Fludrocortisone acetate 0.1mg 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 0.1mg 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.

In this leaflet:

1. What Fludrocortisone acetate is and what it is used for
2. Before you take Fludrocortisone acetate
3. How to take Fludrocortisone acetate
4. Possible side effects
5. How to store your Fludrocortisone acetate
6. Further Information

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

The name of this medicine is Fludrocortisone acetate. Each tablet contains 0.1mg of the active ingredient, fludrocortisone acetate.

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. Before you take Fludrocortisone acetate

Do not take this medicine if you:

- Have ever had an **allergic (hypersensitivity)** reaction to any of the ingredients in Fludrocortisone acetate or any other similar medicines (listed in section 6).
- Are suffering from an **infection** and are not taking any prescribed medication for it.
- 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.

**Take Special Care**

**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 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 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 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
- 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 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.
Taking Fludrocortisone acetate with other medicines

Please tell your doctor 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 cyclosporin
- 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 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.

Important information about some of the ingredients of Fludrocortisone acetate

Fludrocortisone acetate contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, you should discuss this with them before taking this medicine.

Pregnancy and breastfeeding

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 or operating machinery

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

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

Take the tablets exactly as your doctor has instructed.

**Adults and the Elderly**

To treat Addison's Disease the usual daily dose range is: 0.05mg (one-half tablet) to 0.3mg (3 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.

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

**Children**

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 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.

**Mental problems while taking Fludrocortisone acetate tablets**

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.

### 4. Possible 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/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.

**Tell your doctor** if the following occur:

- 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)
- Muscle weakness, pain or wasting, tendon rupture (where muscles connect to bones)
- 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 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
- Heart failure (shortness of breath with activity, or after lying down for a while)
- Irregular heartbeats
- High blood pressure
- Epilepsy or seizures
- Fainting
- Diarrhoea
- Vertigo (spinning feeling)
- Fits
- Sleep problems
- Headaches
- 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
- 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
- Blurred vision

**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](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

5. **How to store Fludrocortisone acetate**

Tablets should be stored in a refrigerator between 2°C and 8°C.

If you are unable to store your tablets between 2°C and 8°C, then they may be stored at room temperature (25°C) for up to 30 days. Any tablets stored at room temperature should be disposed of after 30 days.

Do not use after the expiry date which is stated on the bottle label after ‘EXP’. The expiry date refers to the last day of that month.

Keep the bottle tightly closed in order to protect from moisture.

**Keep your medicines out of the reach and sight of children.**

If you are told to stop taking this medicine, return any unused tablets to your pharmacist.

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. Further Information

**What Fludrocortisone acetate Tablets contain**
The active ingredient in Fludrocortisone acetate is Fludrocortisone acetate. Fludrocortisone acetate 0.1mg tablets contain 0.1mg of Fludrocortisone acetate. The other ingredients are: maize starch, dibasic calcium phosphate, lactose anhydrous and monohydrate, talc, sodium benzoate (E211), magnesium stearate.

**What Fludrocortisone acetate Tablets look like and contents of the pack**
Fludrocortisone acetate tablets are white in colour, round, biconvex, scored on one side and engraved on the other side with”SQIIBB and 429”. The tablets are supplied in amber glass bottles of 100 tablets with a cotton plug.

**Marketing Authorisation Holder and Manufacturer**
Aspen Pharma Trading Limited,
3016 Lake Drive,
Citywest Business Campus,
Dublin 24,
Ireland. Tel: (0044 1748 828 391)

Manufactured by:
Swords Laboratories
T/A Lawrence Laboratories
Unit 12 Distribution Centre,
Shannon Free Zone, Shannon Industrial Estate
County Clare
Ireland

Haupt Pharma Amareg GmbH
Donaustaufer Straße 378
93055 Regensburg
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**Medical Information Enquiries**
For any Medical Information enquiries about this product, please contact: 24 Hour Helpline +441748 823 391 (free phone UK only 0800 0087 392).

**Other formats:**
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0303 123 9999 (UK only).

Please be ready to give the following information:

**Product name: Fludrocortisone acetate 0.1 mg**
Reference number: PL 39699/0071

This is a service provided by the Royal National Institute of Blind People.

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