

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

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

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

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:

- **Diarrhea.** ACIPHEX Sprinkle may increase your child's risk of getting severe diarrhea. This diarrhea may be caused by an infection (*Clostridium difficile*) in their intestines. Call your child's doctor right away if your child has 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. Your child should take ACIPHEX Sprinkle exactly as prescribed, at the lowest dose possible for their treatment and for the shortest time needed. Talk to your child's doctor about your child's risk of bone fracture if your child takes ACIPHEX Sprinkle.

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 to 11 years of age to treat Gastroesophageal Reflux Disease (GERD) for up to 12 weeks.

GERD happens when acid in the stomach backs up into the tube (esophagus) that connects the mouth to the stomach. This may cause a burning feeling in the chest or throat, sour taste, or burping.

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.

Who should not take ACIPHEX Sprinkle?

Your child should not take ACIPHEX Sprinkle if they:

- are allergic to rabeprazole or any of the other ingredients in ACIPHEX Sprinkle. See the end of this Medication Guide for a complete list of ingredients in ACIPHEX Sprinkle.
- 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 child's doctor before my child takes ACIPHEX Sprinkle?

Before your child takes ACIPHEX Sprinkle tell your child's doctor if they:

- have low magnesium levels in their 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 Sprinkle can harm an unborn baby. Talk to your child's doctor about the possible risks to an unborn baby if ACIPHEX Sprinkle is taken during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if ACIPHEX Sprinkle passes into breast milk or if it will affect a breastfed baby.

Tell your child's doctor about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ACIPHEX Sprinkle may affect how other medicines work, and other medicines may affect how ACIPHEX Sprinkle works.

Especially tell your child's doctor if your child takes warfarin (COUMADIN, JANTOVEN) or methotrexate (Otrexup, Rasuvo, Trexall).

Know the medicines that your child takes. Keep a list of them to show their doctor and pharmacist when your child gets a new medicine.

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. Do not change your child's dose or have them stop taking ACIPHEX Sprinkle unless you talk to your child's doctor. Your child should take ACIPHEX Sprinkle for as long as it is prescribed even if your child feels better.
- 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 and sprinkle the contents onto a small amount of soft food such as applesauce, 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.
 - **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**. If your child 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 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, skip the missed dose and go back to their normal schedule. 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 hospital emergency room.

What are the possible side effects of ACIPHEX Sprinkle?

ACIPHEX Sprinkle may 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 Proton Pump Inhibitor (PPI) 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:
 - 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 vomit that looks like "coffee grounds"
 - headaches
 - feeling dizzy or weak
- **Vitamin B-12 deficiency.** ACIPHEX Sprinkle reduces the amount of acid in the stomach. Stomach acid is needed to absorb vitamin B-12 properly. Talk with your child's doctor about the possibility of vitamin B-12 deficiency if your child has been on ACIPHEX Sprinkle 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. Your child may or may not have symptoms of low magnesium.
Tell your child's doctor right away and get medical care if your child has any of these symptoms:

- seizures
- abnormal or fast heart beat
- jerking movements or shaking (tremors)
- spasms of the hands and feet
- spasms of the voice box
- dizziness
- jitteriness
- muscle weakness
- cramps or muscle aches

Your child's doctor may check the level of magnesium in their body before they start taking ACIPHEX Sprinkle, during treatment, or if they will be taking ACIPHEX Sprinkle for a long period of time.

The most common side effects of ACIPHEX Sprinkle include:

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

Other side effects:

Serious allergic reactions. Tell your child's doctor if your child gets any of the following symptoms with ACIPHEX Sprinkle:

- rash
- face swelling
- throat tightness
- difficulty breathing

Your child's doctor may stop ACIPHEX Sprinkle if these symptoms happen.

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 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 or call 1-866-764-7822.

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

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