## 1.3.2 PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS**

**S4**

# FLORINEF 0,1 mg tablets

Fludrocortisone acetate

Contains sugar: Lactose anhydrous 58,92 mg, lactose monohydrate 0,7 mg

**Read all of this leaflet carefully before you start taking FLORINEF**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- FLORINEF has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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


## 1. What FLORINEF is and what it is used for

FLORINEF contains the active substance fludrocortisone acetate.

FLORINEF tablets belong to a group of medicines called steroids, also known as 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 on 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 hypersensitive (allergic) to fludrocortisone acetate or any of the other ingredients of FLORINEF (listed in section 6).
- If you are suffering from an infection and are not taking any prescribed medicine for it (systemic infections).
- If you are planning to take it to treat any condition not listed under "What FLORINEF is used for".
- If you have tuberculosis (TB).
- If you suffer from a mental disorder (acute psychosis).
- If you have a viral infection of the eye (ocular herpes simplex).
- If you have or have had sores in your stomach with symptoms such as indigestion, nausea or vomiting (active peptic ulcer).
- If you have inflammation of the tiny filters in your kidneys with symptoms such as pink/cola-coloured or foamy urine, high blood pressure and swelling (acute glomerulonephritis).

- If you have any fungal infections (fungal diseases).
- If you have any viral infections, such as vaccinia, with symptoms such as rash, fever, headache and body aches or chicken pox; with symptoms such as blisters, scabs or red spots, tiredness, fever, or loss of appetite (varicella).
- If you have heart problems with symptoms such as tightness or pain in the chest, tiredness, light-headedness or an abnormal heartbeat (congestive heart failure).
- Do not receive a live virus vaccine.
- If you are pregnant or are breastfeeding your baby.

**Warnings and precautions**

**Take special care with FLORINEF:**

- If you develop symptoms such as high blood pressure (symptoms could include headaches, blurred vision, tiredness and chest pain), swelling or weight gain, you should contact your doctor as you may need a lower dose of FLORINEF and to reduce your salt intake.
- If you have a history of allergies to medicines or if you have had a previous allergic reaction to a steroid.
- If you have been taking FLORINEF for a long time, stopping FLORINEF therapy should be done gradually over weeks or months to avoid side effects. Especially if you are going through times of stress such as trauma, surgery or severe illness, you may need supportive FLORINEF therapy both during the treatment period and for up to a year afterwards.
- If you develop any signs and symptoms of an infection such as fever, chills, muscle ache, cough, runny nose or tiredness as you may need urgent treatment with antibiotics.
- If you have just been or are about to be vaccinated/immunised.

- If you have a history of tuberculosis (TB) or currently have symptoms that suggest that your tuberculosis (TB) is active again. Symptoms such as pain in the chest, coughing, night sweats, weight loss, chills, tiredness or shortness of breath, or if your doctor tells you your X-rays indicate TB.
- If you have never had chickenpox and you are exposed to chickenpox during treatment or within 3 months of taking FLORINEF. Immunisation with varicella zoster immunoglobulin (VZIG) is needed, preferably within 3 days of exposure, and not later than 10 days after exposure to chickenpox. If your doctor confirms that you have chickenpox you may need specialist care (see Do not take FLORINEF).
- If you have or are exposed to measles, symptoms usually don't appear until 10 to 14 days after exposure. Symptoms include cough, runny nose, inflamed eyes, sore throat, fever and a red, blotchy skin rash. In order to prevent you from getting measles, you may need to be vaccinated with normal immunoglobulin.
- If you suffer from a tumour of the adrenal gland (pheochromocytoma).
- If you suffer from a chronic, inflammatory bowel disease that causes inflammation in the digestive tract with symptoms such as rectal bleeding, bloody diarrhoea, abdominal cramps and pain (nonspecific ulcerative colitis).
- If you have recently had an operation/surgery on your intestines (intestinal anastomoses).
- If you have inflammation or infection in one or more small pouches in the digestive tract with symptoms such as abdominal pain, fever, nausea and a change in bowel habit (diverticulitis).
- If you have an infection or inflammation of the veins in your leg with symptoms such as redness, swelling and pain (thrombophlebitis).
- If you suffer from blocking of a blood vessel by a blood clot dislodged from its site of origin with symptoms such as shortness of breath, chest pain, cough or fainting (thromboembolism).

