Fludrocortisone Acetate 0.1 mg Tablets

Package leaflet: Information for the user

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.

- **Fludrocortisone acetate tablets are a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Do not stop taking this medicine** without talking to your doctor – you may need to reduce the dose gradually.
- **Fludrocortisone acetate tablets can cause side effects in some people** (see section 4). Some problems such as mood changes (feeling depressed or 'high') can happen straight away.
  If you feel unwell in any way, keep taking your medicine, **but see your doctor straight away**.
- **Some side effects only happen after weeks or months**. These include weakness of arms and legs or developing a rounder face (see section 4).
- **If you take it for more than three weeks, you will get a blue 'steroid card'**: always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chickenpox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chickenpox or shingles, see your doctor straight away.

- 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.

What is in this leaflet

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2. What you need to know before you take Fludrocortisone acetate tablets
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1. What Fludrocortisone acetate tablets are and what they are used for

Fludrocortisone acetate 0.1mg tablets (called Fludrocortisone acetate tablets in this leaflet) contains the active substance fludrocortisone. This belongs to a group of medicines called corticosteroids or steroids. Fludrocortisone acetate is used to replace the hormones that are normally produced by glands attached to your kidneys. If you suffer from a condition called Addison's disease these hormones will not be produced by your body.

Fludrocortisone acetate is also used 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 tablets

Do not take Fludrocortisone acetate tablets if you:
- have an infection and you are not taking antibiotics
- are **allergic** to Fludrocortisone acetate or any of the other ingredients of this medicine (listed in Section 6).

Warnings and Precautions
Talk to 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 have ever 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 (e.g. measles)
- you have muscle damage caused by steroid treatment
- 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 experience blurred vision or other visual disturbances.

Talk to your doctor before taking this medicine if you or a member of your family have:
- **ever had severe depression or manic depression** (bipolar disorder). This includes having had depression before or while taking steroid medicines like Fludrocortisone acetate tablets.

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.

Chickenpox, shingles or measles
Before taking Fludrocortisone acetate tablets talk to your doctor if you have recently been in contact with a person with chickenpox, shingles or measles or have had any of these diseases recently yourself.

Elderly
If you are over 65 years old you may be more susceptible to side effects (Section 4).

Children and adolescents
Fludrocortisone can delay growth in children and adolescents. Your doctor will make sure your child's treatment is kept to the shortest time and the lowest dose required to treat their condition.

Other medicines and Fludrocortisone acetate tablets
Tell your doctor or pharmacist 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
- 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).

or 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)

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
Tell your doctor before taking this medicine if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Pregnancy
Taking steroids often or for a long time during pregnancy can slow the baby's growth in the womb or may temporarily affect the baby's heart and body movements.

The baby may also make less of its own steroid after birth, but this rarely causes any problems. If you become pregnant whilst taking this medicine, please tell your doctor but **DO NOT stop taking the tablets unless told to do so** (see section 3).

Breast-feeding
Fludrocortisone may pass into breast milk. Ask your doctor or pharmacist for advice before taking this medicine.

Fertility
It is not known if steroids affect fertility.

Driving and using machines
No effects on the ability to drive and use machines have been seen.

Important information about some of the ingredients of Fludrocortisone acetate tablets
This medicine contains:
- **Sodium**: contains less than 23mg of sodium (main component of cooking/table salt) in each tablet, essentially sodium free.
- **Lactose**: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Fludrocortisone acetate tablets

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

Important:
Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not or you are not sure, ask your doctor or pharmacist.

Swallow your tablets. If you need to take **half** a tablet you should break it in half along the scored line on the tablet. Do not keep the remaining half tablet.

Adults and the elderly
The usual dose is between half a tablet (0.05mg) to 3 tablets (0.3mg) 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 and adolescents
The usual dose is between half a tablet (0.05mg) to 1 tablet (0.1mg) once a day.

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.

If you take more Fludrocortisone acetate tablets than you should
If you, or your child, accidentally take too many tablets, **immediately** contact the nearest hospital casualty department or your doctor. Take this leaflet with you. This is so the doctor knows what you have taken.

If you forget to take Fludrocortisone acetate tablets
If you forget a dose, take the next dose as soon as you remember. Do not take a double dose to make up for a forgotten dose.

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.

4. Possible side effects

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

Serious side effects

Stop taking your tablets immediately and see a doctor or go to hospital straightaway if you
- have an allergic reaction. Signs of an allergic reaction include: a rash, problems swallowing or breathing, swelling of the lips, face, throat or tongue.

If the following happen these may be signs of 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:
- 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:

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)
- Headache
- 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
- Failure to grow

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/yellow card 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 tablets

Store below 25°C.

Store in the original package in order to protect from light and moisture.

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

Do not dispose of any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Fludrocortisone acetate tablets contains
- Each tablet contains 0.1mg of the active substance, fludrocortisone acetate.
- The other ingredients are: lactose monohydrate, sodium starch glycolate, talc (E553b) and magnesium stearate.

What Fludrocortisone acetate tablets look like and contents of the pack
The tablets are round, white to off white tablets with a break line on one side and FL printed on the other side.

They are supplied in packs of 30, 50 or 100 tablets.

Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
ROMA Pharmaceuticals Limited
Gibraltar House
Centrum 100
Burton-upon-Trent
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Email: medinfo@romapharma.co.uk

Manufacturer
Galenica Pharmaceutical Industry S.A.
4-6, Asklipiou Str.
14568 Kryoneri, Attiki, Greece

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Carrying a steroid card
If your doctor asks you to carry a steroid card, be sure to keep it with you at all times. The card will show the dose of steroid. Show the card when receiving any other medical treatment.