



Package leaflet: Information for the patient

Fludrocortisone acetate 0.05mg 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.
 - **Fludrocortisone acetate 0.05mg tablets 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 0.05mg tablets 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. This leaflet was last updated on 09/2023.

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
6. Contents of the pack and other information

1 What Fludrocortisone acetate is and what it is used for

This medicine contains fludrocortisone acetate. Each tablet contains 0.05mg of fludrocortisone acetate.

This medicine 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. 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

Do not take this medicine

- 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fludrocortisone acetate tablets. **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 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 (e.g. 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 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 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 or being treated for:

- 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)
- 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
- 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 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 operate machinery.

This medicine 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 (23mg) 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

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

Adults and the Elderly:

The **recommended daily dose range** is: 0.05mg (one tablet) to 0.3mg (6 tablets) 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.

Children:

The recommended dose is one tablet (0.05mg) to two tablets (0.1mg) daily.

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

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 to make up for the forgotten dose.

Mental health problems while taking this medicine

Mental health problems can happen while taking steroids like this medicine (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 health problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental health problems have happened during this time, when doses are being lowered or stopped.

pharm code

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 this medicine 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 (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
- Tiredness
- 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 (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

Keep this medicine out of the sight and reach of children. This medicine does not require any special storage conditions. 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. 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 this medicine contains

- The active substance is fludrocortisone acetate. Each tablet contains 0.05mg of the active ingredient.
- The other ingredients are lactose monohydrate, sodium starch glycolate, talc and magnesium stearate.

What Fludrocortisone acetate tablets looks like and contents of the pack

Fludrocortisone acetate 0.05mg tablets are white to off-white, round, biconvex tablets.

The tablets are packed in blisters in cartons of 30 tablets.

Marketing Authorisation Holder

Aspire Pharma Ltd
Unit 4, Rotherbrook Court
Bedford Road
Petersfield
Hampshire
GU32 3QG
United Kingdom

Manufacturer

Balkanpharma-Razgrad AD
68 Aprilsko vastanie Blvd.
Razgrad
7200
Bulgaria

This leaflet was last revised in 09/2023

This leaflet is available in formats suitable for the blind and partially sighted. Please contact Aspire Pharma Ltd for more information.

pharm code

1010602 - P1.6

ASPIRE[®]
P H A R M A

Aspire Pharma Limited	
Product name	Fludrocortisone
	acetate tablets 50mcg
Size:	x30
PL/PA no:	35533.0197
Type:	Leaflet
Artwork dimensions (mm):	150 x 400
Reason for request:	RFI update
Version no:	1.6
Date of revision:	14.12.23
Font(s):	Strada Pro
Software:	Indesign CC



FOR SUBMISSION ONLY