

Medication Guide

ALKINDI SPRINKLE® (æl'kɪndi spr-en-kle)
(hydrocortisone) oral granules

Read this Medication Guide before you start giving ALKINDI SPRINKLE to your child, and each time your child gets a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your child's medical condition or treatment.

What is the most important information I should know about ALKINDI SPRINKLE?

ALKINDI SPRINKLE may cause serious side effects, including:

Adrenal gland problems. Not giving enough ALKINDI SPRINKLE, stopping ALKINDI SPRINKLE, or switching to ALKINDI SPRINKLE after taking another hydrocortisone medicine (the same class of medicines as ALKINDI SPRINKLE) by mouth, can cause serious and life-threatening adrenal gland problems including death. Do not stop giving ALKINDI SPRINKLE without talking to your healthcare provider. Tell your healthcare provider if your child has any of these symptoms:

- | | | |
|--------------------|--------------|--|
| o loss of appetite | o joint pain | o low blood sugar |
| o fatigue | o nausea | o feeling lightheaded or dizzy |
| o weakness | o vomiting | o problems with body salt (electrolyte) levels |

Your healthcare provider will change the dose of ALKINDI SPRINKLE depending on your child's size. Tell your healthcare provider if your child cannot swallow medicines by mouth. During episodes of acute infections, surgery, major trauma or if your child cannot take medicines by mouth, your healthcare provider may recommend increased doses of ALKINDI SPRINKLE or use of corticosteroid medicines given directly into the bloodstream instead.

The amount of hydrocortisone in a dose of ALKINDI SPRINKLE may not be the same as in previous hydrocortisone medicines that your child takes by mouth if these oral hydrocortisone medicines have been manipulated (e.g., crushed, compounded). When switching to ALKINDI SPRINKLE, your healthcare provider may need to prescribe a starting dose of ALKINDI SPRINKLE that is different from previous hydrocortisone medicines that your child may have been taking by mouth. Watch your child closely after being switched to ALKINDI SPRINKLE and contact your healthcare provider if your child has any symptoms of adrenal gland problems. Your healthcare provider may need to change the dose of ALKINDI SPRINKLE.

See "What are the possible side effects of ALKINDI SPRINKLE?" for more information about side effects.

What is ALKINDI SPRINKLE?

ALKINDI SPRINKLE is a prescription medicine that contains a medicine hydrocortisone. Hydrocortisone belongs to a group of medicines known as corticosteroids. Hydrocortisone is a synthetic version of the hormone cortisol. Cortisol is made naturally by the adrenal glands in the body. ALKINDI SPRINKLE (hydrocortisone) is a man-made (synthetic) corticosteroid used to replace the body's cortisol when the adrenal glands do not make enough (adrenal insufficiency) in children from birth to 17 years of age.

Who should not take or be given ALKINDI SPRINKLE?

Do not give your child ALKINDI SPRINKLE if they:

- are allergic to hydrocortisone or any of the ingredients in ALKINDI SPRINKLE. See the end of this Medication Guide for a complete list of ingredients in ALKINDI SPRINKLE.
- have any reaction like swelling or shortness of breath after being given ALKINDI SPRINKLE. Get medical help right away and tell your healthcare provider as soon as possible as these can be signs of an allergic reaction.

What should I tell my healthcare provider before giving ALKINDI SPRINKLE?

Before you give your child ALKINDI SPRINKLE, tell your healthcare provider about all of your child's medical conditions, including if they:

- are feeling unwell, or their body is under stress because of surgery or trauma. Your healthcare provider may need to increase the dose of ALKINDI SPRINKLE for a short period of time.
- have a fever or infection.
- have nausea, vomiting, or diarrhea.
- are due for vaccinations. Taking ALKINDI SPRINKLE should not stop your child from being vaccinated. Tell your healthcare provider when your child is due for vaccinations.
- are scheduled for surgery.
- cannot swallow medicines by mouth or are fed through a nasogastric or gastric tube.
- are pregnant or plan to become pregnant. It is not known if ALKINDI SPRINKLE will harm your child's unborn baby. Talk to your child's healthcare provider if your child is pregnant or plans to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if ALKINDI SPRINKLE passes into the breast milk. You and your child's healthcare provider should decide if your child will receive ALKINDI SPRINKLE while your child breastfeeds.

Tell your healthcare provider about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines, food and drink can affect the way that ALKINDI SPRINKLE works and may mean that your healthcare

provider needs to change your child's dose of ALKINDI SPRINKLE.

