Package leaflet: Information for the user

Fludrocortisone acetate 0.05 mg tablets Fludrocortisone acetate 0.1 mg tablets

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.
- **Do not 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 blue '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 is and what it is used for
2. What you need to know before you take Fludrocortisone acetate
3. How to take Fludrocortisone acetate
4. Possible side effects
5. How to store Fludrocortisone acetate
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1. What Fludrocortisone acetate is and what it is used for

The name of your medicine is Fludrocortisone acetate 0.05 mg and 0.1 mg tablets (called Fludrocortisone acetate in this leaflet). The tablets contain the active substance called fludrocortisone acetate, which 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 acetate 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.
- 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

Do not take Fludrocortisone acetate
- 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.
- If you are 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.

You must tell your doctor before taking this medicine if:
- You have or have recently had any **bacterial, viral or fungal infection** that is not being treated
- You have or ever have had tuberculosis
- You have or have had any intestinal, **bowel disorder** or stomach ulcer
- You have an infection or inflammation of the veins in your leg (thrombophlebitis)
- You have had any **mental health problems** or epilepsy
- You have had any **kidney, liver or thyroid** problems
- You have recently suffered from any form of **cancer**
- You have thin or **brittle bones** (osteoporosis)
- You have **myasthenia gravis** (a disease which causes weak muscles) or any other muscle weakness
- You have **high blood pressure** or heart failure
- You or someone in your family has **glaucoma** (increased pressure in your eyes)
- You have **ocular herpes simplex** (eye infection caused by a type of herpes)
- You are **diabetic** as your insulin dose may need to be changed or have a family history of diabetes
- You have a skin rash typically caused by viral infection (such as measles)
- You have muscle damage caused by steroid treatment
- You are elderly (over 65 years old) as you may be more susceptible to side effects (see section 4 Possible side effects)
- You are younger than 18 years old, as Fludrocortisone acetate may lead to slowing of growth
- You 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
- You are to have or have had intestinal surgery
- You have pheochromocytoma (a tumour of the adrenal gland).
- **You have ever had severe depression** or manic-depression (bipolar disorder). This includes having had depression before while taking steroid medicines like Fludrocortisone acetate tablets or **if any of your close family** has had these illnesses.

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

Infectious diseases
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, tell your doctor as soon as possible.

Blood tests control
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.

Mental health problems while taking Fludrocortisone acetate tablets
Mental health problems can happen while taking steroids like Fludrocortisone acetate tablets (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.

Steroid Treatment Card
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

Other medicines and Fludrocortisone acetate
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking:
- Aspirin, ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs) as corticosteroids can increase the chance of bleeding from the gut.
- Any antifungals (such as 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.
- 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.
- Some medicines may increase the effects of Fludrocortisone acetate and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).
- Medicines to treat:
  - High blood pressure (e.g. sodium phenylbutyrate, clonidine, methyldopa, ACE inhibitors, α and ß-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).

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

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 has not been shown to impair your ability to drive or use machines.

Fludrocortisone acetate contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Fludrocortisone acetate

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 and elderly
The recommended daily dose range is: 0.05 mg to 0.3 mg to be taken once a day. Patients on long term treatment may require the addition of a different type of steroid tablet during times of illness or stress.

Use in children
The recommended dose is 0.05mg to 0.1mg daily.

If you take more Fludrocortisone acetate than you should
If you take too many tablets, contact your doctor or go to your nearest hospital emergency department immediately. Take the container and any remaining medicine with you.

If you forget to take Fludrocortisone acetate
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 the forgotten dose.

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

4. Possible side effects

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

Serious side effects
The following side effects are presented in order of severity. The most severe side effects are listed first. Side effects that are considered to be of the same severity are listed on the same line.

Stop taking Fludrocortisone acetate tablets and contact your doctor straight away
- 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
- If the following happen as these may be signs of a serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like Fludrocortisone acetate:
  - 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.

Other side effects
Tell your doctor if the following occur:

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

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

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
- irregular or absent periods
- glaucoma
- clouding of the lens (cataract)
- problems with vision
- blurred vision
- infection of the cornea
- problems in the way your body manages your glucose levels including diabetes
- high blood sugar levels
- tired
- weight gain
- increased pain
- fever (increased temperature) and sweating
- abnormal taste
- tingling (lips, fingers, tongue or feet)
- nausea (feeling sick)
- vomiting (getting 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
- not growing as expected

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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

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 blister after 'EXP'. The expiry date refers to the last day of that month.

Store below 30°C.

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 contains
- The active substance is fludrocortisone acetate. Each Fludrocortisone acetate 0.05 mg tablet contains 0.05 mg fludrocortisone acetate. Each Fludrocortisone acetate 0.1 mg tablet contains 0.1 mg fludrocortisone acetate.
- The other ingredients are: mannitol, cellulose microcrystalline, silica colloidal anhydrous, hypromellose, croscarmellose sodium, magnesium stearate.

What Fludrocortisone acetate looks like and contents of the pack
Fludrocortisone acetate 0.05 mg tablets are white to off-white, oblong tablets approximate dimensions 7.5 mm x 3.5 mm with a breakline on both sides.
Fludrocortisone acetate 0.1 mg tablets are white to off-white, round, biconvex tablets approximately 6.4 mm diameter with a breakline on one side and plain on other side.

The breakline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The tablets are packed in Aluminium-Aluminium blister.

Pack sizes: 30 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Zentiva Pharma UK Limited
12 New Fetter Lane
London
EC4A 1JP
United Kingdom

Manufacturer
Athena IPS,
1 Rue Nungesser,
59121 Prouvy,
France

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For information in large print, tape, CD or Braille, telephone 0800 198 5000.

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