MEDICATION GUIDE

ESOMEPRAZOLE STRONTIUM (es-o-mep-ra-zol stron-tee-um)
delayed-release capsules

Read the Medication Guide that comes with esomeprazole strontium before you start taking esomeprazole strontium 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 esomeprazole strontium?

Esomeprazole strontium may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

Esomeprazole strontium can cause serious side effects, including:

- **Diarrhea.** Esomeprazole strontium 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 esomeprazole strontium 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 esomeprazole strontium.

Esomeprazole strontium can have other serious side effects. See “What are the possible side effects of esomeprazole strontium?”

What is esomeprazole strontium?

Esomeprazole strontium is a prescription medicine called a proton pump inhibitor (PPI). Esomeprazole strontium reduces the amount of acid in your stomach.

Esomeprazole strontium is used in adults:

- for 4 to 8 weeks to treat the symptoms of gastroesophageal reflux disease (GERD). Esomeprazole strontium may also be prescribed to heal acid-related damage to the lining of the esophagus (erosive esophagitis), and to help continue this healing.
  
  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 up to 6 months to reduce the risk of stomach ulcers in some people taking pain medicines called non-steroidal anti-inflammatory drugs (NSAIDs)

- to treat patients with a stomach infection (*Helicobacter pylori*), along with the antibiotics amoxicillin and clarithromycin

- for the long-term treatment of conditions where your stomach makes too much acid, including Zollinger-Ellison Syndrome. Zollinger-Ellison Syndrome is a rare condition in which the stomach produces a more than normal amount of acid.

It is not known if esomeprazole strontium is safe and effective in children. Esomeprazole strontium should not be used in children.
Who should not take esomeprazole strontium?

Do not take esomeprazole strontium if you:

- are allergic to esomeprazole strontium or any of the ingredients in esomeprazole strontium. See the end of this Medication Guide for a complete list of ingredients in esomeprazole strontium.
- are allergic to any other Proton Pump Inhibitor (PPI) medicine

What should I tell my doctor before taking esomeprazole strontium?

Before you take esomeprazole strontium, tell your doctor if you:

- have been told that you have low magnesium levels in your blood
- have liver problems
- have kidney problems. You should not take esomeprazole strontium if you have severe kidney problems.
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if esomeprazole strontium can harm your unborn baby.
- are breastfeeding or planning to breastfeed. Esomeprazole strontium passes into your breast milk. You and your doctor should decide if you will take esomeprazole strontium or breastfeed. You should not do both. Talk to your doctor about the best way to feed your baby if you take esomeprazole strontium.

Tell your doctor about all of the medicines you take, including prescription and non-prescription drugs, anti-cancer drugs, vitamins and herbal supplements. Esomeprazole strontium may affect how other medicines work, and other medicines may affect how esomeprazole strontium works.

Especially tell your doctor if you take:

- warfarin (Coumadin, Jantoven)
- ketoconazole (Nizoral)
- voriconazole (Vfend)
- atazanavir (Reyataz)
- nelfinavir (Viracept)
- saquinavir (Fortovase)
- products that contain iron
- digoxin (Lanoxin)
- St.John’s Wort (Hypericum perforatum)
- rifampin (Rimactane, Rifater, Rifamate)
- cilostazol (Pletal)
- diazepam (Valium)
- tacrolimus (Prograf)
- erlotinib (Tarceva)
- methotrexate
- clopidogrel (Plavix)
- Mycophenolate mofetil (Cellcept)

How should I take esomeprazole strontium?

- Take esomeprazole strontium exactly as prescribed by your doctor.
- Do not change your dose or stop esomeprazole strontium without talking to your doctor.
- Take esomeprazole strontium at least 1 hour before a meal.
Swallow esomeprazole strontium delayed-release capsules whole. Never chew or crush esomeprazole strontium delayed-release capsules.

If you have difficulty swallowing esomeprazole strontium, you may open the capsule and empty the contents into a tablespoon of applesauce. Esomeprazole strontium should only be mixed with applesauce. The applesauce should not be hot, and it should be soft enough so that you can swallow it without chewing. Mix the contents with the applesauce. Do not crush or chew the granules. Be sure to swallow the applesauce right away. Do not store it for later use.

If you take too much esomeprazole strontium, call your doctor or local poison control center right away, or go to the nearest hospital emergency room.

See the “Instructions for Use” at the end of this Medication Guide for instructions about how to mix and give esomeprazole strontium through a nasogastric tube.

What are the possible side effects of esomeprazole strontium?

Esomeprazole strontium can cause serious side effects, including:

- See “What is the most important information I should know about esomeprazole strontium?”
- Chronic (lasting a long time) inflammation of the stomach lining (Atrophic Gastritis). Using esomeprazole strontium 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. Esomeprazole strontium reduces 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 esomeprazole strontium 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 heart beat
- 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 esomeprazole strontium or during treatment if you will be taking esomeprazole strontium for a long period of time.

The most common side effects with esomeprazole strontium may include:

- headache
- diarrhea
- nausea
- gas
- abdominal pain

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• constipation
• dry mouth

Other side effects:

**Serious allergic reactions.** Tell your doctor if you get any of the following symptoms with esomeprazole strontium:
• rash
• face swelling
• throat tightness
• difficulty breathing

Your doctor may stop esomeprazole strontium if these symptoms happen.

Tell your doctor if you have any side effects that bother you or that do not go away. These are not all the possible side effects with esomeprazole strontium.

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 esomeprazole strontium?**

• Store esomeprazole strontium at room temperature between 68°F to 77°F (20°C to 25°C).
• Keep the container of esomeprazole strontium closed tightly.

**Keep esomeprazole strontium and all medicines out of the reach of children.**

**General information about esomeprazole strontium**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use esomeprazole strontium for a condition for which it was not prescribed. Do not give esomeprazole strontium to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about esomeprazole strontium. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about esomeprazole strontium that is written for health professionals.
For more information, go to [www.amneal.com](http://www.amneal.com) or call 1-877-835-5472.

**What are the ingredients in esomeprazole strontium?**

Active ingredient: esomeprazole strontium tetrahydrate

Inactive ingredients: calcium carbonate, hypromellose, methacrylic acid copolymer dispersion, mono- and diglycerides, polysorbate 80, sugar spheres, talc, triethyl citrate.

The 24.65 mg capsule shells contain: gelatin, titanium dioxide, synthetic iron oxide.
The 49.3 mg capsule shells contain: gelatin, titanium dioxide, FD&C Blue #1, FD&C Red #40, FD&C Yellow #6.

**Instructions for Use**

For instructions on taking esomeprazole strontium delayed-release capsules, see the section of this Medication Guide called “**How should I take esomeprazole strontium?**”

Esomeprazole strontium delayed-release capsules may be given through a nasogastric tube (NG tube) as prescribed by your doctor. Follow the instructions below:
• Open the capsule and empty the granules into a 60 mL catheter tipped syringe. Mix with 50 mL of water. Use only a catheter tipped syringe to give esomeprazole strontium through a NG tube.
• Replace the plunger and shake the syringe well for 15 seconds. Hold the syringe with the tip up and check for granules in the tip.
• Give the medicine right away.
• Do not give the granules if they have dissolved or have broken into pieces.
• Attach the syringe to the NG tube. Give the medicine in the syringe through the NG tube into the stomach.
• After giving the granules, flush the NG tube with more water.

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