PHARMACEUTICALS	
Azure Job No.:	AZ24017P
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Product Name	Fludrocortisone 0.1 mg tabs
Market	Ireland
Component	PIL
Dimensions	420mm x 170mm
Pharmacode	xxxxxxx
Minimum Font Size	9pt Times New Roman
Designer Name/Initials	LD
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AZURE

PACKAGE LEAFLET: INFORMATION FOR THE USER Other medicines and Fludrocortisone Acetate Please tell your doctor if you are taking or have recently taken any other medicines, including Fludrocortisone Acetate Code medicines obtained without a prescription. This Renata 0.1 mg Tablets is especially important if you are taking: Aspirin, ibuprofen or other non-steroidal anti-inflammatory Fludrocortisone acetate drugs (NSAIDs) as corticosteroids can increase the chance of bleeding from the gut. Read all of this leaflet carefully before you start taking this Any antifungals (e.g. ketoconazole, amphotericin) medicine because it contains important information for Warfarin or other medicines to thin the blood Oral contraceptive pill or hormone replacement therapy Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or Human growth hormone pharmacist. Muscle relaxants e.g. atracurium. These drugs are used This medicine has been prescribed for you only. Do not pass during anaesthesia for surgery. Please inform your it on to others. It may harm them, even if their signs of anaesthetist if you're on Fludrocortisone acetate. illness are the same as yours. A medicine called cyclosporin If you get any side effects, talk to your doctor or pharmacist. Barbiturates. These drugs are used as sedatives (to produce This includes any possible side effects not listed in this a calming effect), as hypnotics (to produce sleep), or as an leaflet. See section 4. adjunct in anesthesia Some medicines may increase the effects of Fludrocortisone What is in this leaflet acetate and your doctor may wish to monitor you carefully 1. What Fludrocortisone Acetate is and what it is used for if you are taking these medicines (including some medicines 2. What you need to know before you take Fludrocortisone for HIV: ritonavir, cobicistat). 3. How to take Fludrocortisone Acetate 4. Possible side effects • High blood pressure (e.g. sodium phenylbutyrate, clonidine, 5. How to store Fludrocortisone Acetate methyldopa, ACE inhibitors, α and β-blockers, angiotensin 6. Contents of the pack and other information II receptor antagonists, calcium-channel blockers and 1. What Fludrocortisone Acetate is and what it is used for Irregular heartbeat (e.g. digoxin) Epilepsy or other sorts of fits (e.g. phenytoin, primidone, The name of this medicine is Fludrocortisone Acetate Renata 0.1 mg Tablets (referred to as 'Fludrocortisone acetate' • Tuberculosis (TB) (e.g. isoniazid, rifampicin, rifabutin) throughout this leaflet). Each tablet contains 0.1 mg of the Diabetes active ingredient, fludrocortisone acetate. Thyroid problems Anti-progestogenic steroids (e.g. mifepristone) Fludrocortisone acetate tablets belong to a group of medicines Cushing's syndrome (e.g. aminoglutethimide) called steroids. Their full name is *corticosteroids*. These • Glaucoma (e.g. acetazolamide) corticosteroids occur naturally in the body, and help to maintain • Intestinal pain (e.g. hyoscine) health and well-being. Boosting your body with extra Asthma and Chronic Obstructive Pulmonary Disease (e.g. corticosteroid (such as Fludrocortisone acetate tablets) is an effective way to treat various illnesses involving inflammation Urinary retention (e.g. doxazosin) (swelling) in the body. Fludrocortisone acetate tablets reduce • Alzheimer's dementia (e.g. donepezil, galantamine) this inflammation, which could otherwise go on making your Myasthenia Gravis (e.g. neostigmine). condition worse. You must take this medicine regularly to get maximum benefit from it. While you are being treated with this medicine (or if you have recently stopped a course of treatment) do not have any Fludrocortisone acetate is used to replace the hormones that are vaccinations without consulting your doctor. normally produced by glands attached to your kidneys. These hormones will not be produced by your body if you suffer from Pregnancy and breastfeeding a condition called Addison's disease. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or Fludrocortisone acetate is also used to treat a condition called pharmacist for advice before taking this medicine. 'salt losing adrenogenital syndrome' which is a different form **Driving and using machines** Fludrocortisone acetate has not been shown to impair your 2. What you need to know before you take Fludrocortisone ability to drive or use machines. Do not take Fludrocortisone Acetate Your doctor or pharmacist will have given you a Steroid - if you are **allergic** to fludrocortisone or any of the other Treatment Card with your prescription or medicine. YOU ingredients of this medicine (listed in section 6) or any other SHOULD ALWAYS CARRY THIS CARD WITH YOU as it similar medicines. must be shown to any of the following persons: if you are suffering from an infection and are not taking any prescribed medication for it. **Doctor or Nurse** - before having any surgery or emergency if you have a peptic ulcer, active tuberculosis or a mental treatment or if any new treatment is prescribed illness in which you lose touch with reality and are unable to **Dentist** - before having any dental surgery think and judge clearly. **Pharmacist** - before buying any medicine **Optician** - it is advisable to have regular eye tests. Warnings and precautions Talk to your doctor or pharmacist before taking Fludrocortisone Acetate contains the excipient lactose: Fludrocortisone acetate. If your doctor has told you that have an intolerance to some sugars, contact your doctor before taking this medicine. You must tell your doctor before taking this medicine if: • you have or have recently had any bacterial, viral or 3. How to take Fludrocortisone Acetate **fungal infection** that is not being treated you have or ever have had tuberculosis Always take this medicine exactly as your doctor or pharmacist • you have or have had any intestinal, **bowel disorder** or has told you. Check with your doctor or pharmacist if you are stomach ulcer you have an infection or inflammation of the veins in your This medicine is for oral use. leg (thrombophlebitis) The tablet can be divided into equal doses. • you have had any **mental disorders** or epilepsy • you have had any kidney, liver or thyroid problems Adults and the Elderly • you have recently suffered from any form of cancer To treat Addison's Disease the recommended daily dose range • you have thin or **brittle bones** (osteoporosis) is: 0.05 mg (one-half tablet) to 0.3 mg (3 tablets) to be taken • you have myasthenia gravis (a disease which causes weak once a day. Patients on long term treatment may require the muscles) or any other muscle weakness addition of a different type of steroid tablet during times of • you have **high blood pressure** or heart failure illness or stress. you or someone in your family has **glaucoma** (increased pressure in your eyes) you have ocular herpes simplex (eye infection caused by a range is: 0.1 mg (one tablet) to 0.2 mg (2 tablets). type of herpes) you are **diabetic** as your insulin dose may need to be changed or have a family history of diabetes The recommended dose is one-half tablet (0.05 mg) to one you have a skin rash typically caused by viral infection tablet (0.1 mg) daily. Make sure you take the full course as (e.g. measles) prescribed by your doctor. Do **not** suddenly stop taking • you have muscle damage caused by steroid treatment Fludrocortisone acetate as this may make you ill. • vou are elderly (over 65 years old), as you may be more susceptible to side effects (see section 4 Possible side If you take more Fludrocortisone Acetate than you should effects) If you take too many tablets contact your doctor or go to your vou are vounger than 18 years old, as Fludrocortisone nearest hospital emergency department immediately. Take the acetate may lead to slowing of growth container and any remaining medicine with you. 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

