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PATIENT INFORMATION

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

READ THE PATIENT INFORMATION THAT COMES WITH ACIPHEX BEFORE YOU START TAKING IT AND EACH TIME YOU GET A REFILL. THERE MAY BE NEW INFORMATION. THIS LEAFLET DOES NOT TAKE THE PLACE OF TALKING TO YOUR DOCTOR ABOUT YOUR MEDICAL CONDITION OR TREATMENT.

WHAT IS ACIPHEX?

ACIPHEX is a medicine called a proton pump inhibitor or an "acid pump inhibitor". This means it reduces the amount of acid that is made by your stomach. ACIPHEX is used in adults:

- for the short-term (4 to 8 weeks) treatment in the healing and symptom relief of damaging (erosive) Gastroesophageal Reflux Disease (GERD).
- to maintain healing of damage (erosions) and relief of heartburn symptoms with GERD. ACIPHEX has not been studied for treatment lasting longer than 12 months (1 year).
- for the treatment of day-time and night-time heartburn and other symptoms that happen with GERD.
- for short-term treatment (up to 4 weeks) in the healing and relief of stomach-area (duodenal) ulcers. The duodenal area is the area where food passes when it leaves the stomach. The main symptom of a duodenal ulcer is a steady pain in the stomach area.
- with certain antibiotic medicines for the treatment of 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 condition called Zollinger-Ellison syndrome.

Your stomach needs acid to help your body digest food. Stomach acid is made by tiny acid pumps in the cells that line your stomach. If your body makes too much acid or cannot protect itself against a normal amount of acid, medical problems such as GERD can happen.

GERD happens when acid in your stomach backs up into the tube (esophagus) that connects your mouth to your stomach. Stomach acid can damage (erode) the lining of your esophagus. Some symptoms of GERD are heartburn, sour taste in the back of your throat and burping.

Who should not take ACIPHEX?

Do not take ACIPHEX if you:

- are allergic to any of the ingredients in ACIPHEX. The active ingredient is rabeprazole sodium. See the end of this leaflet for a complete list of ingredients in ACIPHEX.
- are allergic to any other medicines called proton pump inhibitors. The other proton pump inhibitor medicines include lansoprazole (Prevacid®), omeprazole (Prilosec®, Zegerid®), esomeprazole (Nexium®) and pantoprazole (Protonix®).

What should I tell my doctor before I take ACIPHEX?

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Tell your doctor about all of your medical conditions, including if you:

- 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 or if it can harm your baby. You should choose to breastfeed or take ACIPHEX, but not both. Talk to your doctor about other ways to feed your baby while taking ACIPHEX.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. ACIPHEX and certain medicines can affect each other. This can cause serious side effects. Know the medicines that you take. Keep a list of them with you and show it to your doctor when you get a new medicine. Be sure to tell your doctor if you are taking:

- cyclosporine (Sandimmune®, Neoral®)
- digoxin (Lanoxin®)
- ketoconazole (Nizoral®)
- warfarin (Coumadin®)

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 once a 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.
- Swallow each ACIPHEX tablet whole with water. **Do not chew, crush, or split ACIPHEX tablets** because this will damage the tablet and the medicine will not work. Tell your doctor if you cannot swallow tablets whole. You may need a different medicine.
- ***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 emergency room.
- Your doctor may prescribe antibiotic medicines with ACIPHEX to help treat a stomach infection and heal stomach-area (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, like other proton pump inhibitors, may cause serious allergic reactions.

Symptoms of a serious allergic reaction include:

- hives

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- swelling of your face, eyelids, lips, tongue, or throat, and trouble swallowing
- asthma (wheezing) or other breathing problems such as chest tightness or shortness of breath
- shock (loss of blood pressure and consciousness).

Get emergency help right away if you get any of these symptoms.

Stop ACIPHEX and call your doctor right away if you get a skin rash.

The most common side effect of ACIPHEX is headache.

These are not all the side effects of ACIPHEX. For more information, ask your doctor or pharmacist.

How should I store ACIPHEX?

- Store ACIPHEX in a dry place at room temperature, 59°F to 86°F (15°C to 30°C).
- **Keep ACIPHEX and all medicines out of the reach of children.**

General Information about ACIPHEX

Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not use ACIPHEX for any condition for which it was not prescribed by your doctor. Do not give ACIPHEX to other people, even if they have the same symptoms as you. It may harm them.

This leaflet 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 full product information, visit the website at http://www.aciphex.com/ or call the toll free number 1-888-4-ACIPHEX or 1-800 JANSSEN.

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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, sodium hydroxide, sodium stearyl fumarate, talc, titanium dioxide, and yellow ferric oxide as a coloring agent.

Rx only

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Sandimmune® and Neoral® (Novartis Pharmaceuticals Corporation), Lanoxin® (GlaxoSmithKline), Nizoral® (Janssen Pharmaceutica Products, LP), and Coumadin® (Bristol-Myers Squibb Company).