MEDICATION GUIDE

Pantoprazole Sodium Delayed-Release Tablets, USP
(pan toe' pra zole soe' dee um)

Read this Medication Guide before you start taking pantoprazole sodium delayed-release tablets and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about pantoprazole sodium delayed-release tablets?

Pantoprazole sodium delayed-release tablets may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

Pantoprazole sodium delayed-release tablets can cause serious side effects, including:

- **Diarrhea**. Pantoprazole sodium delayed-release tablets may increase your risk of getting severe diarrhea. This diarrhea may be caused by an infection (*Clostridium difficile*) in your intestines.

  Call your doctor right away if you have watery stool, stomach pain, and fever that does not go away.

- **Bone fractures**. 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. You should take pantoprazole sodium delayed-release tablets exactly as prescribed, at the lowest dose possible for your treatment and for the shortest time needed. Talk to your doctor about your risk of bone fracture if you take pantoprazole sodium delayed-release tablets.

Pantoprazole sodium delayed-release tablets can have other serious side effects. See **"What are the possible side effects of pantoprazole sodium delayed-release tablets?"**

What are pantoprazole sodium delayed-release tablets?

Pantoprazole sodium delayed-release tablets are a prescription medicine called a proton pump inhibitor (PPI).

Pantoprazole sodium delayed-release tablets reduce the amount of acid in your stomach.

Pantoprazole sodium delayed-release tablets are used in adults:

- for up to 8 weeks to heal acid-related damage to the lining of the esophagus (erosive esophagitis or EE) and to relieve symptoms caused by gastroesophageal reflux disease (GERD). If needed, your doctor may decide to prescribe another 8 weeks of pantoprazole sodium delayed-release tablets.
- to maintain the healing of acid-related damage to the lining of the esophagus and help prevent return of heartburn symptoms caused by GERD. It is not known if pantoprazole sodium delayed-release tablets are safe and effective if used longer than 12 months (1 year).

GERD happens when acid in your stomach backs up into the tube (esophagus) that connects your mouth to your stomach. This may cause a burning feeling in your chest or throat, sour taste, or burping.

- for the long-term treatment of conditions where your stomach makes too much acid. This includes a

rare condition called Zollinger-Ellison syndrome.

Pantoprazole sodium delayed-release tablets are used in children 5 years of age and older for up to 8 weeks to heal acid-related damage to the lining of the esophagus (erosive esophagitis or EE) caused by GERD.

It is not known if pantoprazole sodium delayed-release tablets are safe if used longer than 8 weeks in children. Pantoprazole sodium delayed-release tablets are not for use in children under 5 years of age.

Who should not take pantoprazole sodium delayed-release tablets?

Do not take pantoprazole sodium delayed-release tablets if you are:

- allergic to pantoprazole sodium or any of the other ingredients in pantoprazole sodium delayed-release tablets. See the end of this Medication Guide for a complete list of ingredients in pantoprazole sodium delayed-release tablets.
- allergic to any proton pump inhibitor (PPI) medicine.

What should I tell my doctor before taking pantoprazole sodium delayed-release tablets?

Before taking pantoprazole sodium delayed-release tablets, tell your doctor if you:

- have been told that you have low magnesium levels in your blood
- have liver problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if pantoprazole sodium delayed-release tablets will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Pantoprazole sodium may pass into your milk. You and your doctor should decide if you will take pantoprazole sodium delayed-release tablets or breastfeed. You should not do both. Talk with your doctor about the best way to feed your baby if you take pantoprazole sodium delayed-release tablets.

Tell your doctor about all of the medicines you take, including prescription and non-prescription drugs, vitamins and herbal supplements. Pantoprazole sodium delayed-release tablets may affect how other medicines work, and other medicines may affect how pantoprazole sodium delayed-release tablets work.

Especially tell your doctor if you take:

- atazanavir (Reyataz)
- nelfinavir (Viracept)
- warfarin (Coumadin, Jantoven)
- ketoconazole (Nizoral)
- a product that contains iron
- an antibiotic that contains ampicillin
- methotrexate
- mycophenolate mofetil (Cellcept)

Ask your doctor or pharmacist for a list of these medicines, if you are not sure.

Know the medicines that you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take pantoprazole sodium delayed-release tablets?

- Take pantoprazole sodium delayed-release tablets exactly as prescribed by your doctor.
- Do not change your dose or stop pantoprazole sodium delayed-release tablets without talking to your doctor.
- If you forget to take a dose of pantoprazole sodium delayed-release tablets, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose. Take the next dose at your regular time. Do not take two doses to try to make up for a missed dose.
- If you take too much pantoprazole sodium, call your doctor right away or go to the nearest hospital emergency room.
- See the Instructions for Use at the end of this Medication Guide for detailed instructions about:
  - how to take pantoprazole sodium delayed-release tablets

What are the possible side effects of pantoprazole sodium delayed-release tablets?

