

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr PANTOPRAZOLE

Pantoprazole Delayed-Release Tablets

(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.
- **Duodenal ulcer caused by the bacteria *Helicobacter pylori* (*H. pylori*).**
PANTOPRAZOLE is used in combination with two antibiotics.
- **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.

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, 20 mg and 40 mg.

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.
- 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:

Tell your doctor if you experience the following symptoms before taking PANTOLOC:

- unexplained weight loss.
- severe or persistent diarrhea.
- repeated vomiting.
- vomiting blood.
- dark stools.
- tiredness (anemia).
- difficulty in swallowing.

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
- methotrexate
- itraconazole
- erlotinib
- nelfinavir
- saquinavir/ritonavir
- ketoconazole
- posaconazole

How to take PANTOPRAZOLE:

- Take PANTOPRAZOLE in the morning.
 - with or without food
 - with breakfast, is recommended
- 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.

PANTOPRAZOLE may be used in combination with two antibiotics to treat ulcers caused by *H. pylori*. PANTOPRAZOLE and both antibiotics are to be taken twice a day, or as prescribed by your doctor.

Overdose:

If you think you, or a person you are caring for, have taken too much PANTOPRAZOLE, contact a 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 have when taking PANTOPRAZOLE. If you experience any side effects not listed here, tell your healthcare professional.

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.			✓
UNKNOWN			
Liver damage. Symptoms include a yellow tinge to the skin and eyes.			✓
Severe Cutaneous Adverse Reactions (SCAR) (Severe Skin Reactions): Skin rash which may have blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet). You may also experience fever, chills, body aches, shortness of breath, or enlarged lymph nodes.			✓
Muscle wasting.			✓
<i>Clostridium difficile</i> colitis (bowel inflammation). Symptoms include severe (watery or bloody) diarrhea, fever, and abdominal pain or			✓

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	
tenderness.			
Microscopic colitis (inflammation of the gut). Symptoms include chronic watery diarrhea, abdominal pain, cramps or bloating, weight loss, nausea, uncontrollable bowel movement, signs of dehydration such as extreme thirst, less frequent urination, dark-coloured urine, fatigue, dizziness, confusion. The symptoms of microscopic colitis can come and go frequently. If you have watery diarrhea that lasts more than a few days, contact your doctor.	✓		

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.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 PANTOPRAZOLE 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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.sivem.ca), or by calling 1 855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC.

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