MEDICATION GUIDE

Lansoprazole Delayed-Release Capsules, USP

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

What is the most important information that I should know about lansoprazole delayed-release capsules?

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

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

- **Diarrhea**. Lansoprazole 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 lansoprazole 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 lansoprazole delayed-release capsules.

Lansoprazole delayed-release capsules can have other serious side effects. See "**What are the possible side effects of lansoprazole delayed-release capsules**?"

What are lansoprazole delayed-release capsules?

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

Lansoprazole delayed-release capsules are used in adults:

- for 4 weeks for the healing and symptom relief of duodenal ulcers. The duodenal area is the area where food passes when it leaves the stomach.
- with certain antibiotics to treat an infection called H. pylori. Sometimes H. pylori bacteria can cause duodenal ulcers. The infection needs to be treated to prevent ulcers from coming back.
- for continued healing of duodenal ulcers. for up to 8 weeks to heal stomach ulcers.
- for up to 8 weeks to heal stomach ulcers in some people taking pain medicines called non-steroidal anti-inflammatory drugs (NSAIDs).
- for reducing the risk of stomach ulcers in some people taking NSAIDs.
- for up to 8 weeks for the relief of heartburn and other symptoms of gastroesophageal reflux disease (GERD).
- 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 8 weeks to heal the acid-related damage to the lining of the esophagus (called erosive esophagitis) and to relieve symptoms. If needed, your doctor may prescribe another 8 weeks of lansoprazole delayed-release capsules.
- for continued healing of erosive esophagitis.
- for the long-term treatment of conditions where your stomach makes too much acid. This includes a condition called Zollinger-Ellison syndrome.

Lansoprazole delayed-release capsules are used in children and adolescents (ages 1 to 17):

- for up to 12 weeks to treat GERD and erosive esophagitis in children 1 to 11 years old.
- for up to 8 weeks to treat GERD and erosive esophagitis in adolescents 12 to 17 years old.

Lansoprazole delayed-release capsules are not effective for symptoms of GERD in children under the age of 1 year.

Who should not take lansoprazole delayed-release capsules?

- Do not take lansoprazole delayed-release capsules if you are allergic to lansoprazole or any of the other ingredients in lansoprazole delayed-release capsules. See the end of this Medication Guide for a complete list of ingredients in lansoprazole delayed-release capsules.

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

Before you take lansoprazole delayed-release capsules, 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 lansoprazole delayed-release capsules will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if lansoprazole delayed-release capsules passes into your breast milk. You and your doctor should decide if you will take lansoprazole delayed-release capsules or breastfeed. You should not do both. Talk to your doctor about the best way to feed your baby if you take lansoprazole delayed-release capsules.

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

Especially tell your doctor if you take:

- atazanavir (Reyataz)
- erlotinib (Tarceva)
- digoxin (Lanoxin)
- a product that contains iron
- ketoconazole (Nizoral)
- warfarin (Coumadin, Jantoven)
- tacrolimus (Prograf)
- theophylline (Theo-24, Elixophyllin, Theochron, Theolair)
- an antibiotic that contains ampicillin or clarithromycin
- 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 lansoprazole delayed-release capsules?

- Take lansoprazole delayed-release capsules exactly as prescribed by your doctor.
- Do not change your dose or stop taking lansoprazole delayed-release capsules without talking to your doctor.
- You should take lansoprazole delayed-release capsules before eating.
- **Lansoprazole Delayed-Release Capsules**:
    - You should swallow lansoprazole delayed-release capsules whole.
    - Do not crush or chew lansoprazole delayed-release capsules.

    - If you have trouble swallowing a whole capsule, you can open the capsule and take the contents with certain foods or juices. See the "Instructions for Use" at the end of this Medication Guide for instructions on how to take lansoprazole delayed-release capsules with certain foods and juices.
    - See the "Instructions for Use" at the end of this Medication Guide for instructions on how to mix and give lansoprazole delayed-release capsules through a nasogastric tube.