Pantoprazole sodium delayed-release tablets may cause serious side effects, including:

See "What is the most important information I should know about pantoprazole sodium delayed-release tablets?"

- **Chronic (lasting a long time) inflammation of the lining of the stomach (Atrophic Gastritis).** Taking pantoprazole sodium delayed-release tablets for a long period of time may increase the risk of inflammation to your stomach lining. You may or may not have symptoms. Tell your doctor if you have stomach pain, nausea, vomiting or weight loss.
- **Vitamin B-12 deficiency.** Pantoprazole sodium delayed-release tablets reduce the amount of acid in your stomach. Stomach acid is needed to absorb vitamin B-12 properly. Talk with your doctor about the possibility of vitamin B-12 deficiency if you have been on pantoprazole sodium delayed-release tablets for a long time (more than 3 years).
- **Low magnesium levels in your body.** This problem can be serious. Low magnesium can happen in some people who take a proton pump inhibitor medicine for at least 3 months. If low magnesium levels happen, it is usually after a year of treatment. You may or may not have symptoms of low magnesium.

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

- seizures
- dizziness
- abnormal or fast heartbeat
- jitteriness
- jerking movements or shaking (tremors)
- muscle weakness
- spasms of the hands and feet
- cramps or muscle aches
- spasm of the voice box

Your doctor may check the level of magnesium in your body before you start taking pantoprazole sodium delayed-release tablets or during treatment, if you will be taking pantoprazole sodium delayed-release tablets for a long period of time.

The most common side effects with pantoprazole sodium delayed-release tablets in adults include:

- Headache
- Diarrhea
- Nausea
- Stomach pain
- Vomiting
- Gas
- Dizziness
- Pain in your joints

The most common side effects with pantoprazole sodium delayed-release tablets in children include:

- Upper respiratory infection
- Headache
- Fever
- Diarrhea
- Vomiting
- Rash
- Stomach pain

Other side effects:

- **Serious allergic reactions**. Tell your doctor if you get any of the following symptoms with pantoprazole sodium delayed-release tablets:

- rash
- face swelling
- throat tightness
- difficult breathing

Your doctor may stop pantoprazole sodium delayed-release tablets if these symptoms happen.

Tell your doctor about any side effects that bother you or that do not go away.

These are not all the possible side effects with pantoprazole sodium delayed-release tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store pantoprazole sodium delayed-release tablets?

- Store pantoprazole sodium delayed-release tablets at room temperature between 20° to 25°C (68° to 77° F).

Keep pantoprazole sodium delayed-release tablets and all medicines out of the reach of children.

General information about pantoprazole sodium delayed-release tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use pantoprazole sodium delayed-release tablets for a condition for which it was not prescribed. Do not give pantoprazole sodium delayed-release tablets to other people, even if they have the same symptoms you have. They may harm them.

This Medication Guide summarizes the most important information about pantoprazole sodium delayed-release tablets. For more information, ask your doctor. You can ask your doctor or pharmacist for information that is written for healthcare professionals.

For more information, call Prasco Laboratories at 1-866-525-0688.

What are the ingredients in pantoprazole sodium delayed-release tablets?

Active ingredient: pantoprazole sodium

Inactive ingredients in pantoprazole sodium delayed-release tablets: calcium stearate, crospovidone, ferric oxide, hydroxypropyl cellulose, hypromellose, mannitol, methacrylic acid copolymer dispersion, sodium carbonate, and triethyl citrate. The tablets are imprinted with brown ink containing ammonium hydroxide, iron oxide black, iron oxide red, iron oxide yellow, isopropyl alcohol, N-butyl alcohol, propylene glycol, and shellac glaze in ethanol.

Instructions for Use

- You can take pantoprazole sodium delayed-release tablets with food or on an empty stomach.
- Swallow pantoprazole sodium delayed-release tablets whole.
- If you have trouble swallowing a pantoprazole sodium delayed-release tablet 40 mg, you can take two 20 mg tablets instead.
- Do not split, chew, or crush pantoprazole sodium delayed-release tablets.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

The brands listed are trademarks of their respective owners and are not trademarks of Aurobindo Pharma Limited.

Manufactured for:
Prasco Laboratories
Mason, OH 45040 USA

Manufactured by:
Aurobindo Pharma Limited
Unit-VII (SEZ)
Mahaboob Nagar (Dt)-509302
India

Revised: 12/2015