

MEDICATION GUIDE
ACIPHEX® Sprinkle™ (a-se-feks spr-en-kle)
(rabeprazole sodium delayed-release capsules)

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

Your child should take ACIPHEX Sprinkle exactly as prescribed, at the lowest dose possible and for the shortest time needed.

ACIPHEX Sprinkle may help your child's acid-related symptoms, but your child could still have serious stomach problems. Talk with your child's doctor.

ACIPHEX Sprinkle 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 Sprinkle, may develop a kidney problem called acute interstitial nephritis that can happen at any time during treatment with ACIPHEX Sprinkle. Call your child's doctor right away if your child has a decrease in the amount that they urinate or if they have blood in their urine.
- **Diarrhea caused by an infection (*Clostridium difficile*) in your child's intestines.** Call your child's doctor right away if your child has watery stools or stomach pain that does not go away. Your child 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 child's doctor if your child has 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 Sprinkle, may develop certain types of lupus erythematosus or have worsening of the lupus they already have. Call your child's doctor right away if they have new or worsening joint pain or a rash on their cheeks or arms that gets worse in the sun.

Talk to your child's doctor about your child's risk of serious side effects.

ACIPHEX Sprinkle can have other serious side effects. See "What are the possible side effects of ACIPHEX Sprinkle?"

What is ACIPHEX Sprinkle?

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

ACIPHEX Sprinkle is used in children 1 year to 11 years of age to treat Gastroesophageal Reflux Disease (GERD) for up to 12 weeks.

ACIPHEX Sprinkle is not effective in treating GERD in children under 1 year of age.

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

Your child should not take ACIPHEX Sprinkle if they are:

- allergic to rabeprazole, any other PPI medicine, or any of the ingredients in ACIPHEX Sprinkle. 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 your child takes ACIPHEX Sprinkle, tell your child's doctor about all of your child's medical conditions, including if they:

- have low magnesium levels in their blood.
- have liver problems.
- are pregnant or plan to become pregnant. It is not known if ACIPHEX Sprinkle can harm an unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ACIPHEX Sprinkle passes into breast milk. Talk to your child's doctor about the best way to feed her baby if she takes ACIPHEX Sprinkle.

Tell your child's doctor about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. **Especially tell your child's doctor** if your child takes warfarin (COUMADIN, JANTOVEN) or methotrexate (Otrexup, Rasuvo, Trexall, Xatmep).

How should my child take ACIPHEX Sprinkle?

- Your child should take ACIPHEX Sprinkle exactly as prescribed. Your child's doctor will prescribe the dose that is right for your child.
- Your child should take ACIPHEX Sprinkle 1 time each day.
- Your child should take ACIPHEX Sprinkle 30 minutes before a meal.
- Your child **should not** swallow the ACIPHEX Sprinkle capsule whole.
- **Prepare and give a dose of ACIPHEX Sprinkle to your child as follows:**
 - Open the ACIPHEX Sprinkle capsule in the direction that the arrow (↑) on the capsule is pointing. Sprinkle all of the capsule contents onto a small amount of soft food such as applesauce, fruit or vegetable based baby food, or yogurt. You may also empty all of the capsule contents into a small amount of infant formula, apple juice, or a pediatric electrolyte solution. The food or liquid that you use should be at or below room temperature.
 - **Your child should swallow the entire mixture. They should not chew or crush the granules.**
 - Your child should take the entire dose **within 15 minutes** of preparing it. Do not save it for use later.
- If your child misses a dose of ACIPHEX Sprinkle, they should take it as soon as possible. If it is almost time for their next dose, they should not take the missed dose. Your child should take their next dose at their regular time. They should not take 2 doses at the same time.
- If your child takes too much ACIPHEX Sprinkle, call your child's doctor or your poison control center at 1-800-222-1222 right away, or go to the nearest emergency room.

What are the possible side effects of ACIPHEX Sprinkle?

ACIPHEX Sprinkle can cause serious side effects, including:

- See "What is the most important information I should know about ACIPHEX Sprinkle?"
- **Interaction with warfarin.** Taking warfarin with a PPI medicine may lead to an increased risk of bleeding and death. If your child takes warfarin, their doctor may check their blood to see if they have an increased risk of bleeding. If your child takes warfarin during treatment with ACIPHEX Sprinkle, tell their doctor right away if they 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 takes 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 Sprinkle for a long time (more than 3 years). Tell your child's doctor if your child has 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 Sprinkle for at least 3 months. Tell your child's doctor if your child has symptoms of low magnesium levels, including seizures, dizziness, irregular heartbeat, jitteriness, muscle aches or weakness, and spasms of hands, feet or voice.

- **Stomach growths (fundic gland polyps).** People who take PPI medicines for a long time have an increased risk of developing a certain type of stomach growths called fundic gland polyps, especially after taking PPI medicines for more than 1 year.

The most common side effects of ACIPHEX Sprinkle include: vomiting, stomach-area (abdomen) pain, diarrhea, headache, and nausea.

These are not all of the possible side effects of ACIPHEX Sprinkle. Call your child's doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ACIPHEX Sprinkle?

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

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

General information about the safe and effective use of ACIPHEX Sprinkle.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ACIPHEX Sprinkle for a condition for which it was not prescribed. Do not give ACIPHEX Sprinkle to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your child's doctor or pharmacist for information about ACIPHEX Sprinkle that is written for health professionals.

What are the ingredients in ACIPHEX Sprinkle?

Active ingredient: rabeprazole sodium

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.

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For more information, go to www.aciphexsprinkle.com

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

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