

Package leaflet: Information for the user

Fludrocortisone acetate 0.1 mg/ml Oral Solution

Fludrocortisone acetate

Read all of this leaflet carefully before you start taking 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 you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- **Don't stop taking this medicine** without talking to your doctor – you may need to reduce the dose gradually.
- **If you take it for more than 3 weeks, you will get a 'steroid card'**: always keep it with you and show it to any doctor or nurse treating you.

What is in this leaflet

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

1. What Fludrocortisone acetate oral solution is and what it is used for

The name of your medicine is Fludrocortisone acetate 0.1 mg/ml Oral Solution. Each 1 ml contains 0.1 mg of the active ingredient, fludrocortisone acetate, called Fludrocortisone throughout this leaflet.

Fludrocortisone belongs to a group of medicines called steroids. Their full name is corticosteroids. These corticosteroids occur naturally in the body, and help to maintain health and well-being.

Fludrocortisone is used:

- To replace the hormones that are normally produced by glands attached to your kidneys. These hormones will not be produced by your body if you suffer from a condition called Addison's disease.
- To treat a condition called 'salt losing adrenogenital syndrome' which is a different form of hormone imbalance.

2. What you need to know before you take Fludrocortisone acetate oral solution

Do not take Fludrocortisone acetate oral solution if you are:

- allergic to fludrocortisone acetate or any of the other ingredients of this medicine (listed in Section 6) or any other similar medicines.
- suffering from an infection and are not taking any prescribed medication for it.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fludrocortisone acetate oral solution if you:

- have recently had any bacterial, viral or fungal infection that is not being treated
- have or ever have had tuberculosis
- have or have had any intestinal, bowel disorder or stomach ulcer
- have an infection or inflammation of the veins in your leg (thrombophlebitis)
- have had any mental health problems
- have epilepsy
- have had any kidney, liver or thyroid problems
- have recently suffered from any form of cancer
- have thin or brittle bones (osteoporosis)
- have myasthenia gravis (a disease which causes weak muscles) or any other muscle weakness
- have high blood pressure or heart failure or someone in your family has glaucoma (increased pressure in your eyes)
- have a sore/infection of the eye (herpes)
- are diabetic as your insulin dose may need to be changed or have a family history of diabetes
- have a skin rash typically caused by viral infection (e.g. measles) or have been in contact with anyone with chicken pox, shingles or measles
- have muscle damage caused by steroid treatment
- are elderly (over 65 years old) as you may be more susceptible to side effects (listed in section 4.8 Possible side effects)
- are younger than 18 years old, as fludrocortisone may lead to slowing of growth
- are suffering from stress (such as trauma, surgery or severe illness), as you may require supportive corticosteroid therapy both during the treatment period and for a year afterwards
- having or have had intestinal surgery
- have a rare skin reaction related to taking medicines

Contact your doctor if you experience blurred vision or other visual disturbances.

Check with your doctor first if:

- you have ever had severe depression or manic-depression (bipolar disorder). This includes having had depression before or while taking steroid medicines like fludrocortisone acetate.
- any of your close family has had these illnesses.

Steroid medicines **suppress** your body's natural **immune response**. Therefore, if you come into contact with anyone who has an infectious disease such as chickenpox, shingles or measles, consult your doctor as soon as possible.

Your doctor may want to send you for **blood tests** from time to time and check your salt intake regularly to make sure you do not develop high blood pressure, fluid retention or become overweight.

Other medicines and Fludrocortisone acetate oral solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines bought without a prescription, including herbal medicines.

In particular, tell your doctor if you are taking any of the following medicines:

- Aspirin, ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs) as corticosteroids can increase the chance of bleeding from the gut.
- Any antifungals (e.g. ketoconazole, amphotericin)
- Warfarin or other medicines to thin the blood
- Oral contraceptive pill or hormone replacement therapy (HRT)
- Human growth hormone
- Muscle relaxants e.g. atracurium. These drugs are used during anaesthesia for surgery. Please inform your anaesthetist if you're taking Fludrocortisone acetate oral solution.
- A medicine called ciclosporin (normally used after a transplant)
- Barbiturates. These drugs are used as sedatives (to produce a calming effect), as hypnotics (to produce sleep), or as an adjunct in anaesthesia.
- HIV medicines such as ritonavir, cobicistat. These medicines may increase the effects of Fludrocortisone acetate oral solution and your doctor may wish to monitor you carefully if you are taking these medicines.

