PACKAGE LEAFLET

Package leaflet: Information for the user

Alkindi 0.5 mg granules in capsules for opening
Alkindi 1 mg granules in capsules for opening
Alkindi 2 mg granules in capsules for opening
Alkindi 5 mg granules in capsules for opening
hydrocortisone

⚠ **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.

Read all of this leaflet carefully before you start giving this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as those of the child for whom this medicine has been prescribed.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Alkindi is and what it is used for
2. What you need to know before you give Alkindi
3. How to give Alkindi
4. Possible side effects
5. How to store Alkindi
6. Contents of the pack and other information

1. What Alkindi is and what it is used for

Alkindi contains the active substance hydrocortisone. Hydrocortisone belongs to a group of medicines known as corticosteroids.

Hydrocortisone is a synthetic version of the natural hormone cortisol. Cortisol is made by the adrenal glands in the body. Alkindi is for use in children and adolescents aged birth to 18 years 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).

2. What you need to know before you give Alkindi

Do not give Alkindi:
- If your child is allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6).

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

Warnings and precautions
Talk to your endocrinologist 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 has an adrenal crisis. 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.

- if your child is due for a vaccination. Taking Alkindi should not stop your child being vaccinated. Let your endocrinologist know when your child is due for vaccinations.

- if your child is due for an operation. Let the anaesthetist know your child is receiving Alkindi before your child has their operation.

- if your child is being fed through a nasogastric tube. Alkindi granules are not suitable for giving through a nasogastric tube as the granules may block the tube.

- when your child is 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. Your doctor will tell you when you can increase the dose 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 checking with 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 less likely, 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 (see section 4).

- 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 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 (see section 4).

- 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 has 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.

Other medicines and Alkindi
Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

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

Your endocrinologist may need to increase your child's dose of Alkindi if your child take certain medicines, including:
- 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.

Your endocrinologist may need to decrease your child's dose of Alkindi if your child take certain medicines, including:
- 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 need your doctor 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.

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.

3. How to give Alkindi

Always use this medicine exactly as your doctor, nurse or pharmacist has told you. Check with them 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, around the time of surgery and during times of serious stress, your endocrinologist may recommend additional doses of Alkindi and may also advise that your child receives another corticosteroid 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 follows:

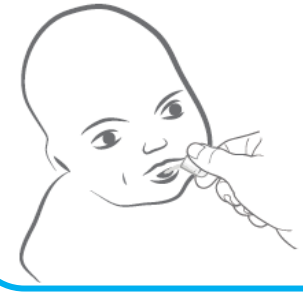
How to open the Alkindi capsule and give the granules

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



Either pour all the granules directly onto the child's tongue

OR pour all the granules directly onto a spoon and place them in the mouth

OR for children who are able to take soft food, sprinkle the granules onto a spoonful of cold or room temperature soft food (such as yoghurt or fruit puree) and give immediately

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.

⚠ **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.

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.

If you forget to give Alkindi or your child had incomplete dose
If a full dose of Alkindi is missed, 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.

Contact your healthcare provider if your child regurgitates, vomits or spits out most of the granules in a dose administered, as a repeat dose may be required to avoid adrenal insufficiency.

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 (see section 2).

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported for 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 (see section 2).

- Stomach pains (gastritis) or feeling sick (nausea).

  Contact your endocrinologist if your child complains of these.

- Changes in blood potassium levels, leading to excessive alkalinity 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 (see section 2).

Reporting of side effects
If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alkindi

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.

Do not store above 30°C. Store in the original bottle in order to protect from light.

Once the bottle has been opened, use the capsules within 60 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

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 ethyl cellulose.
- The capsule is made from hypromellose.
- The printing ink on the 0.5 mg capsules contains shellac, propylene glycol, concentrated ammonia solution, potassium hydroxide and red iron oxide (E172).
- The printing ink on the 1 mg strength capsule contains shellac, propylene glycol, concentrated ammonia solution and indigotine (E132).
- The printing ink on the 2 mg strength capsule contains shellac, propylene glycol, concentrated ammonia solution, indigotine (E132), yellow iron oxide (E172), and titanium dioxide (E171).
- The printing ink on the 5 mg strength capsule contains shellac, propylene glycol, concentrated ammonia solution, potassium hydroxide, titanium dioxide (E171), and black iron oxide (E172).

What Alkindi looks like and contents of the pack

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 (approx. 25.3 mm long) is printed with "INF-0.5" in red ink.
- Alkindi 1 mg granules in capsules for opening: the capsule (approx. 25.3 mm long) is printed with "INF-1.0" in blue ink.
- Alkindi 2 mg granules in capsules for opening: the capsule (approx. 25.3 mm long) is printed with "INF-2.0" in green ink.
- Alkindi 5 mg granules in capsules for opening: the capsule (approx. 25.3 mm long) is printed with "INF-5.0" in grey ink.

Alkindi comes in high density polyethylene plastic bottle.
Pack size: 1 bottle containing 50 capsules.

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