

MEDICATION GUIDE

**ACIPHEX[®] (a-se-feks)
(rabeprazole sodium)
Delayed-Release Tablets**

**ACIPHEX^(R) Sprinkle[™] (a-se-feks spr-en-kle)
(rabeprazole sodium)
Delayed-Release Capsules**

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:

- **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. Talk to your doctor about your risk of bone fracture 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 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.

ACIPHEX is used in children 1 to 11 years of age to treat GERD for up to 12 weeks.

ACIPHEX is not effective in treating symptoms of GERD in children 1 month to 11 months of age.

ACIPHEX should not be used to treat GERD in babies younger than 1 month 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.

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 planning to become pregnant. It is not known if ACIPHEX can harm your unborn baby.
- are breastfeeding. It is not known if ACIPHEX passes into 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 non-prescription 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:

- atazanavir (Reyataz)
- cyclosporine (Sandimmune, Neoral)
- digoxin (Lanoxin)
- ketoconazole (Nizoral)
- warfarin (Coumadin)
- theophylline (THEO-24 Thelair)
- diazepam (Valium)
- phenytoin (Dilantin)
- an antibiotic that contains amoxicillin or clarithromycin
- a “water pill” (diuretic)
- methotrexate

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 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 one time each day. Your doctor will tell you the time of day to take ACIPHEX, based on your medical condition.
- **ACIPHEX Tablets** 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 with water. **Do not chew, crush, or split ACIPHEX Tablets.** Tell your doctor if you cannot swallow tablets whole.
- **Take a dose of ACIPHEX Sprinkle Delayed-Release Capsules** as follows:
 - Take the dose 30 minutes before a meal.
 - Open the capsule and sprinkle the contents onto a small amount of soft food such as apple sauce, fruit or vegetable based baby food, or yogurt. You may also empty the capsule contents into a small amount of infant formula, apple juice, or a pediatric electrolyte solution such as Pedialyte[®]. The food or liquid that you use should be at or below room temperature.
 - **Swallow the entire mixture. Do not chew or crush the granules.**
 - Take the entire dose **within 15 minutes**. If you cannot take the dose within 15 minutes of preparing it, throw it away and prepare a new dose. Do not save it for use later.

- 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 Poison Control Center 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 can cause serious side effects, including:

- **See "What is the most important information I should know about ACIPHEX?"**
- **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 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 with ACIPHEX include:

- headache
- pain
- sore throat
- gas
- infection
- constipation

The most common side effects with ACIPHEX in children include:

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

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.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the side effects of ACIPHEX. 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 ACIPHEX?

- Store ACIPHEX Tablets and ACIPHEX Sprinkle Delayed-Release Capsules 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.

This Medication Guide summarizes the most important information about ACIPHEX. If you would like more information, talk to your doctor. You can also ask your doctor or pharmacist for information about ACIPHEX that is written for healthcare professionals. For more information, go to <http://www.aciphex.com/> or call 1-888-4-ACIPHEX.

What are the ingredients in ACIPHEX?

Active ingredient: rabeprazole sodium

ACIPHEX Delayed-Release Tablets 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.

ACIPHEX Sprinkle Delayed-Release Capsules inactive ingredients: colloidal silicon dioxide, diacetylated monoglycerides, ethylcellulose, hydroxypropyl cellulose, hypromellose phthalate, magnesium oxide, magnesium stearate, mannitol, talc, titanium dioxide, carrageenan, potassium chloride, FD&C Blue No.2 Aluminum Lake (in the 5 mg capsule), FD&C Yellow, No. 6 (in the 10 mg capsule), and gray printing ink.

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

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