Tell your doctor if you are taking medicines to treat:

- High blood pressure (e.g. sodium phenylbutyrate, clonidine, methyldopa, ACE inhibitors, alpha and beta blockers, angiotensin II receptor antagonists, calcium-channel blockers and diuretics)
- Irregular heartbeat (e.g. digoxin)
- Epilepsy or other sorts of fits (e.g. phenytoin, primidone, carbamazepine)
- Tuberculosis (TB) (e.g. isoniazid, rifampicin, rifabutin)
- Diabetes
- Thyroid problems
- Cushing's syndrome (e.g. aminoglutethimide)
- Glaucoma (e.g. acetazolamide)
- Intestinal pain (e.g. hyoscine)
- Asthma and Chronic Obstructive Pulmonary Disease (e.g. tiotropium)
- Urinary retention (e.g. doxazosin)
- Alzheimer's dementia (e.g. donepezil, galantamine)
- Myasthenia Gravis (e.g. neostigmine)

While you are being treated with this medicine (or if you have recently stopped a course of treatment) do not have any vaccination without consulting your doctor.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Fludrocortisone acetate oral solution has not been shown to impair your ability to drive or use machines.

Steroid Treatment Card

If you take this medicine for more than three weeks, your doctor or pharmacist will have given you a **Steroid Treatment card** with your prescription or medicine. **YOU SHOULD ALWAYS CARRY THIS CARD WITH YOU** as it must be shown to any of the following persons:

Doctor or Nurse - before having any surgery or emergency treatment or if any new treatment is prescribed.

Dentist - before having any dental surgery

Pharmacist - before buying any medicine

Optician - it is advisable to have regular eye tests.

3. How to take Fludrocortisone acetate oral solution

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults

The recommended daily dose range is: 0.5 ml (0.05mg) to 3 ml (0.3 mg) to be taken once a day. Patients on long term treatment may require the addition of a different type of steroid therapy during times of illness or stress.

Children

The recommended daily dose range is: 0.5 ml (0.05mg) to 1 ml (0.1mg) to be taken once a day.

Method of administration

Fludrocortisone acetate 0.1 mg/ml Oral Solution is to be administered orally. Alternatively, it is also suitable for administration via certain enteral feeding tubes.

Your medicine is provided in a bottle, with a syringe and an adaptor.

Fig. 1



Fig. 2



1. Shake the bottle well before use and remove the cap.
 2. When the medicine is used for the first time, insert the plastic adaptor firmly into the bottle neck.
 3. Insert the syringe firmly into the adaptor. Make sure the plunger is at the bottommost position (Fig 1).
 4. Turn the bottle upside down in order to fill the syringe. While holding the syringe in place, pull the plunger down gently and draw the medicine to the millilitre (ml) level corresponding to the dose prescribed by your doctor.
 5. Turn the bottle upright again and remove the filled syringe from the adaptor by gentle twisting (Fig 2).
 6. Insert the syringe tip into the mouth and press the plunger slowly to release the medicine.
 7. Replace the bottle cap after use, leaving the adaptor in place.
- Wash the syringe with water after each use and allow it to dry completely before the next use.

For infants and smaller children, the medicine should be given by parents and professional childcare providers, following the instructions below:

Follow Steps 1-5 as above.

6. Make sure your child is sitting upright (Fig.3).
7. Put the tip of the oral syringe inside your child's mouth between the gums and the inside surface of their cheek.
8. Gently push the plunger to squirt small amounts of medicine into the side of your child's mouth.
9. Allow your child to swallow before you carry on pushing the plunger. Note: Do not squirt the entire dose into your child's mouth in one go – they may choke.
10. Give your child a drink to wash down the medicine.
11. Replace the bottle cap after use, leaving the adaptor in place.



Fig 3

Rinse and wash the syringe with cold or warm water after each use and allow it to dry completely before the next use.

Any unused oral solution should be disposed after 4 months after first opening of the bottle. A dosing syringe is provided for accurate measurement of the prescribed dose of the oral solution.

Alternatively, it is also suitable for administration via certain enteral feeding tubes.

Care should be taken during administration due to the oily nature of the product.

It is recommended to administer the drug product following the instructions below:

Ensure that the enteral feeding tube is free from obstruction before administration.

1. Flush the enteral tube with water. A minimum flush volume of 10ml is required.
2. Administer the required dose of Fludrocortisone Oral Solution with a suitable measuring device.
3. Flush the enteral tube 3 consecutive times, using a minimum volume of 10ml of water each time.

This product can be used with silicon or polyurethane nasogastric (NG) and percutaneous endoscopic gastrostomy (PEG) tubes of size Fr 13 and Fr 10 respectively with maximum length 120 cm.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Make sure you take the full course as prescribed by your doctor. Do not suddenly stop taking your medicine as this may make you ill.

If you take more Fludrocortisone acetate oral solution than you should

If you take more of this medicine than you should, seek immediate medical advice from your doctor or go to your nearest hospital straight away. Take the medicine pack with you.

If you forget to take Fludrocortisone acetate oral solution

If you forget to take a dose, do not worry, just take it as soon as you remember unless it is nearly time for your next dose then you should miss the forgotten dose and continue as before. Do not take a double dose to make up for a forgotten dose.