- If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Just take the next dose at your regular time. Do not take 2 doses at the same time.
- If you take too much lansoprazole delayed-release capsules, call your doctor right away.

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

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

- **See "What is the most important information that I should know about lansoprazole delayed-release capsules?"**
- **Vitamin B12 deficiency.** Lansoprazole delayed-release capsules reduces the amount of acid in your stomach. Stomach acid is needed to absorb vitamin B12 properly. Talk with your doctor about the possibility of vitamin B12 deficiency if you have been on lansoprazole delayed-release capsules 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 develop 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 lansoprazole delayed-release capsules, or during treatment; if you will be taking lansoprazole delayed-release capsules for a long period of time.

The most common side effects of lansoprazole delayed-release capsules in adults and children include:

- diarrhea
- stomach pain
- nausea
- constipation
- headache

Other side effects:

- **Serious allergic reactions.** Tell your doctor if you get any of the following symptoms with lansoprazole delayed-release capsules.

    - rash face swelling throat tightness difficulty breathing

Your doctor may stop lansoprazole delayed-release capsules if these symptoms happen.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of lansoprazole delayed-release capsules. 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 lansoprazole delayed-release capsules?

- Store lansoprazole delayed-release capsules at room temperature between 20° to 25° C (68° to 77° F)

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

General information about lansoprazole delayed-release capsules

Medicines are sometimes prescribed for conditions other than those listed in a Medication Guide. Do not use lansoprazole delayed-release capsules for conditions for which it was not prescribed. Do not give lansoprazole 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 lansoprazole delayed-release capsules. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about lansoprazole delayed-release capsules that is written for healthcare professionals.

For more information, call 1-888-375-3784.

What are the ingredients in lansoprazole delayed-release capsules?

Active ingredient: lansoprazole.

Inactive ingredients in lansoprazole delayed-release capsules:

Ammonium hydroxide, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol, polysorbate 80, propylene glycol, shellac, simethicone, starch, sucrose, sugar spheres, talc, and titanium dioxide.

Components of the gelatin capsule include gelatin, iron oxide red, iron oxide yellow, FD&C Blue 2, sodium lauryl sulphate and titanium dioxide for 15 mg capsules and gelatin, iron oxide black, iron oxide red, iron oxide yellow, sodium lauryl sulphate and titanium dioxide for 30 mg capsules.

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

Instructions for Use

Lansoprazole Delayed-Release Capsules USP

Lansoprazole Delayed-Release Capsules

- Swallow lansoprazole delayed-release capsules whole. Do not crush or chew them.
- You should take lansoprazole delayed-release capsules before eating.

<u>Lansoprazole Delayed-Release Capsule with certain food:</u>

You can only use applesauce, ENSURE pudding, cottage cheese, yogurt or strained pears.

- Open the capsule.
- Sprinkle the granules on 1 tablespoon of either applesauce, ENSURE pudding, cottage cheese, yogurt or strained pears.
- Swallow right away.

<u>Lansoprazole Delayed-Release Capsule with certain juices:</u>

You can only use apple juice, orange juice or tomato juice.

- Open the capsule.
- Sprinkle the granules into 60 mL (about ¼ cup) of either apple juice, orange juice or tomato juice.
- Stir.
- Swallow right away.
- To make sure that the entire dose is taken, rinse the glass with 1/2 cup or more of juice to get out any leftover granules. Swallow the juice right away.

Lansoprazole Delayed-Release Capsules through a nasogastric tube (NG tube) 16 French or larger, as prescribed by your doctor:

You can only use apple juice.

- Open the capsule and empty the granules into a syringe.
- Do not break or crush the granules.
- Mix with 40 mL of apple juice. Do not use other liquids.
- Attach the syringe to the NG tube and give the medicine in the syringe through the NG tube into the stomach.
- After giving the granules, flush the NG tube with more apple juice to clear the tube.

Lansoprazole delayed-release capsules should not be used in foods or liquids not listed above.

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This instruction for Use has been approved by the U.S. Food and Drug Administration.

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Revised: 0115

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