

ALKINDI®

Hydrocortisone (0.5 mg, 1 mg, 2 mg or 5 mg) granules in capsules for opening

Consumer Medicine Information

WARNING

ALKINDI granules come in a capsule that must be opened before use, discard the empty capsule after use out of reach of children. Do NOT swallow the capsule – small children may choke.

What is in this leaflet

This leaflet answers some of the more common questions about ALKINDI.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of your child being given this medicine against the benefits this medicine is expected to have for your child.

If you have any concerns about giving this medicine, ask your doctor or pharmacist.

Keep this leaflet, you may need to read it again.

What ALKINDI is used for

ALKINDI contains a medicine called 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 is used when the body is not making enough

cortisol, because part of the adrenal gland is not working (adrenal insufficiency, often caused by an inherited condition called congenital adrenal hyperplasia).

Ask your doctor if you have any questions about why ALKINDI has been prescribed for your child.

This medicine is available only with a doctor's prescription.

Before you give ALKINDI

When you must not give it

Do not give ALKINDI: If your child is allergic to hydrocortisone or any of the other ingredients of this medicine.

If your child has difficulties swallowing food, or is a premature baby who cannot yet be fed by mouth.

Before you give ALKINDI

Talk to your doctor or pharmacist before giving ALKINDI if your child is:

- unwell or has an infection. The endocrinologist may need to increase the dose of ALKINDI temporarily; talk

to your endocrinologist if your child is unwell. If your child is vomiting or seriously unwell, your child may need an injection of hydrocortisone. Your endocrinologist will train you how to do this in an emergency.

- due for a vaccination. Taking ALKINDI should not stop your child being vaccinated. Let your endocrinologist know when your child is due for vaccinations.
- due for an operation. Let the anaesthetist know your child is receiving ALKINDI before your child has their operation.
- being fed through a nasogastric tube. ALKINDI granules are not suitable for giving through a nasogastric tube as the granules may block the tube
- changing to Alkindi from another hydrocortisone preparation. Differences between hydrocortisone preparations when changing to Alkindi may mean your child could be at risk of receiving an incorrect dose of hydrocortisone in the first week after switching to Alkindi. This may lead to a risk of adrenal crisis. You should watch your child carefully in the week after changing to Alkindi and give extra doses of Alkindi if there are symptoms of adrenal crisis such as unusual tiredness, headache, a raised or low temperature or

vomiting. If this happens medical attention should be sought right away.

You should not stop giving ALKINDI without the advice of your endocrinologist as this could make your child seriously unwell very quickly.

As ALKINDI is replacing the normal hormone your child lacks, side effects are uncommon, however:

- Too much ALKINDI can affect your child's growth, so your endocrinologist will adjust the dose depending on your child's size and monitor your child's growth carefully. Let your endocrinologist know if you are worried about your child's growth.
- Too much ALKINDI can affect your child's bones so your endocrinologist will adjust the dose depending on your child's size.
- Some adult patients taking hydrocortisone (similar to ALKINDI) became anxious, depressed or confused. It is not known if this would happen with children, but tell your endocrinologist if your child develops any unusual behaviour after starting ALKINDI.
- In some patients with allergies to other medicines, allergy to hydrocortisone has been seen. Tell your endocrinologist straight away if your child has any reaction like swelling or shortness of breath after being given ALKINDI.
- Contact your endocrinologist if your child experiences blurred vision or

other visual disturbances.

ALKINDI granules can sometimes appear in a child's nappy or poo after taking ALKINDI. This is because the centre of the granule is not absorbed in the gut after it has released the medicine. This does not mean the medicine will not work and you do not need to give your child another dose.

Taking Other Medicines

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription.

Some medicines can affect the way that ALKINDI works, and may mean that your endocrinologist needs to alter your child's dose of ALKINDI.

Medicines that may mean your endocrinologist will increase your child's dose of ALKINDI include:

- Medicines used to treat epilepsy: phenytoin, carbamazepine, and oxcarbazepine.
- Medicines used to treat infections (antibiotics): rifampicin and rifabutin.
- Medicines called barbiturates, which can be used to treat convulsions (including phenobarbital and primidone).
- Medicines used to treat AIDS: efavirenz and nevirapine.

Medicines that may mean your endocrinologist will decrease your child's dose of ALKINDI include:

- Medicines used to treat fungal diseases: itraconazole, posaconazole, and voriconazole.
- Medicines used to treat

infections (antibiotics): erythromycin and clarithromycin.

