

PART III: PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr PANTOPRAZOLE T Pantoprazole Magnesium Enteric-Coated Tablets

Read this carefully before you start taking PANTOPRAZOLE T 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 T.

What is PANTOPRAZOLE T used for?

PANTOPRAZOLE T is used to treat acid-related stomach 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 T is used in combination with two antibiotics.
- **Reflux esophagitis.**
This is a severe form of heartburn.
- **Symptoms of gastro-esophageal reflux disease.**
The symptoms include heartburn and acid regurgitation. GERD is a condition in which stomach acid backs up into your esophagus.

How does PANTOPRAZOLE T work?

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

What are the ingredients in PANTOPRAZOLE T?

Medicinal ingredients: pantoprazole (as pantoprazole magnesium hemipentahydrate)

Non-medicinal ingredients: calcium stearate, crospovidone, hypromellose, hydroxypropyl cellulose, mannitol, methacrylic acid copolymer, propylene glycol, povidone, sodium carbonate anhydrous, titanium dioxide, triethyl citrate. Coating: HPMC 2910/hypromellose, iron oxide yellow, propylene glycol, talc, titanium dioxide. Ink: ammonium hydroxide, iron oxide black, isopropyl alcohol, n-Butyl alcohol, propylene glycol, shellac glaze.

PANTOPRAZOLE T comes in the following dosage forms:

- Tablet, 40 mg.

Do not use PANTOPRAZOLE T if:

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

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

- are taking other medications (see **The following may interact with PANTOPRAZOLE T**).
- 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 T 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 T 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 T:

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

How to take PANTOPRAZOLE T:

- Take PANTOPRAZOLE T in the morning.
 - with or without food.
 - before 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.

Keep taking PANTOPRAZOLE T until you have finished all your tablets. Do not stop even when you start to feel better. If you stop taking PANTOPRAZOLE T too soon, your symptoms may return.

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

Overdose:

If you think you have taken too much PANTOPRAZOLE T, 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 T?

Like all medication, PANTOPRAZOLE T 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 T.

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 call your doctor or pharmacist
	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.			✓
Clostridium difficile 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 PANTOPRAZOLE T at controlled room temperature (15°C-30°C).
Keep out of reach and sight of children.

If you want more information about PANTOPRAZOLE T:

- 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>); or by contacting Sivem Pharmaceuticals ULC at: 1 855 788-3153
- This document can be found at: www.sivem.ca.

This leaflet was prepared by:
Sivem Pharmaceuticals ULC
4705 Dobrin Street
Saint-Laurent, Quebec, Canada
H4R 2P7

www.sivem.ca

Last revised: August 25, 2021