**PART III: CONSUMER INFORMATION**

*Sandoz® Pantoprazole*

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

This leaflet is part III of a three-part “Product Monograph” published when Sandoz 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 Sandoz Pantoprazole. Contact your doctor or pharmacist if you have any questions about the drug.

**ABOUT THIS MEDICATION**

What the medication is used for:
Sandoz 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 antiinflammatory 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:
Sandoz Pantoprazole works by reducing the amount of acid made in your stomach.

When it should not be used:
You should not use Sandoz Pantoprazole if you think you might be allergic to any of the ingredients (see What the important nonmedicinal ingredients are). You should not use Sandoz Pantoprazole at the same time as atazanavir sulphate (Reyataz).

What the medicinal ingredient is:
pantoprazole sodium sesquihydrate

What the important nonmedicinal ingredients are:
Calcium stearate, microcrystalline cellulose, crospovidone, ferric oxide black, ferric oxide red, ferric oxide yellow, hydroxypropylcellulose, hypromellose, macrogol, methacrylic acid, ethyl acrylate copolymer, polysorbate 80, ponceau 4R aluminium lake, povidone, quinoline yellow aluminium lake, shellac, silica-colloidal anhydrous, sodium carbonate anhydrous, sodium laurilsulfate, titanium dioxide, triethyl citrate.

What dosage forms it comes in:
Delayed-release tablets of 20 mg and 40 mg pantoprazole.

**WARNINGS AND PRECAUTIONS**

BEFORE you use Sandoz 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 allergic to pantoprazole or to the nonmedicinal ingredients which are present in Sandoz Pantoprazole.
- if you are pregnant, plan to become pregnant or are breastfeeding. In one study, a possible increased risk in miscarriage was observed in pregnant women taking pantoprazole in their first trimester. However, it is not known if pantoprazole could cause birth defects or other problems in the unborn baby. This is a concern only if you have been taking pantoprazole for several weeks or months. If you are pregnant or planning to become pregnant, talk to your doctor about the risks and benefits of pantoprazole.
- if you suffer unexplained weight loss, recurrent vomiting or vomiting blood, dark stools, fatigue (anemia) or difficulty in swallowing.

**INTERACTIONS WITH THIS MEDICATION**

Talk to your doctor or pharmacist if you are taking warfarin. Warfarin may interact with Sandoz Pantoprazole.

Sandoz Pantoprazole may interact with atazanavir sulphate.

**PROPER USE OF THIS MEDICATION**

Usual adult dose:
Your doctor will have explained why you need to be treated with Sandoz 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.

Sandoz Pantoprazole should be taken in the morning, with or without food. Swallow the tablet whole, with water. Do not crush or chew the tablets.

**OVERDOSE:**
If you or someone you know takes a lot more than the recommended dose (an overdose) you should contact immediately your doctor, pharmacist, hospital emergency department or regional poison control centre.

**MISSED DOSE:**
If you forget to take one dose of Sandoz 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, Sandoz 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 Sandoz Pantoprazole, consult your doctor.

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

<table>
<thead>
<tr>
<th>Symptom/effect</th>
<th>Stop taking drug and call your doctor or pharmacist</th>
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</thead>
<tbody>
<tr>
<td>Uncommon</td>
<td>Disturbances in vision*</td>
</tr>
<tr>
<td>Very rare</td>
<td>Liver damage (symptoms include yellowing of the skin and eyes)</td>
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<tr>
<td>Isolated cases</td>
<td>Severe skin reactions such as Stevens-Johnson syndrome, erythema multiforme, exfoliative dermatitis, toxic epidermal necrolysis, photosensitivity</td>
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<tr>
<td></td>
<td>Muscle wasting</td>
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*Most cases reported are not serious.

This is not a complete list of side effects. For any unexpected effects while taking Sandoz Pantoprazole, consult your doctor or pharmacist.

**HOW TO STORE IT**

Store between 15 and 30°C and keep out of reach of children.

**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
  - 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

**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: www.sandoz.ca
or by contacting the sponsor, Sandoz Canada Inc., at: 1-800-361-3062
or by written request at: 145, Jules-Léger, Boucherville (QC) Canada J4B 7K8
or by e-mail at: medinfo@sandoz.com
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