manic-depression (bipolar disorder). This includes having

had depression before while taking steroid medicines like

• Contact your doctor if you experience blurred vision or

vou are to have or have had intestinal surgery

• If you have ever had severe depression or

• If any of your close family has had these illnesses.

or measles, consult your doctor as soon as possible.

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

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

85 mm —

afterwards

overweight.

other visual disturbance.

Check with your doctor first:

Fludrocortisone acetate tablets

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 Mental health problems can happen while taking steroids like Usually they start within a few days or weeks of starting the

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 • 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 • 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 Weight gain

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 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 PVDC/PVC/PE-Alu blister packs of 14, 28, 30, 42, 50, 56 or Not all pack sizes may be marketed. Marketing authorisation holder Renata Pharmaceuticals (Ireland) Limited 12 Crowe Street, Dundalk, Co. Louth, Ireland, A91 NN29. Manufacturer Alterno Labs d.o.o., Brnčičeva ulica 29, Ljubljana-Črnuče, 1231, 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 March 2024.

• An imbalance in your body's sodium, potassium or chloride Low blood urea nitrogen levels

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:

HPRA Pharmacovigilance Website: www.hpra.ie

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

85 mm 170 mm

If you forget to take Fludrocortisone Acetate

Fludrocortisone acetate tablets (see also Section 4).

They are more likely to happen at high doses.

Most of these problems go away if the dose is lowered or the

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

medicine is stopped. However, if problems do happen they

These illnesses can be serious.

doses are being lowered or stopped.

might need treatment.