Package leaflet: Information for the user

Hydrocortisone 5 mg/5 ml Oral Solution
Hydrocortisone

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.

The name of your product is Hydrocortisone 5 mg/5 ml Oral Solution, but it will be referred to as Hydrocortisone oral solution throughout this leaflet.

If your child is given a steroid card by their doctor, make sure they carry it with them at all times. Show the Steroid card to any doctor or nurse treating your child.

What is in this leaflet

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

1. What Hydrocortisone oral solution is and what it is used for

Hydrocortisone oral solution contains a medicine called hydrocortisone. This belongs to a group of medicines called corticosteroids, often referred to as 'steroids'. Hydrocortisone is a synthetic version of the naturally occurring hormone cortisol which is made by the adrenal glands. Hydrocortisone is used when the body is not making enough cortisol because part of the adrenal gland is not working properly (this is called adrenal insufficiency). This is often caused by an inherited condition called congenital adrenal hyperplasia.

2. What you need to know before you give Hydrocortisone oral solution

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

Warnings and precautions

Talk to your doctor or pharmacist before giving Hydrocortisone oral solution if your child:

- is unwell or has an infection. The doctor may need to increase the dose of Hydrocortisone oral solution temporarily; talk to your doctor if your child is unwell. If your child is vomiting or seriously unwell, your child may need an injection of hydrocortisone. Your doctor will train you how to do this in an emergency.
- is due for a vaccination. Taking Hydrocortisone oral solution should not stop your child being

vaccinated. Let your doctor know when your child is due for vaccinations.
- is due for an operation. Let the anaesthetist know your child is receiving Hydrocortisone oral solution before your child has their operation.
- has an over-active thyroid gland (hyperthyroidism). Contact your doctor promptly if your child experiences muscle weakness, muscle aches, cramps and stiffness while using hydrocortisone. These can be symptoms of a condition called Thyrotoxic Periodic Paralysis, which may occur in patients with an over-active thyroid gland (hyperthyroidism) who are treated with hydrocortisone. Your child may need additional treatment to alleviate this condition.

You should not stop giving Hydrocortisone oral solution without the advice of your doctor as this could make your child seriously unwell very quickly.

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

- Too much Hydrocortisone oral solution can affect your child's growth, so your doctor will adjust the dose depending on your child's size and monitor your child's growth carefully. Let your doctor know if you are worried about your child's growth (see section 4).
- Too much Hydrocortisone oral solution can affect your child's bones so your doctor will adjust the dose depending on your child's size.
- Some adult patients taking hydrocortisone (similar to Hydrocortisone oral solution) became anxious, depressed or confused. It is not known if this would happen with children, but tell your doctor if your child develops any unusual behaviour after starting Hydrocortisone oral solution (see section 4).
- In some patients with allergies to other medicines, allergy to hydrocortisone has been seen. Tell your doctor straight away if your child has any reaction like swelling or shortness of breath after being given Hydrocortisone oral solution (see section 4).
- Contact your doctor if your child experiences blurred vision or other visual disturbances.

Other medicines and Hydrocortisone oral solution

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

Some medicines can affect the way that Hydrocortisone oral solution works, and may mean that your doctor needs to alter your child's dose of Hydrocortisone oral solution.

Medicines that may mean your doctor will increase your child's dose of Hydrocortisone oral solution 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 doctor will decrease your child's dose of Hydrocortisone oral solution 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.

Hydrocortisone oral solution with food and drink

Some food and drink may affect the way Hydrocortisone oral solution works, and may mean that your doctor 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 Hydrocortisone oral solution on fertility.

Driving and using machines

Hydrocortisone oral solution has no influence on a child's ability to perform skilled tasks (e.g. riding a bicycle) or using machines.

Important – Steroid Treatment Card

A steroid card would usually be given to your child by their nurse or doctor if they have adrenal insufficiency. If your child is given a steroid card, they must always carry it with them – it contains details of their steroid type and dosage, which is important information if they need medical treatment in an emergency. The doctor may also advise you that your child needs to carry this card for up to a year following completion of their steroid treatment.

Hydrocortisone oral solution contains sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, sodium and propylene glycol.

This medicine contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate that may cause allergic reactions (possibly delayed).

This medicine contains 1.24 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.06 % of the recommended maximum daily dietary intake of sodium for an adult.

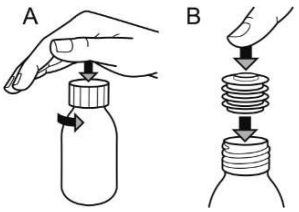
This medicine contains 0.80 mg propylene glycol in each ml.

