

MEDICATION GUIDE

Esomeprazole magnesium (es" oh mep' ra zole mag nee' zee um) Delayed-Release Capsules, USP

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:

- **A type of kidney problem (acute tubulointerstitial nephritis).** Some people who take proton pump inhibitor (PPI) medicines, including esomeprazole magnesium delayed-release capsules, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with esomeprazole magnesium delayed-release capsules. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.
- **Diarrhea caused by an infection (*Clostridium difficile*) in your intestines.**
Call your doctor right away if you have watery stools or stomach pain that does not go away. You may or may not have a fever.
- **Bone fractures (hip, wrist, or spine).** Bone fractures in the hip, wrist, or spine may happen in people who take multiple daily doses of PPI medicines and for a long period of time (a year or longer). Tell your doctor if you have a bone fracture, especially in the hip, wrist, or spine.
- **Certain types of lupus erythematosus.** Lupus erythematosus is an autoimmune disorder (the body's immune cells attack other cells or organs in the body). Some people who take PPI medicines, including esomeprazole magnesium delayed-release capsules, may develop certain types of lupus erythematosus or have worsening of the lupus they already have. Call your doctor right away if you have new or worsening joint pain or a rash on your cheeks or arms that gets worse in the sun.

Talk to your doctor about your risk of these serious side effects.

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 is esomeprazole magnesium delayed-release capsule?

A prescription medicine called a proton pump inhibitor (PPI) used to reduce the amount of acid in your stomach.

Esomeprazole magnesium delayed-release capsule is used in adults for:

- 4 to 8 weeks for the healing and symptom relief of acid-related damage to the esophagus (erosive esophagitis or EE). Your doctor may prescribe another 4 to 8 weeks of esomeprazole magnesium in patients whose EE does not heal.
- maintaining healing of EE.
- 4 to 8 weeks to treat heartburn and other symptoms that happen with gastroesophageal reflux disease (GERD).
- up to 6 months to reduce the risk of stomach ulcers in some people taking pain medicines called non-steroidal anti-inflammatory drugs (NSAIDs).
- treating patients with a stomach infection (*Helicobacter pylori*) and a stomach ulcer, along with the antibiotics amoxicillin and clarithromycin.
- 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.

Esomeprazole magnesium is used in children and adolescents 12 years to 17 years of age for:

- 4 to 8 weeks to heal EE.
- 4 weeks to treat heartburn and other symptoms that happen with GERD.

It is not known if esomeprazole magnesium is safe and effective in children to reduce the risk of stomach ulcers in children who take medicines called NSAIDs, to treat *Helicobacter pylori* stomach infection to lower the risk of a stomach ulcer returning, and to treat conditions where your stomach makes too much acid.

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

- allergic to esomeprazole magnesium, any other PPI medicine, or any of the ingredients in esomeprazole magnesium delayed-release capsule. See the end of this Medication Guide for a complete list of ingredients in esomeprazole magnesium delayed-release capsules.

Tell your doctor right away or get emergency medical help if you get any of the following symptoms of an allergic reaction with esomeprazole magnesium:

- o rash
- o throat tightness
- o face swelling
- o difficulty breathing
- o taking a medicine that contains rilpivirine (EDURANT, COMPLERA, ODEFSEY) used to treat HIV-1 (Human Immunodeficiency Virus).

Before taking esomeprazole magnesium delayed-release capsules, tell your doctor about all of your medical conditions, including if you:

- have low magnesium levels, low calcium levels and low potassium 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 over-the-counter medicines, vitamins and herbal supplements.

Especially tell your doctor if you take: clopidogrel (Plavix), methotrexate (Otrxup, Rasuvo, Trexall, XATMEP), digoxin (LANOXIN), rilpivirine (EDURANT), St. John's Wort (*Hypericum perforatum*), or rifampin (Rimactane, Rifater, Rifamate).

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.
- Antacids may be taken with esomeprazole magnesium delayed-release capsules.
- 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 granules into 1 tablespoon of applesauce. The applesauce used should not be hot and should be soft enough to swallow without chewing. Do not mix the esomeprazole magnesium granules with any other food.
- Do not crush or chew the granules. Be sure to swallow the applesauce right away. Throw away any remaining mixture. 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 much esomeprazole magnesium delayed-release capsules, call your doctor or local poison control center right away at 1-800-222-1222, 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.

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?”**
- **Low vitamin B-12 levels in your body** can happen in people who have taken esomeprazole magnesium delayed-release capsules for a long time (more than 3 years). Tell your doctor if you have symptoms of low vitamin B-12 levels, including shortness of breath, lightheadedness, irregular heartbeat, muscle weakness, pale skin, feeling tired, mood changes, and tingling or numbness in the arms and legs.
- **Low magnesium levels in your body** can happen in people who have taken esomeprazole magnesium delayed-release capsules for at least 3 months. Tell your doctor right away if you have symptoms of low magnesium levels, including seizures, dizziness, irregular heartbeat, jitteriness, muscle aches or weakness, and spasms of hands, feet or voice.
- **Stomach growths (fundic gland polyps).** People who take PPI medicines for a long time have an increased risk of developing a certain type of stomach growths called fundic gland polyps, especially after taking PPI medicines for more than 1 year.
- **Severe skin reactions.** Esomeprazole magnesium delayed-release capsules can cause rare but severe skin reactions that may affect any part of your body. These serious skin reactions may need to be treated in a hospital and may be life threatening:
 - 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 have fever, chills, body aches, shortness of breath, or enlarged lymph nodes.

Stop taking esomeprazole magnesium delayed-release capsules and call your doctor right away. These symptoms may be the first sign of a severe skin reaction.

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

- | | |
|------------|----------------------------|
| o headache | o stomach (abdominal) pain |
| o diarrhea | o constipation |
| o nausea | o dry mouth |
| o gas | |

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 at 20°C to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
- 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 the safe and effective use of 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 it was 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.

You can ask your pharmacist or doctor for information about esomeprazole magnesium delayed-release capsules that is written for health professionals.

Please address medical inquiries to, MedicalAffairs@zydususa.com or Tel.: 1-877-993-8779.

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

Active ingredient: esomeprazole magnesium dihydrate

Inactive Ingredients: FD&C blue 1, hydroxypropyl cellulose, gelatin, magnesium oxide, magnesium stearate, mannitol, methacrylic acid copolymer dispersion, mono- and di-glycerides, povidone, polysorbate 80, sodium lauryl sulfate, starch (source: maize), sucrose, talc, titanium dioxide and triethyl citrate.

Additionally, each 20 mg capsule shell contains: FD&C red 3 and each 40 mg capsule shell contains: D&C red 28.

The capsule shell is printed with black pharmaceutical ink which contains following ingredients: black iron oxide, potassium hydroxide, propylene glycol and shellac.

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Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.

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

Instructions for Use

**Esomeprazole magnesium (es'' oh mep' ra zole mag nee' zee um)
Delayed-Release Capsules, USP**

Esomeprazole Magnesium Delayed-Release Capsules:

- 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 delayed-release capsules 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.

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