

Package Leaflet: Information for the User
FLORINEF 0.1MG TABLETS
Fludrocortisone acetate

Please read this leaflet carefully before you start taking your medicine. This leaflet provides a summary of the information available on your medicine. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If you want to know more or are not sure ask your Doctor or Pharmacist.

- **Florinef 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.
- **Florinef 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 Florinef is and what it is used for
2. Before you take Florinef
3. How to take Florinef
4. Possible side effects
5. How to store your Florinef
6. Further Information

1. What Florinef is and what it is used for

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

Florinef 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 Florinef tablets) is an effective way to treat various illnesses involving inflammation (swelling) in the body. Florinef 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.

Florinef 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.

Florinef is also used to treat a condition called 'salt losing adrenogenital syndrome' which is a different form of hormone imbalance.

2. Before you take Florinef

Do not take this medicine if you:

- Have ever had an **allergic (hypersensitivity)** reaction to any of the ingredients in Florinef 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
- if you have or ever have had tuberculosis
- if 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 Florinef 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

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 Florinef tablets.
- **If any of your close family** has had these illnesses.

If either of these applies to you, **talk to a doctor before taking Florinef 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 Florinef with other medicines

Always tell your doctor about any medicines you are taking, or have recently taken, including those 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 Florinef.
- 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.

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 Florinef

Florinef 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 Florinef.

Driving or operating machinery

Florinef 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 Florinef

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 Florinef as this may make you ill.

If you take more Florinef 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 Florinef

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 Florinef tablets

Mental health problems can happen while taking steroids like Florinef 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 Florinef 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 Florinef.

- 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

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 HPRRA

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie

Email: medsafety@hpra.ie

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

5. How to store Florinef

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

Any unintended storage of tablets outside of the refrigerator up to 25 °C is allowed for up to 30 days and any unused tablets stored outside of the refrigerator should be disposed of and not returned to refrigerated storage (2°C - 8°C).

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 Florinef Tablets contain

The active ingredient in Florinef is Fludrocortisone acetate. Florinef 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 Florinef Tablets look like and contents of the pack

Florinef tablets are white in colour, round, biconvex, scored on one side and engraved on the other side with "SQUIBB and 429".

The tablets are supplied in amber glass bottles of 100 tablets with a cotton plug.

Marketing Authorisation Holder and Manufacturer

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