

PACKAGE LEAFLET: INFORMATION FOR THE USER

Florinef® 0.1mg Tablets / Fludrocortisone acetate 0.1mg Tablets

(fludrocortisone acetate)

This product is available using either of the above names but will be referred to as Florinef throughout this leaflet.

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 Florinef is and what it is used for
2. What you need to know before you take Florinef
3. How to take Florinef
4. Possible side effects
5. How to store your Florinef
6. Contents of the pack and other 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 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.

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. What you need to know before you take Florinef

Do not take Florinef:

- **if you:**

- Are **allergic** to Fludrocortisone acetate or any of the other ingredients of this medicine (listed in section 6) or any other similar medicines
- 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 Florinef.

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 health problems** 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 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
- 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 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.
- **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 Florinef

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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 Florinef
- A medicine called ciclosporin (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 Florinef 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
- 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 breastfeeding

If you are pregnant or breastfeeding, 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

Florinef 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

Florinef contains lactose and sodium benzoate

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.

Florinef contains 0.01 mg sodium benzoate in each tablet. Sodium benzoate may cause local irritation. Sodium benzoate may worsen jaundice (yellowing of the skin and eyes) in newborns (under 4 weeks of age).

This medicine contains less than 1 mmol sodium (23 mg) per mg, that is to say essentially 'sodium-free'.

3. How to take Florinef

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

Adults and the Elderly

The recommended 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.

Use in Children

The recommended dose is one-half tablet (0.05mg) to one tablet (0.1mg) daily. 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 health problems while taking Florinef

Mental health problems can happen while taking steroids like Florinef (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 health problems have happened when doses are being lowered or stopped.

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 Florinef 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 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 having 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.

Less serious side effects

Tell your doctor if the following occur:

Very common (these 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: (These may affect up to 1 in 10 people)

- Muscle weakness, pain or wasting, tendon rupture (where muscles connect to bones)
- Headaches
- Increased swelling

Uncommon: (These may affect up to 1 in 100 people)

- Irregular heartbeats
- Epilepsy or seizures (fits)
- Fainting or loss of consciousness
- Diarrhoea

Other side-effects (Frequency 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, 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 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 Florinef

- **Keep out of the sight and reach of children.**
- 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.
- Keep the bottle tightly closed in order to protect from light and moisture.
- 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.
- 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.
- If your medicine become discoloured or show signs of any deterioration, consult your doctor or pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Florinef contain

Each tablet contains 0.1mg Fludrocortisone acetate. The other ingredients are: maize starch, dibasic calcium phosphate, lactose anhydrous, talc (E553b), magnesium stearate (E470b), and sodium benzoate (E211).

What Florinef 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 "FT01" supplied in an amber glass bottle with a cotton plug and tamper-evident plastic screw cap.

Florinef is supplied in bottles of 100 tablets.

Manufactured by Haupt Pharma Amareg GmbH, Donaustauer Straße 378, 93055 Regensburg, Germany **OR** Swords Laboratories T/A Lawrence Laboratories, Unit 12 Distribution Center, Shannon Free Zone, Shannon Industrial Estate, County Clare, Ireland.

Procured from within the EU and repackaged by the Product Licence holder: O.P.D. Laboratories Ltd., Unit 6 Colonial Way, Watford, Herts WD24 4PR.

PL: 15814/1148

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Leaflet revision and issue date (Ref.) 27.05.2025

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