

Package Leaflet: Information for the patient

FLUDROCORTISONE ACETATE 0.1 MG TABLETS

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.
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- **Fludrocortisone Acetate 0.1 mg tablet is a steroid medicine** prescribed for many different conditions, including serious illnesses.
 - **You need to take it regularly** to get the maximum benefit.
 - **Don't stop taking this medicine** without talking to your doctor – you may need to reduce the dose gradually.
 - **Fludrocortisone Acetate 0.1 mg tablet can cause side effects in some people** (read section 4 below). Some problems such as mood changes (feeling depressed or 'high'), or stomach problems can happen straight away. If you feel unwell in any way, keep taking your tablets, 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 (read section 4 for more information).
 - **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.
 - **Keep away from people who have chicken pox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chicken pox or shingles, **see your doctor straight away**.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for 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 Tablets
3. How to take Fludrocortisone Acetate Tablets
4. Possible side effects
5. How to store Fludrocortisone Acetate Tablets
6. Contents of the pack and other information

1. What Fludrocortisone Acetate is and what it is used for

Fludrocortisone Acetate tablets belong 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. Boosting your body with extra corticosteroid (such as Fludrocortisone Acetate tablets) is an effective way to treat various illnesses involving inflammation (swelling) in the body. Fludrocortisone Acetate tablets reduce this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

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.

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 are **allergic** to Fludrocortisone Acetate or any of the ingredients of this medicine (listed in section 6).
- If you are suffering from **an infection** and are not taking any prescribed medication for it.
- If you have a peptic ulcer, active tuberculosis or a mental illness in which you lose touch with reality and are unable to think and judge clearly.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fludrocortisone Acetate 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 had any intestinal, **bowel disorder** or stomach ulcer
- you have an infection or inflammation of the veins in your leg (thrombophlebitis)
- you have problems due to the formation of blood clots in the blood vessels (thromboembolism)
- you have had any **mental disorders** 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 have disorder with signs such as weight gain, fat build-up on the face and bruising caused by too much of corticosteroid hormone)
- 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
- Contact your doctor if you experience blurred vision or other visual disturbances.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

Check with your doctor first:

- **If 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.
- **If any of your close family** has had these illnesses.

If either of these applies to you, talk to a doctor before taking Fludrocortisone Acetate tablets.

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

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. 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 (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 on 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, methyl dopa, ACE inhibitors, α and β -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
- Anti-progestogenic steroids (e.g. mifepristone)
- 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.

If you are unsure of the types of medicines you are taking, ask your doctor or pharmacist.

Pregnancy and breast feeding

If you are pregnant, planning to become pregnant, or if you are breast-feeding you should make sure you discuss this with your doctor before taking Fludrocortisone Acetate.

Driving and using machines

Fludrocortisone Acetate has not been shown to impair your ability to drive or operate machinery.

Fludrocortisone Acetate contains lactose and sodium

This product contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

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

3. How to take Fludrocortisone Acetate Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with them if you are not sure.

This medicine is for oral use. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Adults and the Elderly:

To treat Addison's Disease the usual daily dose range is: 0.05 mg to 0.3 mg (3 tablets) to be taken once a day. For a dose of 0.05 mg, other suitable fludrocortisone products should be used. Patients on long term treatment may require the addition of a different type of steroid tablet during times of illness or stress.

To treat Adrenal hyperplasia the usual daily dose range is: 0.1mg (one tablet) to 0.2mg (2 tablets).

Children:

The recommended dose is one-half tablet (0.05mg) to one tablet (0.1mg) daily. For a dose of 0.05 mg, other suitable fludrocortisone products should be used.

The dose is adjusted according to size and weight but is always kept as low as possible.

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 than you should:

If you take too much of your medicine seek **immediate** medical advice from your doctor or your nearest hospital. Take the container and any remaining medicine with you.

If you forget to take Fludrocortisone Acetate:

If you have missed a dose take it as soon as you remember unless it is nearly time for your next dose. Then continue your normal dose times. Do not take a double dose.

Mental problems while taking Fludrocortisone Acetate:

Mental health problems can happen while taking steroids like Fludrocortisone Acetate tablets (see also section 4 Possible Side Effects).

- 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 problems have happened when doses are being lowered or stopped.

If you have any further questions on the use of this product, 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 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/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

Serious effects - Tell your doctor straight away:

Steroids including fludrocortisone acetate can cause 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 have 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. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

If you notice any of these problems **talk to a doctor straight away**.

Less serious side effects

Tell your doctor if the following occur:

Very common (these 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 (these may affect up to 1 in 10 people)

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

Uncommon (these may affect up to 1 in 100 people)

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

Other side-effects (Frequency not known: frequency cannot be estimated from the available data)

- An increased susceptibility to infections (lowered resistance to infections)
- Infection of the veins in the legs
- Blood clots (thromboembolism)
- 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
- Diverticulitis which is an inflammatory condition which may cause abdominal pain or diarrhoea
- Ulcers of the stomach or intestine (which can lead to perforation or bleeding), pain or burning in your stomach or esophagus
- 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
- Reactions to skin tests may be reduced
- Vertigo (spinning feeling)
- Sleep problems
- Pins and needles
- Severe blood loss
- Increased number of white cells or other blood disorders
- Irregular or absent periods
- Failure to grow
- Water and sodium (salt) retention
- 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
- Changes in your body's mineral levels for example, calcium
- High blood sugar levels
- Tired
- Weight gain
- An imbalance in your body's sodium, potassium or chloride levels
- Low blood urea nitrogen levels
- 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

Reporting of side effects

If you get any side effects, talk to your doctor or 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 Tablets

Keep all medicines out of the sight and reach of children.

Store below 30 °C. Keep the tablets in the original container in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and blister as [EXP MM/YYYY]. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Fludrocortisone Acetate Tablets contain:

The active substance (the ingredient that makes the tablets work) is fludrocortisone acetate. Each tablet contains 100 micrograms of the active ingredient.

The tablets also contain sodium starch glycolate, lactose monohydrate (see section 2 “Fludrocortisone Acetate contains lactose and sodium”), talc and magnesium stearate.

What Fludrocortisone Acetate Tablets looks like and contents of the pack:

Fludrocortisone Acetate 0.1 mg Tablets are white to off-white round tablets, marked with ‘FL 0.1’ on one side and a score-line on the other side.

Fludrocortisone Acetate tablets are available in boxes of 30, 50 and 100 tablets.

Marketing authorisation holder:

Mylan
Potters Bar
EN6 1TL
United Kingdom

Manufacturer:

Tiofarma B.V.
Benjamin Franklinstraat 5-10
3261 LW Oud-Beijerland
The Netherlands

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