

**MEDICATION GUIDE**  
**PREVACID (prev-a-sid)**  
**(lansoprazole) delayed-release capsules, for oral use**  
**and**  
**PREVACID SoluTab (prev-a-sid sol-u-tab)**  
**(lansoprazole) delayed-release orally disintegrating tablets**

**What is the most important information that I should know about PREVACID and PREVACID SoluTab?**

**You should take PREVACID and PREVACID SoluTab exactly as prescribed, at the lowest dose possible and for the shortest time needed.**

**PREVACID and PREVACID SoluTab may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.**

**PREVACID and PREVACID SoluTab can cause serious side effects, including:**

- **A type of kidney problem (acute interstitial nephritis).** Some people who take proton pump inhibitor (PPI) medicines, including PREVACID and PREVACID SoluTab, may develop a kidney problem called acute interstitial nephritis that can happen at any time during treatment with PPI medicines including PREVACID and PREVACID SoluTab. 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 PREVACID and PREVACID SoluTab, 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.

PREVACID and PREVACID SoluTab can have other serious side effects. See **“What are the possible side effects of PREVACID and PREVACID SoluTab?”**

**What are PREVACID and PREVACID SoluTab?**

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

**In adults,** PREVACID and PREVACID SoluTab are 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. PREVACID 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 non-steroidal anti-inflammatory drugs (NSAIDs). PREVACID 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. PREVACID 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 PREVACID or PREVACID SoluTab for patients whose EE does not improve or whose symptoms return.
- maintaining healing of EE. PREVACID 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.

**In children 1 to 11 years of age**, PREVACID and PREVACID SoluTab are 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**, PREVACID and PREVACID SoluTab are used for:

- up to eight weeks to treat heartburn and other symptoms that can happen with GERD.
- up to eight weeks for the healing and symptom relief of EE.

PREVACID and PREVACID SoluTab are not effective for treating the symptoms of GERD in children less than 1 year of age.

**Do not take PREVACID or PREVACID SoluTab if you are:**

- allergic to lansoprazole, any other PPI medicine, or any of the ingredients in PREVACID or PREVACID SoluTab. See the end of this Medication Guide for a complete list of ingredients.
- taking a medicine that contains rilpivirine (EDURANT, COMPLERA, ODEFSEY) used to treat HIV-1 (Human Immunodeficiency Virus)

**Before you take PREVACID or PREVACID SoluTab, tell your doctor about all of your medical conditions, including if you:**

- have low magnesium levels in your blood.
- have liver problems.
- have phenylketonuria. PREVACID SoluTab contains aspartame.
- are pregnant or plan to become pregnant. It is not known if PREVACID or PREVACID SoluTab will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if PREVACID or PREVACID SoluTab passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take PREVACID or PREVACID SoluTab.

**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).

**How should I take PREVACID and PREVACID SoluTab?**

- Take PREVACID or PREVACID SoluTab exactly as prescribed by your doctor.
- Do not change your dose or stop taking PREVACID or PREVACID SoluTab without talking to your doctor.
- Take PREVACID or PREVACID SoluTab before meals.

**PREVACID capsules:**

- Swallow PREVACID capsules whole.
- **Do not crush or chew PREVACID 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 PREVACID 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 PREVACID capsules through a nasogastric tube (NG tube).

**PREVACID SoluTab:**

- PREVACID SoluTab is a tablet that melts in your mouth with or without water.
- **Do not break, cut, crush or chew the tablets.**
- See the "Instructions for Use" at the end of this Medication Guide for instructions on how to mix and give PREVACID SoluTab through a syringe and NG tube.
- If you miss a dose of PREVACID or PREVACID SoluTab, 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 PREVACID or PREVACID SoluTab, 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 PREVACID and PREVACID SoluTab?**

**PREVACID and PREVACID SoluTab can cause serious side effects, including:**

- See “What is the most important information that I should know about PREVACID and PREVACID SoluTab?”
- **Low vitamin B12 levels** in the body can happen in people who have taken PREVACID or PREVACID SoluTab 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.
- **Low magnesium levels** in the body can happen in people who have taken PREVACID for at least 3 months. Tell your doctor 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.

**The most common side effects of PREVACID and PREVACID SoluTab include:** diarrhea, stomach-area (abdomen) pain, nausea and constipation.

These are not all the possible side effects of PREVACID and PREVACID SoluTab.

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 PREVACID and PREVACID SoluTab?**

Store PREVACID at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep PREVACID and PREVACID SoluTab and all medicines out of the reach of children.**

**General information about the safe and effective use of PREVACID and PREVACID SoluTab.**

Medicines are sometimes prescribed for conditions other than those listed in a Medication Guide. Do not use PREVACID or PREVACID SoluTab for conditions for which it was not prescribed. Do not give PREVACID or PREVACID SoluTab 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 PREVACID and PREVACID SoluTab that is written for health professionals.

**What are the ingredients in PREVACID and PREVACID SoluTab?**

**Active ingredient:** lansoprazole.

**Inactive ingredients in PREVACID capsules:** sugar sphere, sucrose, methacrylic acid copolymer, low substituted hydroxypropyl cellulose, starch, magnesium carbonate, talc, polyethylene glycol, titanium dioxide, polysorbate 80, hydroxypropyl cellulose, colloidal silicon dioxide, D&C Red No. 28, FD&C Blue No. 1, and FD&C Red No. 40.

**PREVACID 15 mg capsule only:** FD&C Green No. 3.

**Inactive ingredients in PREVACID SoluTab:** mannitol, methacrylic acid, hydroxypropyl cellulose, lactose monohydrate-microcrystalline cellulose sphere, triethyl citrate, crospovidone, polyacrylate, magnesium carbonate, aspartame, glyceryl monostearate, hypromellose, magnesium stearate, citric acid, titanium dioxide, talc, artificial strawberry flavor, polyethylene glycol, polysorbate 80 and ferric oxide.

**PREVACID SoluTab contains 2.5 mg of phenylalanine in each 15 mg tablet and 5.1 mg of phenylalanine in each 30 mg tablet.**

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For more information go to [www.PREVACID.com](http://www.PREVACID.com) or call 1-877-825-3327.

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

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