

PART III: PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **PANTOPRAZOLE**

Pantoprazole Delayed-Release Tablets

40 mg Pantoprazole (as pantoprazole sodium sesquihydrate)

Read this carefully before you start taking PANTOPRAZOLE and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about PANTOPRAZOLE.

What is PANTOPRAZOLE used for?

PANTOPRAZOLE is used to treat stomach acid related problems. This includes:

- **Stomach ulcer.**
A stomach ulcer is a sore on the lining of the stomach. This is also known as a gastric ulcer.
- **Duodenal ulcer.**
A sore on the lining of the duodenum. The duodenum is the first part of the small intestine.
- **Reflux esophagitis.**
This is a severe form of heartburn.
- **Symptoms of gastro-esophageal reflux disease (GERD).**
The symptoms include heartburn and acid regurgitation. GERD is a condition in which stomach acid backs up into your esophagus.
- ***When taking Non-steroidal anti-inflammatory drugs (NSAIDs).**
Stops stomach and duodenal ulcers from forming.

* Note: The recommended adult oral dose is 20 mg. Sanis Health Inc. currently does not market the 20 mg strength.

How does PANTOPRAZOLE work?

PANTOPRAZOLE is a proton pump inhibitor. It reduces the amount of acid your stomach makes.

What are the ingredients in PANTOPRAZOLE?

Medicinal ingredients: pantoprazole sodium sesquihydrate

Non-medicinal ingredients: Calcium stearate, cellulose microcrystalline, 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.

PANTOPRAZOLE comes in the following dosage forms:

Delayed-Release tablets of 40 mg pantoprazole (as pantoprazole sodium sesquihydrate).

Do not use PANTOPRAZOLE if:

- You are allergic to any of its ingredients. (See What are the ingredients in PANTOPRAZOLE?)
- You are taking rilpivirine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PANTOPRAZOLE. Talk about any health conditions or problems you may have, including if you:

- are taking other medications (see The following may interact with PANTOPRAZOLE).
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breast feed. Pantoprazole has been found in human breast milk. Talk with your doctor.
- suffer these effects:
 - unexplained weight loss.
 - severe or persistent diarrhea.
 - repeated vomiting.
 - vomiting blood.
 - dark stools.
 - tiredness (anemia).
 - difficulty in swallowing.
 - have a history of liver problems.
- have low magnesium in the body, which may cause symptoms such as:
 - rapid heartbeat.
 - dizziness, seizures.
 - muscle cramping, twitches or spasms.
- are due to have a specific blood test (Chromogranin A).

Other warnings you should know about:

You should take PANTOPRAZOLE exactly as prescribed. You will use the lowest dose and shortest time suitable for your condition. Talk to your doctor if you have any concerns about your treatment.

Depending on your condition, your doctor may tell you to use this type of medicine (proton pump inhibitors) for a longer period.

Using proton pump inhibitors for a long time (every day for a year or longer) may increase risks of broken bones of the hip, wrist or spine. Talk to your doctor about this risk.

Long term use of proton pump inhibitors may interfere with the absorption of Vitamin B₁₂ from the diet. This may cause a shortage of Vitamin B₁₂ in your body. Talk to your doctor.

Using PANTOPRAZOLE for a long period of time may cause a growth in your stomach (polyp), especially after one year.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PANTOPRAZOLE:

Warfarin, atazanavir, nelfinavir, saquinavir/ritonavir, methotrexate.

How to take PANTOPRAZOLE:

- Take PANTOPRAZOLE in the morning.
 - with or without food
- Swallow the tablet(s) whole with water.
- Do not crush or chew the tablet(s).

Usual adult dose:

Your doctor will have told you what dose to take for your condition. Follow your doctor's directions carefully as they may be different from the information provided in this leaflet.

If you think you have taken too much PANTOPRAZOLE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, 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 the next dose, skip the missed dose. Take the next dose at your regular time. Do not double doses.

What are possible side effects from using PANTOPRAZOLE?

Like all medicines, PANTOPRAZOLE may cause side effects. Side effects have generally been mild and did not last a long time. These are not all the possible side effects you may feel when taking PANTOPRAZOLE.

The most common side effects are:

- headache.
- diarrhea.
- nausea.

Tell your doctor right away if you have any of these symptoms:

- new or worsening joint pain
- rash on your cheeks or arms that gets worse in the sun

Your symptoms may get worse after stopping your medication. This may occur as your stomach may increase the production of acid.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE Disturbances in vision. Most cases reported are not serious.			✓
ISOLATED CASES Liver damage. Symptoms include a yellow tinge to the skin and eyes.			✓
Serious skin reactions. Symptoms include widespread rash, itching, or hives. Peeling of the skin, blisters on the skin, mouth, nose, eyes and genitals are other symptoms.			✓
Muscle wasting			✓
<i>Clostridium difficile</i> colitis (bowel inflammation). Symptoms include severe (watery or bloody) diarrhea, fever, and abdominal pain or tenderness.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

Storage:

Store in a dry place at room temperature (between 15°C and 30 °C).
Keep out of reach and sight of children.

If you want more information about PANTOPRAZOLE:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website(<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.sanis.com, or by contacting Sanis Health Inc. at:

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