Mental health problems while taking Fludrocortisone acetate oral solution

Mental health problems can happen while taking steroids like Fludrocortisone acetate oral solution (see also Section 4).

- These illnesses can be serious.
- Usually they start within a few days or weeks of starting the medicine.
- They are more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or the medicine is stopped.

However, if problems do happen, they might need treatment.

Talk to a doctor if you (or someone taking this medicine), shows any signs of mental problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental health problems have happened when doses are being lowered or stopped.

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.

Serious side effects

Stop taking Fludrocortisone acetate oral solution and contact your doctor straight away/immediately if the following happen as these may be signs of:

- an allergic reaction (hypersensitivity reaction including anaphylaxis):
 - Difficulty breathing
 - Swelling of the face, lips or tongue
 - Severe pains in your stomach or abdomen
 - Skin rash
- a serious mental health problem. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like Fludrocortisone acetate oral solution:
 - Feeling depressed, including thinking about suicide.
 - Feeling high (mania) or having moods that go up and down.
 - Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory.
 - Feeling, seeing or hearing things which do not exist (hallucinations). Having strange and frightening thoughts, changing how you act or feeling lonely.

Side effects listed below have been reported with Fludrocortisone in the following frequencies:

Very common (may affect more than 1 in 10 people)

- Heart failure (shortness of breath with activity, or after lying down for a while)
- High blood pressure
- Low blood potassium levels

Common (may affect up to 1 in 10 people)

- Muscle weakness, pain or wasting, tendon rupture (where muscles connect to bones)
- Headaches
- Increased swelling

Uncommon (may affect up to 1 in 100 people)

- Irregular heartbeats
- Epilepsy or seizures (fits)
- Fainting or loss of consciousness
- Diarrhoea
- Decreased appetite

Other side effects associated with steroid therapy

Not known (frequency cannot be estimated from the available data)

- Infection of the veins in the legs

- Thrush (white patches) or fungal infections (or sores in your mouth)
- Bone problems, including thinning or wasting or fractures and delays in bone healing
- Pancreatitis (inflammation of the pancreas) which causes severe pain in the abdomen and back
- Abdominal pain
- Ulcers of the stomach or intestine (which can lead to perforation or bleeding), pain or burning in your stomach or oesophagus
- Ulcers of the windpipe (pain in your windpipe)
- Indigestion
- Swelling of the stomach (feeling full or bloated)
- Increased or decreased appetite
- Skin problems including thinning of the skin and eye, bruising, facial redness, stretch marks, increased facial hair, acne
- Poor wound healing
- Increased sweating
- Vertigo (spinning feeling)
- Sleep problems
- Pins and needles
- Thinning of the skin
- Irregular or absent menstrual periods
- Increased pressure in the eye (Glaucoma)
- Clouding of the lens (cataract)
- Problems with vision
- Blurred vision
- Infection of the eye (cornea)
- Problems in the way your body manages your glucose levels including diabetes
- High blood sugar levels
- Feeling tired
- Weight gain
- Increased pain
- Fever (increased temperature) and sweating
- Abnormal taste
- Tingling (lips, fingers, tongue or feet)
- Feeling or being sick
- Skin turning yellow
- Problems with your endocrine system, which controls your hormones, including those which regulate your body's growth and metabolism. Symptoms include increased appetite, weight gain, sweating and tiredness
- Decreased pituitary function (a change in the levels of some hormones, mineral balance or protein in blood tests)
- Hormone imbalance causing Cushing's Syndrome (typical symptoms: a round face often called a 'moon face', upper body weight gain and rash on the face)
- Increase in blood clotting

Additional side effects in children and adolescents

- Failure to grow

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 Fludrocortisone acetate 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 bottle label. The expiry date refers to the last day of that month.

Store in the original packaging in order to protect from light.

After first opening: Use within four months.

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 Fludrocortisone acetate oral solution contains

The active substance is fludrocortisone acetate. Each 1 ml contains 0.1 mg fludrocortisone acetate.

The other ingredient is Medium Chain Triglycerides.

What Fludrocortisone acetate oral solution looks like and contents of the pack

Fludrocortisone acetate oral solution is a clear colourless or slight yellowish, oily liquid. It is packed in 60 ml size Type III amber glass bottles and sealed with a plastic child-resistant and tamper evident plastic cap (HDPE inside cap body, PP outside cap body, LDPE inside seal top). It contains a 3 ml oral syringe (polystyrene plunger, LDPE plunger piston, LDPE barrel) with 0.1 ml graduations and a neck fitted syringe LDPE adaptor for the bottle.

Marketing Authorisation Holder

Aristo Pharma GmbH
Wallenroder Straße 8-10
13435 Berlin
Germany

Manufacturer

Labomed Pharmaceutical Company S.A.
84 Ioannou Metaxa str.
19441, Koropi,

Athens,
Greece

This leaflet was last revised in 08/2022.