3. How to give Hydrocortisone oral solution

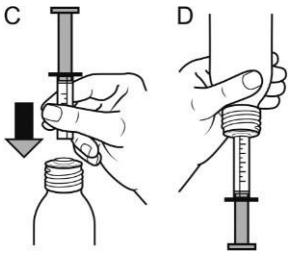
Always use this medicine exactly as your doctor, nurse or pharmacist has told you. Check with your doctor, nurse or pharmacist if you are not sure. Hydrocortisone oral solution can be used in children and adolescents aged between 1 month and 18 years. It is given by mouth, usually in three doses during the day. Your doctor will decide on the right dose of Hydrocortisone oral solution based on your child's size (height and weight) and will adjust the dose according to response and as your child grows. During illness, when undergoing surgery and during times of serious stress, your doctor may recommend additional doses of Hydrocortisone oral solution or may advise that your child receives other forms of hydrocortisone as well as, or instead of, Hydrocortisone oral solution.

How to give this medicine

Hydrocortisone oral solution should be given by mouth.
A 5 ml graduated oral syringe with intermediate graduations of 0.1 ml and a "Press-In" Bottle Adapter (PIBA) are provided with the product.
1. Open the bottle and at first use insert the "Press-In" Bottle Adapter (PIBA) (see pictures A-B).



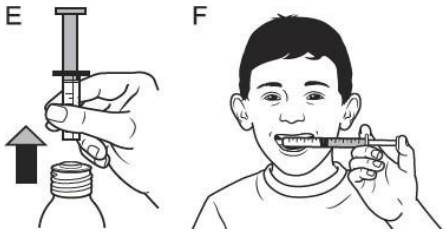
2. Insert the syringe into the PIBA and draw out the required volume from the inverted bottle (see pictures C-D).



3. Remove the filled syringe from the bottle in the upright position (see picture E).

4. Giving the medicine:

   - Make sure that your child is sitting up or standing.
   - Put the syringe into your child's mouth, placing the barrel-opening in the area between the gums and the inside of the cheek (see picture F).
   - Push the plunger slowly, giving your child time to swallow the medicine as it squirts out. Do not push the plunger too quickly as the medicine may come out too quickly and your child may choke. Repeat steps 2 to 4 as needed to achieve the required dose.
   - Give your child some water to drink in order to ensure that all the medicine is washed down.



5. Rinse the syringe and replace the cap on the bottle (PIBA remains in place).

Alternative method of administration (with feeding tubes)

If necessary, this medicine can be given down a feeding tube (called a nasogastric or gastrostomy tube). If this is the case, the following procedure should be followed and your doctor or nurse will show you how to do it:

Administering this medicine via NG or PEG tubes

1. Ensure the tube is clear before administering the medicine.

2. Administer the medicine into the tube with a suitable measuring device.
3. Immediately flush the tube with 5 ml of boiled cooled water.

If you give more Hydrocortisone oral solution than you should

If you give your child more Hydrocortisone oral solution than you should, contact your doctor or pharmacist for further advice as soon as possible.

If you forget to give Hydrocortisone oral solution

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 Hydrocortisone oral solution

Do not stop giving your child Hydrocortisone oral solution without asking your doctor first. Stopping the medicine suddenly could quickly make your child very unwell.

If your child becomes unwell

Tell your doctor or pharmacist if your child becomes ill, suffers severe stress, gets injured or is about to have surgery because your doctor may need to increase the dose of Hydrocortisone oral solution 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.

- If your child has any reaction like swelling or shortness of breath after being given Hydrocortisone oral solution, **get medical help straight away and tell your doctor as soon as possible** as these can be signs of an allergic reaction (see section 2).

The following side-effects have been reported with hydrocortisone medicines used to replace cortisol:
- 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 their behaviour, contact your doctor (see section 2).
- Stomach pains (gastritis) or feelings of sickness (nausea).

Contact your doctor if your child complains of these.

Hydrocortisone can sometimes upset the level of potassium in the blood. Your doctor 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 doctor will monitor your child's growth and bones (see section 2).

Reporting of side effects

If you get 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 the 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 Hydrocortisone oral solution

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 carton and label after EXP. The expiry date refers to the last day of that month.

Unopened bottle: Store in a refrigerator ($2^{o}C$ – $8^{o}C$).

After first opening: Store below 25°C and use within 2 months (60 days).

Do not freeze.

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 Hydrocortisone oral solution contains

- Each 5 ml of Hydrocortisone Oral Solution contains 5 mg of the active substance hydrocortisone (as hydrocortisone sodium phosphate).
- The other ingredients are: disodium edetate, sodium propyl parahydroxybenzoate (E217), sodium methyl parahydroxybenzoate (E219), sodium dihydrogen phosphate dihydrate (E339), sucralose, sodium hydroxide (E524), purified water and orange flavour (including propylene glycol (E1520), triacetine, orange oil, ethyl butyrate and acetaldehyde).

What Hydrocortisone oral solution looks like and contents of the pack

Hydrocortisone oral solution is a clear, colourless to yellowish solution with orange odour. It is supplied in amber type III glass bottle, safely closed with a child-resistant, screw cap with tamper evident closure. Each bottle contains 100 ml or 150 ml of this medicine. Not all pack sizes may be marketed.

A 5 ml graduated oral syringe with intermediate graduations of 0.1 ml and a “press-in” syringe/bottle adapter are also provided.

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