- If you or your immediate family have or have had any mental health problems such as feelings of sadness, worthlessness, thoughts of suicide or death (depression), and false perceptions (hallucinations) (severe affective disorders, acute psychoses). Seek medical advice if worrying psychological symptoms develop, especially if depressed mood or suicidal ideation develops when your FLORINEF dose is lowered or stopped. The use of an antidepressant medicine may make the symptoms worse. If you have had any of the symptoms mentioned above while taking steroids, including FLORINEF, on a previous occasion, tell your doctor immediately.
- If you develop a skin eruption or rash usually due to measles or scarlet fever (exanthematous disease).
- If you suffer from Cushing's syndrome, a condition that occurs from exposure to high cortisol levels in the blood for a long time, with symptoms such as a fatty hump between the shoulders, a rounded face and pink or purple stretch marks.
- If you suffer from diabetes mellitus, a disease that results in too much sugar in the blood with symptoms such as excessive thirst or urination, tiredness, weight loss or blurred vision. If you are already using medicine for your high blood sugar, you may need a higher insulin dosage or a higher dose of the tablets that you are taking to lower your blood sugar.
- If you suffer from fits (convulsive disorders) such as epilepsy.
- If you have kidney problems with symptoms such as weakness, shortness of breath, high blood pressure, tiredness, swelling, and confusion (chronic nephritis, renal insufficiency, glomerulonephritis).
- If you have cancer (metastatic carcinoma).
- If you have a disease which causes weak muscles (myasthenia gravis).
- If you have high blood pressure with symptoms such as flushed face, headache, tiredness, confusion and difficulty breathing (hypertension).

- If you have thinning of the bones, especially post-menopausal females (osteoporosis).
- If you or someone in your family has group a of eye conditions that can cause blindness with symptoms such as slow vision loss (glaucoma). Prolonged use of FLORINEF may lead to a cloudy area on the back surface of the lens of your eye (posterior subcapsular cataracts), glaucoma as well as eye infections with symptoms such as pain, itching, or sensation of a foreign body in the eye (secondary ocular infections).
- If you have an eye infection caused by a type of herpes (ocular herpes simplex).
- If you develop symptoms such as blurred vision or other visual disturbances, you should see an eye doctor (ophthalmologist).
- If you have had previous muscle weakness after taking steroids (steroid myopathy).
- If you have liver problems with symptoms such as skin and eyes that appear yellowish (jaundice), stomach pain and swelling, swelling in the legs and ankles, itchy skin, tiredness, nausea or vomiting, loss of appetite and a tendency to bruise easily (liver failure, cirrhosis).
- If you are a woman and you experience changes in your periods or your period stops completely.
- If you have been taking FLORINEF for a long period of time, ensure that you eat enough protein to avoid weight or muscle loss.
- If you have thyroid problems with symptoms such as tiredness, cold sensitivity, constipation, dry skin and unexplained weight gain (hypothyroidism) or symptoms such as weight loss, rapid or irregular heartbeat, sweating and irritability (hyperthyroidism).
- If you have a rare blood disorder where your blood does not clot as it should, called hypoprothrombinaemia, you should not take aspirin (medicine used to treat pain, fever or inflammation) with FLORINEF.
- If FLORINEF is given to an infant, child or adolescents, as FLORINEF may lead to slowing of growth.

- If you are an elderly person as you may be more susceptible to side effects (see Possible side effects).

**Other medicines and FLORINEF**

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Amphotericin B injection: medicine used to treat serious fungal infections.
- Potassium-depleting diuretics: (e.g. furosemide): medicines used to treat high blood pressure by reducing fluid in the body.
- Anticholinesterases (e.g. donepezil, neostigmine, pyridostigmine): medicines used to treat Alzheimer's disease.
- Anticoagulants taken by mouth (e.g. warfarin): medicines used to thin the blood and prevent clotting.
- Antidiabetics (oral medicines and insulin): medicines used to treat diabetes.
- Antihypertensives (including diuretics) such as acetazolamide: medicines used to treat high blood pressure.
- Antitubercular medicines (e.g. rifampicin, rifabutin, isoniazid, pyrazinamide and ethambutol): medicines used to prevent and treat tuberculosis.
- Barbiturates (e.g. phenobarbitone, thiopental): medicines used for anxiety, sleeplessness (insomnia), and fits (seizure disorders).
- Ciclosporin: medicine used to prevent organ rejection after a transplant.
- Medicines that inhibit a specific metabolism pathway in the liver called CYP3A inhibitors (e.g. cobicistat, atazanavir, indinavir, ritonavir, saquinavir used to treat HIV,

clarithromycin, telithromycin used to treat bacterial infections and itraconazole and ketoconazole used to treat fungal infections).

