

MEDICATION GUIDE

Lansoprazole [lan soe' pra zole] Delayed-Release Capsules, for oral use

What is the most important information that I should know about lansoprazole delayed-release capsules?
You should take lansoprazole delayed-release capsules exactly as prescribed, at the lowest dose possible and for the shortest time needed. 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:

- **A type of kidney problem (acute tubulointerstitial nephritis).** Some people who take proton pump inhibitor (PPI) medicines, including lansoprazole delayed-release capsules, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with PPI medicines including lansoprazole 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 lansoprazole 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.
Lansoprazole delayed-release capsules can have other serious side effects. See “**What are the possible side effects of lansoprazole delayed-release capsules?**”.

What is lansoprazole delayed-release capsules?
A prescription medicine called a proton pump inhibitor (PPI) used to reduce the amount of acid in your stomach.

- In adults,** lansoprazole delayed-release capsules is used for:
- 4 weeks for the healing and symptom relief of duodenal ulcers.
 - 10 to 14 days with certain antibiotics to treat an infection caused by bacteria called *H. pylori*.
 - maintaining healing of duodenal ulcers. Lansoprazole has not been studied beyond 12 months for this purpose.
 - up to 8 weeks for the healing and symptom relief of stomach ulcers.
 - up to 8 weeks for the healing of stomach ulcers in people taking pain medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). Lansoprazole has not been studied beyond 8 weeks for this purpose.
 - reducing the risk of stomach ulcers in people who are at risk of developing stomach ulcers with NSAIDs. Lansoprazole delayed-release capsules has not been studied beyond 12 weeks for this purpose.
 - up to 8 weeks to treat heartburn and other symptoms that happen with 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.
 - up to 8 weeks for the healing and symptom relief of acid-related damage to the lining of the esophagus (called erosive esophagitis or EE). Your doctor may prescribe another 8 to 16 weeks of lansoprazole delayed-release capsules for patients whose EE does not improve or whose symptoms return.
 - maintaining healing of EE. Lansoprazole has not been studied beyond 12 months for this purpose.
 - the long-term treatment of conditions where your stomach makes too much acid. This includes a rare condition called Zollinger-Ellison syndrome.

Children:
Give lansoprazole delayed-release capsules exactly as prescribed by your child's doctor. Do not increase the dose of lansoprazole delayed-release capsules or give your child lansoprazole delayed-release capsules longer than the amount of time your doctor tells you to.

- In children 1 to 11 years of age,** lansoprazole delayed-release capsules is used for:
- up to 12 weeks to treat heartburn and other symptoms that can happen with GERD.
 - up to 12 weeks for the healing and symptom relief of EE.

- In children 12 to 17 years of age,** lansoprazole delayed-release capsules is used for:
- up to 8 weeks to treat heartburn and other symptoms that can happen with GERD.
 - up to 8 weeks for the healing and symptom relief of EE.

Lansoprazole delayed-release capsules are not recommended for treating the symptoms of GERD in children less than 1 year of age and may harm them.

- Do not take lansoprazole delayed-release capsules if you are:**
- allergic to lansoprazole, any other PPI medicine, or any of the ingredients in lansoprazole delayed-release capsules. See the end of this Medication Guide for a complete list of ingredients in lansoprazole delayed-release capsules
 - taking a medicine that contains rilpivirine (EDURANT, COMPLERA, ODEFSEY, JULUCA) used to treat HIV-1 (Human Immunodeficiency Virus).

- Before you take lansoprazole delayed-release capsules, tell your doctor about all of your medical conditions, including if you:**
- have low magnesium, calcium, potassium or sodium levels in your blood or you are taking a diuretic.
 - have liver problems.
 - are pregnant, think you may be pregnant or plan to become pregnant. Lansoprazole delayed-release capsules may harm your unborn baby. Talk to your doctor about the possible risks to an unborn baby if lansoprazole delayed-release capsules is taken during pregnancy.
 - are breastfeeding or plan to breastfeed. It is not known if lansoprazole passes into your breast milk. 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 over-the-counter medicines, vitamins, and herbal supplements. **Especially tell your doctor** if you take methotrexate (OTREXUP, RASUVO, TREXALL, REDITREX, XATMEP).