Especially tell your healthcare provider if your child:

- takes medicines used to treat fungal infections such as itraconazole, posaconazole, and voriconazole.
- takes medicines used to treat bacterial infections such as rifampicin, rifabutin, erythromycin, and clarithromycin.
- takes medicines used to treat human immunodeficiency virus (HIV) infection and AIDS such as ritonavir, efavirenz, and nevirapine.
- takes seizure medicines such as phenytoin, carbamazepine, oxcarbazepine, phenobarbital, and primidone.
- takes estrogen.
- takes warfarin.
- takes nonsteroidal anti-inflammatory medicines such as aspirin, ibuprofen.
- takes cyclosporine.
- takes diabetes medicines.
- drinks grapefruit juice.

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

How should I give ALKINDI SPRINKLE?

- See the detailed Instructions for Use that comes with your ALKINDI SPRINKLE for information on how to give a dose of ALKINDI SPRINKLE the right way.
- Give ALKINDI SPRINKLE exactly as prescribed by your healthcare provider.
- **Do not** stop giving ALKINDI SPRINKLE without talking to your healthcare provider. See **“What is the most important information I should know about ALKINDI SPRINKLE?”**
- **Do not** let your child chew or crush the granules. **Do not** let your child swallow the capsule.
- **Do not** let the capsules get wet as this may make some of the granules stick to the capsule.
- Your child may sometimes pass the ALKINDI SPRINKLE granules in their stools (bowel movement). It does not mean that ALKINDI SPRINKLE is not working. **Do not** give your child another dose of ALKINDI SPRINKLE.
- ALKINDI SPRINKLE granules should not be given through a nasogastric tube because the granules may block the tube.
- If your child takes too much ALKINDI SPRINKLE, call your healthcare provider right away or go to the nearest emergency room.

What are the possible side effects of ALKINDI SPRINKLE?

ALKINDI SPRINKLE may cause serious side effects, including:

- See **“What is the most important information I should know about ALKINDI SPRINKLE?”**
- **Infections.** Taking too much ALKINDI SPRINKLE can increase risk of infections. Tell your healthcare provider if your child has any of these symptoms:
 - fever
 - cough
 - flu-like symptoms
 - stomach area (abdominal) pain
 - diarrhea
- **Slowed growth in children.** Taking too much ALKINDI SPRINKLE and taking it for long periods of time can affect your child's growth. Tell your healthcare provider if you are worried about your child's growth. Your healthcare provider will change the dose depending on your child's size.
- **Cushing's syndrome.** Taking too much ALKINDI SPRINKLE and taking it for long periods of time can cause Cushing's syndrome. Tell your healthcare provider if your child has any of these symptoms:
 - weight gain
 - slowed growth in height
 - high blood sugar
 - high blood pressure
 - swelling
 - bruising easily
 - muscle weakness
 - red, round face
 - feeling depressed
 - mood swings
- **Weak, brittle, or soft bones.** ALKINDI SPRINKLE can affect your child's bones. Your healthcare provider will change the dose depending on your child's size and will monitor your child's growth and bones.
- **Changes in behavior.** Your child's behavior may change after starting or during treatment with ALKINDI SPRINKLE. Tell your healthcare provider right away if your child develops any changes in behavior including:
 - strong feelings of happiness and excitement.
 - overexcited and overactivity.
 - loss of contact with reality, with feelings that are not real, and mental confusion.
 - depression.

- **Vision problems.** Tell your healthcare provider if your child develops blurred vision or other vision problems during treatment with ALKINDI SPRINKLE. Your healthcare provider may have your child see an eye doctor.
- **Gastrointestinal problems.** ALKINDI SPRINKLE can affect your child's stomach or intestine. Tell your healthcare provider if your child has gastrointestinal illnesses such as stomach or intestinal ulcers, infections, or gastrointestinal surgery.

The most common side effects of ALKINDI SPRINKLE include:

- fluid retention
- behavioral and mood changes
- change in blood sugar (glucose) tolerance
- increased appetite and weight gain
- increase in blood pressure

These are not all the possible side effects of ALKINDI SPRINKLE. 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 ALKINDI SPRINKLE?

- Store ALKINDI SPRINKLE at room temperature between 68°F to 77°F (20°C to 25°C).
- Store in the original bottle to protect from light.
- After the bottle has been opened, use the ALKINDI SPRINKLE capsules within 60 days.

Keep ALKINDI SPRINKLE and all medicines out of the reach of children.

