

Medication Guide
KHINDIVI® (kin-div-i:)
(hydrocortisone) oral solution

Read this Medication Guide before you start giving KHINDIVI 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 KHINDIVI?

KHINDIVI may cause serious side effects, including:

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

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

Your healthcare provider will change the dose of KHINDIVI depending on your child's size. During episodes of acute infections, surgery, or major trauma, your healthcare provider may prescribe your child a different hydrocortisone medicine and increase the dose. If your child is vomiting, severely ill, or unable to take medicines by mouth, your healthcare provider may use corticosteroid medicines that are given directly into the bloodstream instead.

The amount of hydrocortisone in a dose of KHINDIVI may not be the same as in previous hydrocortisone medicines that your child takes by mouth if these oral hydrocortisone medicines have been changed (for example, crushed or compounded). When switching to KHINDIVI, your healthcare provider may need to prescribe a starting dose of KHINDIVI that is different from previous hydrocortisone medicines that your child may have been taking by mouth. Watch your child closely after being switched to KHINDIVI 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 KHINDIVI.

See “What are the possible side effects of KHINDIVI?” for more information about side effects.

What is KHINDIVI?

KHINDIVI 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. KHINDIVI (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 5 to 17 years of age.

Who should not take or be given KHINDIVI?

Do not give your child KHINDIVI if they:

- are allergic to hydrocortisone or any of the ingredients in KHINDIVI. See the end of this Medication Guide for a complete list of ingredients in KHINDIVI.
- have any reaction like swelling or shortness of breath after being given KHINDIVI. 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 KHINDIVI?

Before you give your child KHINDIVI, 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 prescribe your child a different hydrocortisone medicine for a short period of time.
- have a fever or infection.
- have nausea, vomiting, or diarrhea.
- are due for vaccinations. Taking KHINDIVI 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 gastric tube.
- are pregnant or plan to become pregnant. It is not known if KHINDIVI 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 KHINDIVI passes into the breast milk. You and your child's healthcare provider should decide if your child will receive KHINDIVI 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 KHINDIVI works and may mean that your healthcare provider needs to change your child's dose of KHINDIVI.

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 and 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 KHINDIVI?

- Give KHINDIVI exactly as prescribed by your healthcare provider.
- Give KHINDIVI by mouth with or without food.
- Give a sip of water right away after giving KHINDIVI to make sure that all of the medicine has been swallowed.
- Give KHINDIVI using the oral syringe provided by the pharmacy.
- **Do not** stop giving KHINDIVI without talking to your healthcare provider. See **“What is the most important information I should know about KHINDIVI?”**
- KHINDIVI can be given through a gastric tube. After KHINDIVI is given through the gastric tube, flush the gastric tube with 20 mL of water right away to make sure all the medicine has been given.
- If your child takes too much KHINDIVI, call your healthcare provider right away or go to the nearest emergency room.

What are the possible side effects of KHINDIVI?**KHINDIVI may cause serious side effects, including:**

- See **“What is the most important information I should know about KHINDIVI?”**
- **Hyperosmolarity, metabolic acidosis, and stomach problems.** Some of the ingredients in KHINDIVI may increase the risk for imbalance of salts and other substances in your blood leading to fluid shifts (hyperosmolarity), too much acid in the blood (metabolic acidosis), vomiting, loose stools, diarrhea, and other side effects, which may increase the risk of adrenal gland problems. Tell your healthcare provider if your child has confusion (altered mental status), urine output that is not normal, or is severely ill. Your healthcare provider may prescribe your child a different hydrocortisone medicine.
- **Weakened immune system and increased risk of infections.** Taking too much KHINDIVI can weaken your body’s immune system and increase your chance of getting infections. Tell your healthcare provider if your child develops any infections or has any of these symptoms:
 - fever
 - cough
 - flu-like symptoms
 - stomach area (abdominal) pain
 - diarrhea
- **Slowed growth in children.** Taking too much KHINDIVI 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 KHINDIVI 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
 - high blood sugar
 - swelling
 - muscle weakness
 - feeling depressed
 - slowed growth in height
 - high blood pressure
 - bruising easily
 - red, round face
 - mood swings
- **Weak, brittle, or soft bones.** KHINDIVI 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 KHINDIVI. Tell your healthcare provider right away if your child develops any changes in behavior including:
 - strong feelings of happiness and excitement.
 - overexcited and overactive.
 - 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 KHINDIVI. Your healthcare provider may have your child see an eye doctor.

- **Gastrointestinal problems.** KHINDIVI 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.
- **Risk of Kaposi's Sarcoma if your child takes too much KHINDIVI.** Kaposi's Sarcoma has happened in people who receive corticosteroid therapy, most often for treatment of long-lasting (chronic) conditions. Taking too much KHINDIVI over a long period of time can increase your child's risk of developing Kaposi's Sarcoma.
- **Vaccinations.** Administration of live vaccine may be acceptable while taking KHINDIVI.

The most common side effects of KHINDIVI include:

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

These are not all the possible side effects of KHINDIVI.

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 KHINDIVI?

- Store KHINDIVI in the refrigerator between 36°F to 46°F (2°C to 8°C) or at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from light and heat.
- After the bottle has been opened, use KHINDIVI within 120 days. Throw away any KHINDIVI that has not been used within 120 days after the bottle has been opened.

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

General information about the safe and effective use of KHINDIVI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use KHINDIVI for a condition for which it was not prescribed. Do not give KHINDIVI 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 KHINDIVI that is written for health professionals.

What are the ingredients in KHINDIVI?

Active ingredient: hydrocortisone

Inactive ingredients: berry flavor, butylated hydroxyanisole, ethyl maltol, glycerin, methylparaben, propylparaben, polyethylene glycol, propylene glycol, and sucralose,.

KHINDIVI is manufactured for Eton Pharmaceuticals, Inc. by Tulex Pharmaceuticals, Inc., 5 Cedarbrook Dr., Cranbury, NJ 08512, USA.

KHINDIVI® is a registered trademark of Eton Pharmaceuticals, Inc.

KHINDIVI is covered by the following US patent: 11,904,046.

For more information, go to [www. KHINDIVI.com](http://www.KHINDIVI.com) or call **1-833-343-2500**.

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

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