- 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.
 - Take lansoprazole delayed-release capsules before meals.
- Lansoprazole delayed-release capsules:**
- 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 or 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 (NG tube).
- If you miss a dose of lansoprazole 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 your 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 or your poison control center at 1-800-222-1222 right away or go to the nearest hospital emergency room.

- 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?**”.
 - **Low vitamin B12 levels** in the body can happen in people who have taken lansoprazole delayed-release capsules for a long time (more than 3 years). Tell your doctor if you have symptoms of low vitamin B12 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.

• 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 growth called fundic gland polyps, especially after taking PPI medicines for more than 1 year. • Low magnesium levels in the body can happen in people who have taken lansoprazole 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. • Severe skin reactions. Lansoprazole 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 lansoprazole and call your doctor right away. These symptoms may be the first sign of a severe skin reaction. The most common side effects of lansoprazole delayed-release capsules include: diarrhea, stomach-area (abdomen) pain, nausea and constipation. These are not all the possible side effects of lansoprazole 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 lansoprazole delayed-release capsules? Store lansoprazole at room temperature between 68°F to 77°F (20°C to 25°C). Keep lansoprazole delayed-release capsules and all medicines out of the reach of children.
General information about the safe and effective use of lansoprazole delayed-release capsules. Medicines are sometimes prescribed for purposes 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 that you have. It may harm them. You can ask your doctor or pharmacist for information about lansoprazole delayed-release capsules that is written for health professionals.
What are the ingredients in lansoprazole delayed-release capsules? Active ingredient: Lansoprazole USP Inactive ingredients in lansoprazole delayed-release capsules: colloidal silicon dioxide, D&C Red No. 28, FD&C Blue No.1, FD&C Red No. 40, gelatin, hypromellose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol 6000, polysorbate-80, sodium lauryl sulphate, sucrose, sugar spheres, talc and titanium dioxide. The printing ink contains potassium hydroxide, propylene glycol, shellac, strong ammonia, titanium dioxide. In addition to this, the 15 mg capsule also contains FD&C Green No.3. For more information contact at Ascend Laboratories, LLC at 1-877-272-7901.

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

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INSTRUCTIONS FOR USE
Lansoprazole [lan soe' pra zole] delayed-release capsules, for oral use

Important:

- Take lansoprazole delayed-release capsules before meals.
- **Do not** crush or chew lansoprazole delayed-release capsules.
- **Lansoprazole delayed-release capsules should only be used with the foods and juices listed below.**

Lansoprazole delayed-release capsules

Taking lansoprazole delayed-release capsules with certain foods:

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

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

Taking lansoprazole delayed-release capsules with certain juices:

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

1. Open the capsule.
2. Sprinkle the granules into 60 mL (about ¼ cup) of apple juice, orange juice or tomato juice.
3. Stir.
4. Swallow right away.
5. To make sure that the entire dose is taken, add 1/2 cup or more of juice to the glass, stir and swallow right away.

Giving lansoprazole delayed-release capsules through a nasogastric tube (NG tube) size 16 French or larger:

You can only use apple juice.

1. Place 40 mL of apple juice into a clean container.
2. Open the capsule and empty the granules into the container of apple juice.
3. Use a catheter-tip syringe to draw up the apple juice and granule mixture.
4. Gently mix the catheter-tip syringe to keep the granules from settling.
5. Attach the catheter-tip syringe to the NG tube.
6. Give the mixture right away through the NG tube that goes into the stomach. Do not save the apple juice and granule mixture for later use.
7. Refill the catheter-tip syringe with 40 mL of apple juice and mix gently. Flush the NG tube with apple juice.

How should I store lansoprazole delayed-release capsules?

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

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

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

For Medication Guide, please visit:

<http://www.ascendlaboratories.com/mg/lansoprazoledrcap.pdf>

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