- Medicine used to treat human immunodeficiency virus (HIV) infection and AIDS: ritonavir.

ALKINDI with food and drink

Some food and drink may affect the way ALKINDI works, and may mean that your endocrinologist needs to decrease your child's dose. These include:

- Grapefruit juice.
- Liquorice.

Pregnancy, breast-feeding and fertility

Hydrocortisone can be used during pregnancy and breast-feeding when the body is not making enough cortisol.

There is no information on any effects of ALKINDI on fertility.

How ALKINDI is given

Always use this medicine exactly as your endocrinologist, nurse or pharmacist has told you. Check with your endocrinologist, nurse or pharmacist if you are not sure.

Your endocrinologist will decide on the right dose of ALKINDI based on your child's weight or size (body surface area) and then adjust the dose of ALKINDI as your child grows. During illnesses, at times of surgical operations and during times of serious stress, your endocrinologist may recommend additional doses of ALKINDI and may also advise that your child receives other forms of hydrocortisone instead of, or as well as, ALKINDI.

How to give this medicine

The granules should be given into the mouth and should not be chewed. The capsule shell should not be swallowed but should be carefully opened as described in the "How to

open the ALKINDI capsule and give the granules” section.

In Case of Overdose

If you give more ALKINDI than you should

If you give your child more ALKINDI than you should, contact your endocrinologist or pharmacist for further advice as soon as possible.

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital, if you think that your child may have been given too much ALKINDI. Do this even if there are no signs of discomfort or poisoning. Your child may need urgent medical attention.

While your child is taking ALKINDI

If you forget to give ALKINDI

If you forget to give your child a dose, give your child that dose as soon as you remember as well as their next dose at the usual time even if this means that your child receives two doses at the same time.

If you stop giving ALKINDI

Do not stop giving your child ALKINDI without asking your endocrinologist first. Stopping the medicine suddenly could quickly make your child very unwell.

If your child becomes unwell

Tell your endocrinologist or pharmacist if your child becomes ill, suffers severe stress, gets injured or is about to have surgery because your endocrinologist may need to increase the dose of ALKINDI in these circumstances.

Driving and using machines

ALKINDI has no influence on a child’s ability to perform skilled tasks (e.g. riding a bicycle) or using machines.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Your child may need medical treatment if they get some of the side effects.

Do not be alarmed by the list of possible side effects. Your child may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

If your child has any reaction like swelling or shortness of breath after being given ALKINDI, **get medical help straight away and tell your endocrinologist as soon as possible** as these can be signs of an allergic reaction.

No side effects have been observed with ALKINDI, but the following side effects have been reported for other hydrocortisone medicines used to replace cortisol:

Frequency not known (cannot be estimated from the available data):

- Changes in behaviour including:
 - loss of contact with reality (psychosis) with sensations that are not real (hallucinations) and mental confusion (delirium).
 - overexcitement and overactivity (mania).
 - intense feeling of happiness and excitement (euphoria).

If your child has a dramatic change in behaviour, contact your endocrinologist.

- Stomach pains (gastritis) or feelings of sickness (nausea). Contact your endocrinologist if your child complains of these.
- Changes in blood potassium levels, leading to excessive acidity of body tissues or fluids (hypokalaemic alkalosis). Your endocrinologist will monitor your child’s potassium levels to check for any changes.

Long-term treatment with hydrocortisone may be associated with changes in the development of bones and reduced growth. Your endocrinologist will monitor your child’s growth and bones.

Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.

Prior to opening:
Store below 30°C.
Store in the original bottle in order to protect from light.

After opening:
Once opened, use within 60 days and store below 25°C.
Store in the original bottle in order to protect from light.

Disposal

Medicines should not be disposed via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

White to off-white granules which are contained in a transparent colourless hard capsule for opening; the strength is printed on the capsule.

- ALKINDI 0.5 mg granules in capsules for opening: the capsule is printed with "INF-0.5" in red ink.
- ALKINDI 1 mg granules in capsules for opening: the capsule is printed with "INF-1.0" in blue ink.
- ALKINDI 2 mg granules in capsules for opening: the capsule is printed with "INF-2.0" in green ink.
- ALKINDI 5 mg granules in capsules for opening: the capsule is printed with "INF-5.0" in grey ink.

ALKINDI comes in high density polyethylene plastic bottles containing 50 capsules. Each carton contains 1 bottle.

