

MEDICATION GUIDE

**PREVACID (prev-a-sid)
(lansoprazole)
Delayed-Release Capsules
and
PREVACID SoluTab (prev-a-sid sol-u-tab)
(lansoprazole)
Delayed-Release Orally Disintegrating Tablets**

Read this Medication Guide before you start taking PREVACID 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 PREVACID?

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

PREVACID can cause serious side effects, including:

- **Diarrhea.** PREVACID 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 PREVACID 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 PREVACID.

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

What is PREVACID?

PREVACID is a prescription medicine called a proton pump inhibitor (PPI). PREVACID reduces the amount of acid in your stomach.

PREVACID is 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 PREVACID.
- 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.

PREVACID is 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.

PREVACID is not effective for symptoms of GERD in children under the age of 1 year.

Who should not take PREVACID?

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

What should I tell my doctor before taking PREVACID?

Before you take PREVACID, tell your doctor if you:

- have been told that you have low magnesium levels in your blood.
- have liver problems
- have phenylketonuria. PREVACID SoluTab contains aspartame.
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if PREVACID will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if PREVACID passes into your breast milk. You and your doctor should decide if you will take PREVACID or breastfeed. You should not do both. Talk to your doctor about the best way to feed your baby if you take PREVACID.

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

Especially tell your doctor if you take:

- atazanavir (Reyataz)
- nelfinavir (Viracept)
- 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 PREVACID?

- Take PREVACID exactly as prescribed by your doctor.
- Do not change your dose or stop taking PREVACID without talking to your doctor.
- You should take PREVACID before eating.
- **PREVACID Delayed-Release Capsules:**
 - You should swallow PREVACID Delayed-Release Capsules whole.
 - **Do not crush or chew PREVACID 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 PREVACID 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 PREVACID capsules through a nasogastric tube.
- **PREVACID SoluTab:**
 - is a tablet that melts in your mouth with or without water.
 - **Do not break, cut 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 tablets through a syringe and 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 PREVACID, call your doctor right away.

What are the possible side effects of PREVACID?

PREVACID can cause serious side effects, including:

- See “What is the most important information that I should know about PREVACID?”
- **Vitamin B12 deficiency.** PREVACID 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 PREVACID 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 PREVACID, or during treatment; if you will be taking PREVACID for a long period of time.

The most common side effects of PREVACID 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 PREVACID.
 - rash
 - face swelling
 - throat tightness
 - difficulty breathing

Your doctor may stop PREVACID 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 PREVACID. 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 PREVACID?

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

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

General information about PREVACID

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

For more information go to www.PREVACID.com or call 1-877-825-3327.

What are the ingredients in PREVACID?

Active ingredient: lansoprazole.

Inactive ingredients in PREVACID Delayed-Release 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.

In addition PREVACID 15 mg Capsule only: FD&C Green No. 3.

Inactive ingredients in PREVACID SoluTab Delayed-Release Orally Disintegrating Tablets:

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 phenylalanine 2.5 mg per 15 mg Tablet and 5.1 mg per 30 mg Tablet.

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

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