

FLORINEF

fludrocortisone acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Florinef. It does not contain all of the available information. It does not take the place of talking with your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Florinef against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Florinef is used for

Florinef contains fludrocortisone acetate as the active ingredient. It is a type of medicine known as a corticosteroid.

Florinef is used in combination with other medicines when there is an inadequate production of one type of natural steroid hormone produced by the adrenal glands (Addison's disease).

It is also used to treat a disorder (called salt-losing adrenogenital syndrome) which causes too much salt to be lost in the urine. Florinef can help treat this condition by causing the kidneys to retain fluid and salt in the body.

Ask your doctor if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take Florinef if you have ever had an allergy to fludrocortisone acetate or any ingredient listed at the end of this leaflet.

Symptoms of an allergic reaction to Florinef may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Florinef if you have a current serious or uncontrolled infection including systemic fungal infections.

Your doctor will know if this is the case and you will be receiving treatment.

Do not take Florinef after the expiry date printed on the bottle.

Do not take this medicine to treat any other complaints unless your doctor has instructed you to do so.

Do not give this medicine to anyone else.

Before you start to take it

Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- tuberculosis
- been immunised or vaccinated recently
- high blood pressure
- glaucoma, or other eye problems or an infection in your eye
- thyroid gland is not working (hypothyroid)
- cirrhosis of the liver
- ulcerative colitis.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Florinef. These include:

- diabetic medicines e.g. insulin
- oral anticoagulants
- CYP3A inhibitors e.g. cobicistat
- oral contraceptives
- anti-inflammatory drugs
- thyroid drugs.

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of the above, tell them before you start taking Florinef.

How to take it

How much to take

Your doctor will have prescribed a dose of Florinef suitable for you.

The usual dose is one tablet each day, but you may be required to take one tablet on alternate days.

How long to take it

Florinef is taken continuously and your doctor will tell you when to stop taking it.

If you forget a dose

Take it as soon as you remember, and then go back to taking it as you would normally.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Florinef. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things to be aware of

If you think you may have an infection of any kind while you are taking Florinef, you must see your doctor immediately to ensure adequate treatment.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Florinef.

All medicines can have side effects. Sometimes they are serious, most of

the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- fluid retention due to an abnormal amount of salt in the body
- muscle weakness
- thinning of skin
- poor healing
- stomach upsets
- headache
- dizziness
- menstrual irregularities in women
- eye problems
- masking of infections.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Florinef should be stored in a refrigerator between 2-8°C.

Alternatively, and for a period of 3 months only, Florinef can also be stored in a cool dry place where the temperature stays below 25°C.

After this time, discard all Florinef tablets that have not been refrigerated.

Keep this medicine out of the reach of children.

Product description

What it looks like

Florinef are small, round, white, biconvex tablets marked with 'FT01' on one side and scored on the other. Available in bottles of 100 tablets.

Ingredients

Active ingredients:

Florinef tablets contain fludrocortisone acetate 0.1 mg.

Inactive ingredients:

- lactose
- lactose monohydrate
- calcium hydrogen phosphate dihydrate
- maize starch
- magnesium stearate
- purified talc
- sodium benzoate.

Florinef tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

Australian Registration Number:
AUST R 54688

This leaflet was revised in January 2019.