

MEDICATION GUIDE

ACIPHEX[®] (a-se-feks) (rabeprazole sodium) delayed-release tablets

Read the Medication Guide that comes with ACIPHEX before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment.

What is the most important information I should know about ACIPHEX?

ACIPHEX may help your acid-related symptoms, but you could still have serious stomach problems.

Talk with your doctor.

ACIPHEX can cause serious side effects, including:

- **Kidney problems (acute interstitial nephritis).** Kidney problems may happen at any time during treatment with ACIPHEX. Call your doctor if you have a decrease in the amount that you urinate or if you have blood in your urine.
- **Diarrhea.** ACIPHEX 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 (PPI) medicines for a long period of time (1 year or longer) may have an increased risk of fractures of the hip, wrist, or spine. You should take ACIPHEX exactly as prescribed, at the lowest dose possible for your treatment and for the shortest time needed.
- **Joint Pain or Rash that Gets Worse in the Sun.** Rarely people who take proton pump inhibitors (PPIs), including ACIPHEX, develop certain types of an autoimmune disease called 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 rash on your cheeks or arms that gets worse in the sun.

Talk to your doctor about your risk of these serious side effects if you take ACIPHEX.

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

What is ACIPHEX?

ACIPHEX is a prescription medicine called a Proton Pump Inhibitor (PPI).

ACIPHEX reduces the amount of acid in your stomach.

ACIPHEX is used in adults:

- for up to 8 weeks to heal acid-related damage to the lining of the esophagus (called erosive esophagitis or EE) and to relieve symptoms, such as heartburn pain. If needed, your doctor may decide to prescribe another 8 weeks of ACIPHEX.
- to maintain the healing of the esophagus and relief of symptoms related to EE. It is not known if ACIPHEX is safe and effective if used longer than 12 months (1 year).
- for up to 4 weeks to treat daytime and nighttime 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.
- for up to 4 weeks for the healing and relief of duodenal ulcers. The duodenal area is the area where food passes when it leaves the stomach.
- for 7 days with certain antibiotic medicines to treat an infection caused by bacteria called *H. pylori*. Sometimes *H. pylori* bacteria can cause duodenal ulcers. The infection needs to be treated to prevent the ulcers from coming back.
- for the long-term treatment of conditions where your stomach makes too much acid. This includes a rare condition called Zollinger-Ellison syndrome.

ACIPHEX is used in adolescents 12 years of age and older to treat symptoms of Gastroesophageal Reflux Disease (GERD) for up to 8 weeks.

It is not known if ACIPHEX is safe and effective in children to:

- heal acid-related damage to the lining of the esophagus (called erosive esophagitis or EE)
- maintain the healing of the esophagus and relief of symptoms related to EE
- treat symptoms that happen with Gastroesophageal Reflux Disease (GERD)
- heal duodenal ulcers
- treat an infection caused by bacteria called *H. pylori* to reduce the risk of duodenal ulcers from coming back
- treat conditions where your stomach makes too much acid, including Zollinger-Ellison Syndrome.

ACIPHEX delayed-release tablets should not be used in children under 12 years of age.

Who should not take ACIPHEX?

Do not take ACIPHEX if you:

- are allergic to rabeprazole or any of the other ingredients in ACIPHEX. See the end of this Medication Guide for a complete list of ingredients in ACIPHEX.
- are allergic to any other Proton Pump Inhibitor (PPI) medicine
- are taking a medicine that contains rilpivirine (Edurant, Complera) used to treat HIV-1 (Human Immunodeficiency Virus)

What should I tell my doctor before taking ACIPHEX?

Before you take ACIPHEX tell your doctor if you:

- have been told that you have low magnesium levels in your blood
- have liver problems
- have any allergies
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if ACIPHEX can harm your unborn baby. Talk to your doctor about the possible risks to an unborn baby if ACIPHEX is taken during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if ACIPHEX passes into your breast milk or if it will affect your baby or your breast milk. Talk to your doctor about the best way to feed your baby if you take ACIPHEX.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ACIPHEX may affect how other medicines work, and other medicines may affect how ACIPHEX works. Especially tell your doctor if you take an antibiotic that contains clarithromycin or amoxicillin or if you take warfarin (COUMADIN, JANTOVEN) or methotrexate (Otrexup, Rasuvo, Trexall).

