MEDICATION GUIDE

Esomeprazole (ES-oh-MEP-ra-zole) Magnesium (mag-NEE-zee-um) Delayed-Release Capsules USP

Read the Medication Guide that comes with esomeprazole magnesium delayed-release capsules before you start taking esomeprazole magnesium delayed-release capsules 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 magnesium delayed-release capsules?

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

Esomeprazole magnesium delayed-release capsules can cause serious side effects, including:

- **Diarrhea**. Esomeprazole magnesium delayed-release capsules 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 magnesium delayed-release capsules 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 magnesium delayed-release capsules.
  Esomeprazole magnesium delayed-release capsules can have other serious side effects. See **"What are the possible side effects of esomeprazole magnesium delayed-release capsules?"**

What are esomeprazole magnesium delayed-release capsules?

Esomeprazole magnesium delayed-release capsules are a prescription medicine called a proton pump inhibitor (PPI). Esomeprazole magnesium delayed-release capsules reduce the amount of acid in your stomach.

Esomeprazole magnesium delayed-release capsules are used in adults:

- for 4 to 8 weeks to treat the symptoms of gastroesophageal reflux disease (GERD). Esomeprazole magnesium delayed-release capsules 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.

For children and adolescents 1 year to 17 years of age, esomeprazole magnesium delayed-release capsules may be prescribed for up to 8 weeks for short-term treatment of GERD.

Who should not take esomeprazole magnesium delayed-release capsules?

Do not take esomeprazole magnesium delayed-release capsules if you:

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

What should I tell my doctor before taking esomeprazole magnesium delayed-release capsules?

Before you take esomeprazole magnesium delayed-release capsules, tell your doctor if you:

- have been told that you have low magnesium levels in your blood
- have liver problems
- are pregnant or plan to become pregnant. It is not known if esomeprazole magnesium delayed-release capsules can harm your unborn baby.
- are breastfeeding or planning to breastfeed. Esomeprazole magnesium may pass into your breast milk. Talk to your doctor about the best way to feed your baby if you take esomeprazole magnesium delayed-release capsules.

Tell your doctor about all of the medicines you take, including prescription and non-prescription drugs, vitamins and herbal supplements. Esomeprazole magnesium delayed-release capsules may affect how other medicines work, and other medicines may affect how esomeprazole magnesium delayed-release capsules work.

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 magnesium delayed-release capsules?

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

- If you have difficulty swallowing esomeprazole magnesium delayed-release capsules, you may open the capsule and empty the contents into a tablespoon of 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 forget to take a dose of esomeprazole magnesium delayed-release capsules, 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 on time. Do not take a double dose to make up for a missed dose.
- If you take too many esomeprazole magnesium delayed-release capsules, 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 how to mix and give esomeprazole magnesium delayed-release capsules through a nasogastric tube or gastric tube.

What are the possible side effects of esomeprazole magnesium delayed-release capsules?

Esomeprazole magnesium delayed-release capsules can cause serious side effects, including:

- **See "What is the most important information I should know about esomeprazole magnesium delayed-release capsules?"**
- **Chronic (lasting a long time) inflammation of the stomach lining (Atrophic Gastritis).** Using esomeprazole magnesium delayed-release capsules 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 magnesium 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 magnesium for a long time (more than 3 years).
- **Low magnesium levels in your body.** 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 magnesium delayed-release capsules or during treatment if you will be taking esomeprazole magnesium delayed-release capsules for a long period of time.

The most common side effects with esomeprazole magnesium delayed-release capsules may include:

- headache

- diarrhea
- nausea
- gas
- abdominal pain
- constipation
- dry mouth
- drowsiness

Other side effects:
Serious allergic reactions. Tell your doctor if you get any of the following symptoms with esomeprazole magnesium delayed-release capsules:

- rash
- face swelling
- throat tightness
- difficulty breathing

Your doctor may stop esomeprazole magnesium delayed-release capsules 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 magnesium delayed-release capsules.

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 magnesium delayed-release capsules?

- Store esomeprazole magnesium delayed-release capsules at room temperature between 68°F to 77°F (20° C to 25°C).
- Keep the container of esomeprazole magnesium delayed-release capsules closed tightly.

Keep esomeprazole magnesium delayed-release capsules and all medicines out of the reach of children.

General information about esomeprazole magnesium delayed-release capsules

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use esomeprazole magnesium delayed-release capsules for a condition for which they were not prescribed. Do not give esomeprazole magnesium delayed-release capsules 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 magnesium delayed-release capsules. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about esomeprazole magnesium delayed-release capsules that is written for health professionals.

For more information about esomeprazole magnesium delayed-release capsules, call 1-888-838-2872.

What are the ingredients in esomeprazole magnesium delayed-release capsules?

Active Ingredient: esomeprazole (present as 21.69 mg or 43.38 mg esomeprazole magnesium dihydrate)

Inactive ingredients in esomeprazole magnesium delayed-release capsules (including the capsule shells): FD&C blue #1, gelatin, hypromellose, methacrylic acid copolymer dispersion, polysorbate 80, propylene glycol, shellac, sugar spheres, talc, titanium dioxide, triethyl citrate, and yellow iron oxide.

Instructions for Use

For instructions on taking esomeprazole magnesium delayed-release capsules, see the section of this leaflet called "**How should I take esomeprazole magnesium delayed-release capsules?**"

Esomeprazole magnesium delayed-release capsules may be given through a nasogastric tube (NG tube) or gastric 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 magnesium 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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