

**PACKAGE LEAFLET**

## 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.

**Don't 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
6. Contents of the pack and other information

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

The name of this medicine is Fludrocortisone acetate. Each tablet contains 0.1 mg 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.

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 Fludrocortisone acetate if:**

- you are allergic to Fludrocortisone acetate or any of the other ingredients of this medicine (listed in section 6).
- 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 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 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 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)
- Contact your doctor if you experience blurred vision or other visual disturbances.

#### **Check with your doctor 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.
- any of your close family has had these illnesses.

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, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal 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 (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 cyclosporin (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,  $\alpha$  and  $\beta$ -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**

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.

### **Fludrocortisone acetate 0.1 mg tablets contains mannitol**

May have a mild laxative effect.

### **Fludrocortisone acetate 0.1 mg tablets contains sodium**

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**

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

This medicine is for oral use.

The tablet can be divided into equal halves.

### **Adults and the Elderly**

The recommended daily dose range is: 0.05 mg (one-half tablet) to 0.3 mg (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.

### **Use in children**

The recommended dose is one-half tablet (0.05 mg) to one tablet (0.1 mg) daily.

### **Mental health problems while taking Fludrocortisone acetate:**

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 health 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 take more Fludrocortisone acetate than you should**

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

### **If you forget to take Fludrocortisone acetate**

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, **do not** take a double dose to make up for a 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **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/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.
- if the following happen as 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 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 (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**

- Failure to grow.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. 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) 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 in the original package in order to protect from light.

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

### **6. Contents of the pack and other information**

#### **What Fludrocortisone acetate contains**

Each tablet contains 100 micrograms of Fludrocortisone acetate.

The other ingredients are: Microcrystalline Cellulose, Mannitol, Hypromellose, Croscarmellose Sodium, Silica Colloidal Anhydrous and Magnesium Stearate.

#### **What Fludrocortisone acetate looks like and contents of the pack**

Fludrocortisone acetate 0.1 mg are white or white-off, oblong tablets about 9 mm long and about 4 mm wide, with a scoring line on one side.

#### **Fludrocortisone acetate is available in**

The tablets are packed in PVC/PVdC blisters, sealed with Aluminium lidding foil.

They are available in blister packs of 30 and 100 tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

Tillomed Laboratories Ltd  
220 Butterfield  
Great Marlings, Luton  
LU2 8DL, UK

**Manufacturer<sup>1</sup>**

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**This leaflet was last revised in 11/2024**

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<sup>1</sup> Only actual site will be listed on printed leaflet