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PACKAGE LEAFLET: INFORMATION FOR THE USER

Fludrocortisone Acetate Renata 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.

- 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

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 Renata 0.1 mg Tablets (referred to as 'Fludrocortisone acetate' throughout this leaflet). 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. 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 Fludrocortisone Acetate**
- if you are allergic to Fludrocortisone or any of the other ingredients of this medicine (listed in section 6) or any other similar medicines.
 - 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.

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 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 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
- Contact your doctor if you experience blurred vision or other visual disturbance.

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.

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

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, 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 vaccinations** without consulting your doctor.

Pregnancy and breastfeeding

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 use machines.

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.

Fludrocortisone Acetate contains the excipient lactose:

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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 doses.

Adults and the Elderly

To treat Addison's Disease 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.

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

Use in children

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

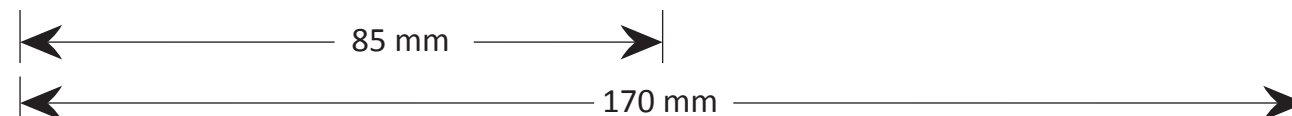
Mental health problems can happen while taking steroids like Fludrocortisone acetate tablets (see also Section 4).

- 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.

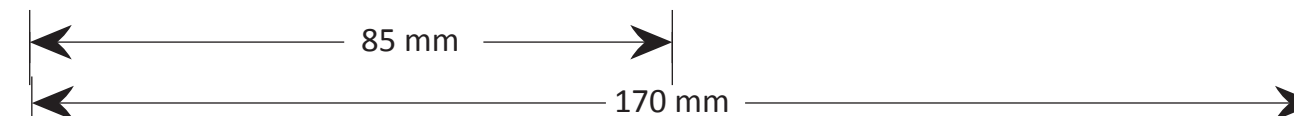
Talk to a doctor if you (or someone taking this medicine), shows any signs of mental problems. This is particularly important if you are depressed or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.



420 mm



420 mm



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.

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 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
- 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
- Fat
- 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:

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie
Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fludrocortisone Acetate

Do not store above 25°C.
Do not use this medicine after the expiry date which is stated on the carton and blister foil after 'EXP'. The expiry date refers to the last day of that month.

Keep this medicine out of the sight and reach of children.
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 Fludrocortisone Acetate contains
The active ingredient in Fludrocortisone acetate Tablets is fludrocortisone acetate.

Fludrocortisone acetate 0.1 mg tablets contain 0.1 mg of fludrocortisone acetate. The other ingredients are: Lactose Monohydrate, Sodium Starch Glycolate, Talc, Magnesium Stearate.

What Fludrocortisone Acetate looks like and contents of the pack

Fludrocortisone acetate tablets are 6.5 mm, round, white to off-white tablets, marked with 'F01' on one side and a break-line on the other side.

Fludrocortisone Acetate tablets are available in PVD/PVC/PE-Alu blister packs of 14, 28, 30, 42, 50, 56 or 100. Not all pack sizes may be marketed.

Marketing authorisation holder

Renata Pharmaceuticals (Ireland) Limited
13-18 City Quay, Dublin 2,
Ireland.

Manufacturer

Alterno Labs d.o.o.,
Brnčičeva ulica 29,
Ljubljana-Črnuče, 1231,
Slovenia.

This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland Fludrocortisone Acetate Renata 0.1 mg Tablets
Malta Fludrocortisone Acetate Renata 0.1 mg Tablets

This leaflet was last revised in October 2023.