- Digitalis glycosides (e.g. digoxin): medicines used to treat heart disease.
- Oestrogens, including oral contraceptives: medicines used to replace hormones or to prevent pregnancy.
- Hepatic enzyme inducers (e.g. aminoglutethimide (used to treat fits, cancer and Cushing's syndrome), phenytoin, carbamazepine, primidone (used to treat fits (convulsions or seizures)).
- Human growth hormone (e.g. somatrem and somatropin): medicine used to regulate normal growth in children.
- Ketoconazole: medicine used to treat fungal infections.
- Non-depolarising muscle relaxants (e.g. atracurium, pancuronium, tubocurarine): used for muscle relaxation during surgery or in intensive care.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin, ibuprofen, diclofenac: medicines used to treat pain and swelling.
- Thyroid medicine (e.g. levothyroxine): medicine used to treat thyroid problems.
- Vaccinations: medicines used to prevent a disease.
- Nitroblue tetrazolium test: test for bacterial infection.

**Pregnancy, breastfeeding and fertility**

You should not become pregnant while taking FLORINEF as your baby may be affected.

While taking FLORINEF, a woman should use effective contraception.

A woman taking FLORINEF should not breastfeed her baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

**Driving and using machines**

Since adverse reactions such as loss of consciousness and blurred vision have been reported in patients receiving FLORINEF, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that FLORINEF does not adversely affect your ability to do so (see Possible side effects).

It is not always possible to predict to what extent FLORINEF may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which FLORINEF affects them.

**FLORINEF contains lactose**

FLORINEF contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take FLORINEF.

## 3. How to take FLORINEF

Do not share medicines prescribed for you with any other person.

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

The usual dose for adults is one (1) tablet of FLORINEF daily.

The usual dose for children and adolescents is half (½) a tablet to one (1) tablet of FLORINEF daily.

Your dose will depend upon the disease, its severity and how quickly you get better.

Your doctor will tell you how long your treatment with FLORINEF will last. If you have the impression that the effect of FLORINEF is too strong or too weak, tell your doctor or pharmacist.

**If you take more FLORINEF than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to take FLORINEF**

Take your missed dose as soon as you remember, if within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

**If you stop taking FLORINEF**

Do not stop taking FLORINEF without speaking to your doctor.

On withdrawal you may experience symptoms such as fever, muscle pain (myalgia), severe joint pains (arthralgia), swelling and irritation inside the nose (rhinitis), inflammation or infection of the outer membrane of the eyeball and the inner eyelid (conjunctivitis), painful itchy skin nodules and weight loss may occur.

Too rapid a reduction in dose following long-term treatment can lead to pain in your lower back, stomach or legs, severe vomiting and diarrhoea, leading to dehydration, low blood pressure, loss of consciousness (acute adrenal insufficiency), high blood pressure and death.

## 4. Possible side effects

FLORINEF can have side effects.

Not all side effects reported for FLORINEF are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLORINEF, please consult your healthcare provider for advice.

**If any of the following happens, stop taking FLORINEF and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to FLORINEF. You may need urgent medical attention or hospitalisation.

**Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:**

- Recurrence of tuberculosis;
- weight gain and fatty tissue deposits, particularly around the midsection and upper back, in the face (moon face), and between the shoulders (buffalo hump) (Cushingoid state);
- low blood levels of potassium which can cause muscle weakness, twitching, confusion, light-headedness or abnormal heart rhythm (hypokalaemia, hypokalaemic alkalosis);
- activation of underlying diabetes mellitus or aggravation of existing diabetes;
- group of eye conditions that can cause blindness with symptoms such as slow vision loss (glaucoma);
- heart problems with symptoms such as tightness or pain in the chest, light-headedness or an abnormal, irregular heartbeat (congestive heart failure, cardiomegaly, cardiac

dysrhythmias);

- blood clot forming in a vein, particularly the legs with symptoms such as redness, swelling, tenderness, or warmth of the affected area (thrombophlebitis);
- blocking of a blood vessel by a blood clot dislodged from its site of origin with symptoms such as shortness of breath, chest pain, cough or fainting (thromboembolism);
- fits (e.g. convulsions, seizures, epilepsy);
- death of bone tissue due to lack of blood supply (avascular osteonecrosis), bone and back fractures, death of the tips of the long bones (femur and humerus);
- swelling and fluid build-up near the eyes and brain called papilloedema (this may result in a throbbing headache which may be worse upon waking up, coughing or sudden movement and patchy vision with blind spots and possible lack of colour vision) (increased intracranial pressure);
- inflammation of the pancreas which causes severe pain in the abdomen and back (pancreatitis).

These are all serious side effects. You may need urgent medical attention.

**Tell your doctor if you notice any of the following:**

*Frequent side effects*:

- Mental disturbances including insomnia, feeling of intense excitement, mood swings, personality changes, irritability, unrealistic feeling of well-being (euphoria), feelings of sadness, worthlessness, thoughts of suicide or death (depression), feeling of unease, such as worry or fear (anxiety), false perceptions, seeing or hearing something that is not really there (hallucinations), aggravation of schizophrenia;
- headache, loss of intellectual functions (including confusion and memory loss);

- high blood pressure with symptoms such as flushed face, headache, blurred vision, tiredness, confusion and difficulty breathing (hypertension);
- muscular weakness;
- swelling.