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 ACIPHEX?

- Take ACIPHEX exactly as prescribed. Your doctor will prescribe the dose that is right for you and your medical condition. Do not change your dose or stop taking ACIPHEX unless you talk to your doctor. Take ACIPHEX for as long as it is prescribed even if you feel better.
- ACIPHEX is usually taken 1 time each day. Your doctor will tell you the time of day to take ACIPHEX, based on your medical condition.
- ACIPHEX can be taken with or without food. Your doctor will tell you whether to take this medicine with or without food based on your medical condition.
- Swallow each ACIPHEX tablet whole. **Do not chew, crush, or split ACIPHEX tablets.** Tell your doctor if you cannot swallow tablets whole.

- If you miss a dose of ACIPHEX, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your normal schedule. Do not take 2 doses at the same time.
- If you take too much ACIPHEX, call your doctor or your poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.
- Your doctor may prescribe antibiotic medicines with ACIPHEX to help treat a stomach infection and heal stomach (duodenal) ulcers that are caused by bacteria called *H. pylori*. Make sure you read the patient information that comes with an antibiotic before you start taking it.

What are the possible side effects of ACIPHEX?

ACIPHEX may cause serious side effects, including:

- See “What is the most important information I should know about ACIPHEX?”
- **Interaction with warfarin.** Taking warfarin with a Proton Pump Inhibitor (PPI) may lead to an increased risk of bleeding and death. If you take warfarin, your doctor may check your blood to see if you have an increased risk of bleeding. If you take warfarin during treatment with ACIPHEX, tell your doctor right away if you have any signs or symptoms of bleeding, including:
 - unexpected bleeding or bleeding that lasts a long time, such as:
 - nosebleeds that happen often
 - unusual bleeding from the gums
 - menstrual bleeding that is heavier than normal or unusual vaginal bleeding
 - bleeding that is severe or that you cannot control
 - red, pink or brown urine
 - bright red or black stools (looks like tar)
 - coughing up blood or blood clots
 - vomiting blood or your vomit looks like “coffee grounds”
 - headaches
 - feel dizzy or weak
- **Vitamin B-12 deficiency.** ACIPHEX reduces the amount of acid in your stomach. Stomach acid is needed to absorb vitamin B-12 properly. Talk with your doctor about the possibility of vitamin B-12 deficiency if you have been on ACIPHEX 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 (PPI) 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 and get medical care if you have any of these symptoms:

- seizures
- dizziness
- abnormal or fast heart beat
- 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 ACIPHEX, during treatment, or if you will be taking ACIPHEX for a long period of time.

The most common side effects of ACIPHEX in adults include:

- pain
- sore throat
- gas

- infection
- constipation

The most common side effects of ACIPHEX in adolescents 12 years of age and older include:

- headache
- diarrhea
- nausea
- vomiting
- stomach-area (abdomen) pain

Other side effects:

Serious allergic reactions. Tell your doctor if you get any of the following symptoms with ACIPHEX:

- rash
- face swelling
- throat tightness
- difficulty breathing

Your doctor may stop ACIPHEX if these symptoms happen.

These are not all of the possible side effects of ACIPHEX. 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 ACIPHEX?

Store ACIPHEX Tablets in a dry place at room temperature between 68°F to 77°F (20°C to 25°C).

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

General Information about ACIPHEX

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ACIPHEX for a condition for which it was not prescribed. Do not give ACIPHEX 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 ACIPHEX that is written for health professionals.

What are the ingredients in ACIPHEX?

Active ingredient: rabeprazole sodium

Inactive ingredients: carnauba wax, crospovidone, diacetylated monoglycerides, ethylcellulose, hydroxypropyl cellulose, hypromellose phthalate, magnesium stearate, mannitol, propylene glycol, sodium hydroxide, sodium stearyl fumarate, talc, and titanium dioxide. Iron oxide yellow is the coloring agent for the tablet coating. Iron oxide red is the ink pigment.

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For more information, go to <http://www.aciphex.com/> or call 1-888-4-ACIPHEX.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: October 2016