General information about the safe and effective use of ALKINDI SPRINKLE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ALKINDI SPRINKLE for a condition for which it was not prescribed. Do not give ALKINDI SPRINKLE to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ALKINDI SPRINKLE that is written for health professionals.

What are the ingredients in ALKINDI SPRINKLE?

Active ingredient: hydrocortisone

Inactive ingredients:

granules: microcrystalline cellulose, hypromellose, magnesium stearate, ethyl cellulose.

capsule: hypromellose

printing ink: shellac, propylene glycol, concentrated ammonia solution.

ALKINDI SPRINKLE is manufactured for Eton Pharmaceuticals, Inc. by Glatt Pharmaceutical Services GmbH & Co. KG Werner-Glatt-Strasse 1, Binzen, Baden-Wuerttemberg, 79589, Germany

ALKINDI® is a registered trademark of Diurnal Limited.

ALKINDI is covered by the following US patents: 9,649,280; 9,675,559; 9,717,740; and other patents in other countries internationally. For more information, go to www.alkindisprinkle.com or call **1-833-343-2500**.

Instructions for Use

ALKINDI SPRINKLE® (æl' kindi spr-en-kle) (hydrocortisone) oral granules

Read this Instructions for Use before you start using ALKINDI SPRINKLE, and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your child's medical condition or treatment.

Important information you need to know before giving ALKINDI SPRINKLE

- ALKINDI SPRINKLE comes in a capsule that **must** be opened before use.
- **Do not** let your child swallow the capsule. Small children may choke.
- **Do not** let your child chew or crush the granules in the capsule.
- **Do not** let the capsules get wet as this may make some of the granules stick to the capsule.
- Your healthcare provider will decide the right dose of ALKINDI SPRINKLE for your child. Follow your healthcare provider's instructions for the dose of ALKINDI SPRINKLE to give your child.
- Ask your healthcare provider or pharmacist if you are not sure how to prepare or give the prescribed dose of ALKINDI SPRINKLE to your child.
- Your child may sometimes pass the ALKINDI SPRINKLE granules in their stools (bowel movement). It does not mean that ALKINDI SPRINKLE is not working. **Do not** give your child another dose of ALKINDI SPRINKLE.

Supplies needed to give ALKINDI SPRINKLE:

- ALKINDI SPRINKLE capsule(s) for prescribed dose
- 1 spoon
- soft food such as yogurt or pureed fruit **or** sip of fluids such as water, milk, breastmilk or formula

Preparing and giving ALKINDI SPRINKLE:

Step 1: Check the expiration date on the ALKINDI SPRINKLE bottle. **Do not** use ALKINDI SPRINKLE after the expiration date on the bottle has passed.

Step 2: Remove the prescribed dose of ALKINDI SPRINKLE capsules from the bottle.

Step 3: Hold and Tap



Hold the capsule with the writing at the top. Tap the capsule to make sure the granules fall to the bottom.

Step 4: Squeeze



Gently squeeze the bottom of the capsule to loosen the top of the capsule from the bottom.

Step 5: Twist



Carefully twist off the top of the capsule.

Step 6: Giving ALKINDI SPRINKLE

ALKINDI SPRINKLE can be given (a) with food onto a spoon, (b) without food onto a spoon, or (c) directly into the child's mouth.

Do not add the granules to a fluid before giving ALKINDI SPRINKLE because it can result in less than the full dose given and it may leave a bitter taste in the mouth.

(a) With food onto a spoon



Pour **all** granules from each capsule directly onto a spoonful of cold or room temperature soft food (such as yogurt or fruit puree) and give right away.

(b) Without food onto a spoon



Pour **all** granules directly onto a spoon and place them in the child's mouth.

(c) Directly onto the child's tongue



Pour **all** granules that make up the prescribed dose directly onto the child's tongue.

Tap the capsule to make sure all granules are removed.

The ALKINDI SPRINKLE granules should be given and swallowed within 5 minutes to avoid a bitter taste.

Step 7: Give Fluids

After giving ALKINDI SPRINKLE, give a sip of fluids such as water, milk, breastmilk or formula right away to make sure all granules are swallowed.

Throwing Away (disposal of) ALKINDI SPRINKLE:

Ask your pharmacist how to throw away medicines you no longer use.

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- Store in the original bottle to protect from light.
- After the bottle has been opened, use the ALKINDI SPRINKLE capsules within 60 days.

Keep ALKINDI and all medicines out of the reach of children.

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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