*Less frequent side effects:*

- Decreased appetite (anorexia);
- illusions;
- fainting, taste disturbance (dysgeusia);
- diarrhoea;
- loss of muscle tissue (muscle atrophy);
- increased susceptibility and severity of infections, masking of infections, fungal infection (candidiasis), worsening of viral eye infections;
- an increase in the number of white cells in the blood, especially during an infection with symptoms such as fever, bleeding or bruising (leucocytosis);
- suppression of growth in children, hormonal imbalances such as a shortage of the body's naturally occurring corticosteroid hormones with symptoms such as tiredness, loss of appetite, weight loss, feeling sick, being sick, diarrhoea, muscle weakness, irritability, and depression (secondary adrenocortical and pituitary unresponsiveness);
- salt and fluid retention with symptoms such as swelling, inability of the small intestine to completely process the nutrient carbohydrate (a classification that includes sugars and starches) (decreased carbohydrate tolerance), weight gain, increased appetite;
- form of dependence that involves emotional withdrawal symptoms (psychological dependence), difficulty sleeping (insomnia), severe mental disturbances, personality changes;
- nerve inflammation with symptoms such as pain and loss of function (neuritis),

numbness, tingling, pins and needles, cold, warmth, tingling pressure of the skin (paraesthesia);

- weakness and rapid fatigue of muscles under voluntary control (myasthenia);
- cloudy area on the back surface of the lens of your eye (posterior subcapsular cataracts), increased pressure in the eye, bulging of the eye out of the socket (exophthalmos), temporary blind spot, blurring of vision (papilloedema), thinning of parts of the eyes with symptoms such as eye redness, tearing, sensitivity to light, (corneal or scleral thinning);
- a feeling of dizziness or spinning (vertigo);
- inflammation of blood vessel walls (necrotising angiitis);
- heartburn, indigestion (dyspepsia), difficulty swallowing, pain when you swallow, sore throat, hoarse voice, chest pain (ulcerative oesophagitis), activation or worsening of stomach or intestine ulcer, bloated stomach, minor gastrointestinal difficulties;
- thin fragile skin, bruising or purple spots (petechiae, ecchymoses), facial redness, increased sweating, stretch marks, abnormal growth of hair on a woman's face and body, acne-like lesions (acneiform eruptions), patchy red skin especially on the nose and cheeks (lupus erythematosus-like lesions), loss of the fat layer under the skin;
- thinning of bones (osteoporosis), one or more bones in the spine weaken and crumple (vertebral compression fractures), delayed healing of fractures, bone fractures, tendon rupture;
- menstrual irregularities/ disturbances such as the absence of a menstrual period (amenorrhoea);
- tiredness (fatigue), impaired wound healing;
- electrolyte disturbances with symptoms such as irregular heartbeat, fast heart rate, tiredness (increased calcium excretion, negative protein and calcium balance), suppressed reactions to skin tests.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA:** via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

**Aspen Pharmacare:**

**E-mail:** Drugsafety@aspenpharma.com

**Tel:** 0800 118 088

By reporting side effects, you can help provide more information on the safety of FLORINEF.

## 5. How to store FLORINEF

Store all medicines out of reach of children.

Store in a refrigerator at 2 °C to 8 °C, in a well-closed container. Excursions to room temperature (25 °C) are permitted for up to 30 days. After temperature excursion, do not return unused tablets to refrigerated storage and dispose of such tablets properly.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

**What FLORINEF contains**

The active substance per tablet of FLORINEF is 0,1 mg fludrocortisone acetate.

The other ingredients are dibasic calcium phosphate, lactose anhydrous, lactose monohydrate, magnesium stearate, maize starch, sodium benzoate, talc.

*Preservative:*

Sodium benzoate 0,01 % *m/m*

**What FLORINEF looks like and contents of the pack**

A round, uniform, biconvex, white tablet, scored on one side and engraved on the other side with "FT01".

100 tablets are packed in a brown glass bottle and sealed with a white polypropylene screw cap, together with cotton or rayon and a leaflet.

**HOLDER OF THE CERTIFICATE OF REGISTRATION**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

**Hotline:** 0800 122 912

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G3134 (Act 101 of 1965)

**Access to the corresponding Professional Information**

**SAHPRA Repository of Professional Information and Patient Information Leaflets:**

https://www.sahpra.org.za/pi-pil-repository/

**Aspen Pharmacare:**

**E-mail:** Medinfo@aspenpharma.com

**Tel:** 0800 118 088

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