MEDICATION GUIDE
ACIPHEX® (a-se-feks)
(rabeprazole sodium)
delayed-release tablets

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

- **A type of kidney problem (acute interstitial nephritis).** Some people who take proton pump inhibitor (PPI) medicines, including ACIPHEX, may develop a kidney problem called acute interstitial nephritis that can happen at any time during treatment with ACIPHEX. 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 ACIPHEX, 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.
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.
In adults, ACIPHEX is used for:

- 8 weeks up to 16 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.
- maintaining 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).
- up to 4 weeks to treat daytime and nighttime heartburn and other symptoms that happen with Gastroesophageal Reflux Disease (GERD).
- up to 4 weeks for the healing and relief of symptoms of duodenal ulcers.
- 7 days with certain antibiotic medicines to treat an infection and stomach (duodenal) ulcers caused by bacteria called *H. pylori*.
- the long-term treatment of conditions where your stomach makes too much acid. This includes a rare condition called Zollinger-Ellison syndrome.

In adolescents 12 years of age and older, ACIPHEX is used for up to 8 weeks to treat symptoms of GERD.
It is not known if ACIPHEX is safe and effective in children less than 12 years of age for other uses.
ACIPHEX delayed-release tablets should not be used in children under 12 years of age.

Do not take ACIPHEX if you are:

- allergic to rabeprazole, any other PPI medicine, or any of the ingredients in ACIPHEX. 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 ACIPHEX, tell your doctor about all of your medical conditions, including if you:

- have low magnesium levels in your blood.
- have liver problems.
- are pregnant or plan to become pregnant. It is not known if ACIPHEX can harm your unborn baby.
- are breastfeeding or plan to breastfeed. 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 over-the-counter medicines, vitamins, and herbal supplements. **Especially tell your doctor** if you take an antibiotic that

contains clarithromycin or amoxicillin or if you take warfarin (COUMADIN, JANTOVEN), methotrexate (OTREXUP, RASUVO, TREXALL, XATMEP), digoxin (LANOXIN), or a water pill (diuretic).

How should I take ACIPHEX?

- Take ACIPHEX exactly as prescribed.
- 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, you should not take the missed dose. You should take your next dose at your regular time. 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 emergency room.
- If your doctor prescribes antibiotic medicines with ACIPHEX, read the patient information that comes with the antibiotic medicines before you take them.

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?"**
- **Interaction with warfarin.** Taking warfarin with a PPI medicine 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:
  - pain, swelling or discomfort
  - headaches, dizziness, or weakness
  - unusual bruising (bruises that happen without known cause or that grow in size)
  - nosebleeds
  - bleeding gums
  - bleeding from cuts take a long time to stop
  - menstrual bleeding that is heavier than normal
  - pink or brown urine
  - red or black stools
  - coughing up blood
  - vomiting blood or vomit that looks like coffee grounds
- **Low vitamin B-12 levels** in the body can happen in people who have taken ACIPHEX for a long time (more than 3 years). Tell your doctor if you have symptoms of low vitamin B-12 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 ACIPHEX 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 ACIPHEX in adults include: pain, sore throat, gas, infection, and constipation.
The most common side effects of ACIPHEX in adolescents 12 years of age and older include: headache, diarrhea, nausea, vomiting, and stomach-area (abdomen) pain.
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 the safe and effective use of 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 www.aciphex.com or call 1-888-274-2378.

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