Ingredients

What ALKINDI contains

- The active substance is hydrocortisone
- ALKINDI 0.5 mg granules in capsules for opening: each capsule contains 0.5 mg of hydrocortisone
- ALKINDI 1 mg granules in capsules for opening: each capsule contains 1 mg of hydrocortisone
- ALKINDI 2 mg granules in capsules for opening: each capsule contains 2 mg of hydrocortisone
- ALKINDI 5 mg granules in capsules for opening: each capsule contains 5 mg of hydrocortisone
- The other ingredients are microcrystalline cellulose, hypromellose, magnesium stearate and ethylcellulose.

Supplier

ALKINDI is supplied in Australia by:

Chiesi Australia Pty Ltd
Suite 3, 22 Gillman Street,
Hawthorn East, VIC. 3123

Email:

medicalaffairs.au@chiesi.com

Website: www.chiesi.com.au

Date of preparation

This leaflet was prepared in June 2021.

ALKINDI 0.5 mg AUST R 319389
ALKINDI 1 mg AUST R 319390
ALKINDI 2 mg AUST R 319410
ALKINDI 5 mg AUST R 319412

ALKINDI®

Hydrocortisone (0.5 mg, 1 mg, 2 mg or 5 mg) granules in capsules for opening

How to open the Alkindi capsule and give the granules

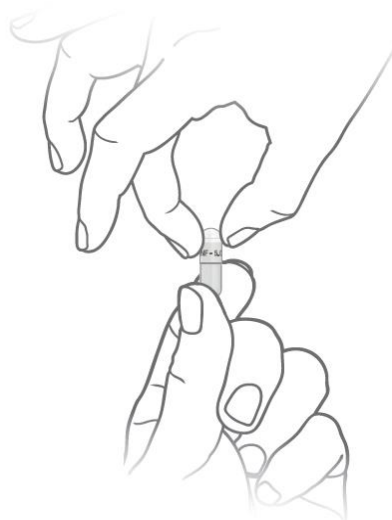
- 1** Hold capsule so that the text is at the top and tap the capsule to make sure the granules are at the bottom



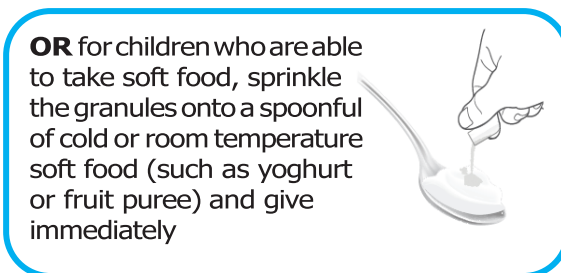
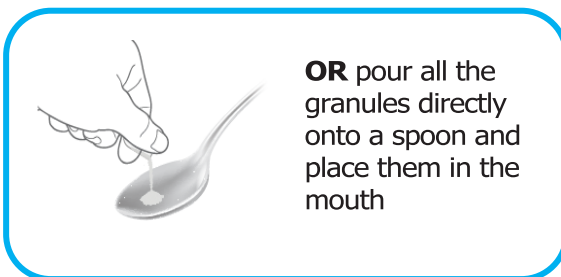
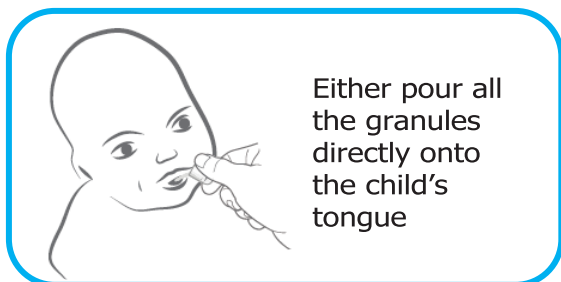
- 2** Gently squeeze the bottom of the capsule



- 3** Twist off the top of the capsule



- 4** Pour all granules out of capsule



Whichever method is used, tap the capsule to ensure all the granules are removed.

If you give the granules directly into the mouth, give a drink (e.g. water, milk, breast-milk or formula-milk) immediately after administration to help ensure all granules are swallowed.

If you give the granules sprinkled onto a spoonful of soft food, administer immediately (within 5 minutes) and do not store for future use.

DO NOT add the granules to liquid before administration as this can result in less than the full dose being given, and might also dissolve the taste masking of the granules allowing the bitter taste of hydrocortisone to become apparent.

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