOLE, 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>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 APO-PANTOPRAZOLE, contact your doctor or pharmacist.

HOW TO STORE IT

Keep your tablets in a safe place where children cannot reach them. Store at controlled room temperature 15°C-30°C (59°F-86°F). Avoid excessive humidity.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:

- Fax to 1-866-678-6789 (toll-free), or
- Mail to: Canada Vigilance Program
Health Canada, Postal Locator
0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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.

MORE INFORMATION

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

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)	✓

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting DISpedia, Apotex's Drug Information Service at:
1-800-667-4708

This leaflet can also be found at:
<http://www.apotex.ca/products>.

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