

FLORINEF

fludrocortisone acetate

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Florinef?

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 to treat 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.

For more information, see Section [1. Why am I using Florinef?](#) in the full CMI.

2. What should I know before I use Florinef?

Do not use if you have ever had an allergic reaction to fludrocortisone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Florinef?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Florinef and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Florinef?

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

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

More instructions can be found in Section [4. How do I use Florinef?](#) in the full CMI.

5. What should I know while using Florinef?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.• 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.• Tell your doctor if you notice anything that is making you feel unwell.• Ask your doctor to answer any questions you may have.
Driving or using machines	<ul style="list-style-type: none">• Your doctor will tell you when it is safe to drive and operate potentially dangerous machinery.• As far as it is known, Florinef has no effect on alertness or concentration.
Looking after your medicine	<ul style="list-style-type: none">• 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.

For more information, see Section [5. What should I know while using Florinef?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, Florinef can cause side effects, but not everyone gets them. Common side effects could be: • 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Florinef

Active ingredient(s): *fludrocortisone acetate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Florinef. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Florinef.**

Where to find information in this leaflet:

- [1. Why am I using Florinef?](#)
- [2. What should I know before I use Florinef?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Florinef?](#)
- [5. What should I know while using Florinef?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Florinef?

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.

Your doctor will have explained why you are being treated with Florinef.

Ask your doctor if you want any more information about this medicine.

Florinef is not addictive.

2. What should I know before I use Florinef?

Warnings

Do not use Florinef if:

- you are allergic to fludrocortisone acetate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Some of the symptoms of an allergic reaction 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

Check with your doctor 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.
- **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
- **have allergies to:**
 - any other medicines
 - any other substances, such as foods, preservatives or dyes
- **take any medicines for any other condition**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of using Florinef if you are pregnant or breast-feeding.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with Florinef and affect how it works.

Tell your doctor if you are taking or have recently taken:

Some medicines that may interfere with Florinef and affect how it works. 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.

4. How do I use Florinef?

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 Florinef

- 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 use too much

If you think that you have used too much Florinef, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Florinef?

Things you should do

Tell your doctor:

- 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.

Things you should not do

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Florinef affects you.

As far as it is known, fludrocortisone has no effect on alertness or concentration.

Looking after your medicine

- 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.

- Follow the instructions in the carton on how to take care of your medicine properly.
- Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:
 - in the bathroom or near a sink, or
 - in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<ul style="list-style-type: none">• 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.	Speak to your doctor if you have any of these side effects and they worry you.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

Florinef tablets contain fludrocortisone acetate 0.1 mg.

What Florinef contains

Active ingredient (main ingredient)	Fludrocortisone acetate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactose• lactose monohydrate• calcium hydrogen phosphate dihydrate• maize starch• magnesium stearate• purified talc• sodium benzoate.
Potential allergens	<ul style="list-style-type: none">• none

Do not take this medicine if you are allergic to any of these ingredients.

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

What Florinef looks like

Florinef are small, round, white, biconvex tablets marked with 'FT 01' on one side and scored on the other. Available in bottles of 100 tablets.

AUST R 54688

Who distributes Florinef

Aspen Pharmacare Australia. Pty Ltd
34-36 Chandos St
St Leonards NSW 2065 Australia

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