

ANDROFEME® 1 (And-ro-feme) Testosterone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about ANDROFEME® 1. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine 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.

What ANDROFEME® 1 is used for

This medicine is used to treat hypoactive sexual desire dysfunction (HSDD) in postmenopausal women.

It contains the active ingredient testosterone. Testosterone belongs to a group of medicines called androgens and this form of testosterone is identical to the testosterone produced by the ovaries of women and the testes of men.

HSDD is characterised by absence or marked reduction in desire or motivation to engage in sexual activity and is associated with distress. Testosterone has been shown to increase sexual motivation including sexual desire, pleasure, orgasm, responsiveness, and self-image, and reduce sexual concerns and distress in postmenopausal women.

The skin readily absorbs testosterone and ANDROFEME® 1 is a simple and effective means of getting testosterone into the bloodstream. **Ask your doctor if you have any questions about why this medicine has been prescribed for you.** Your doctor may have prescribed it for another reason.

Before you use ANDROFEME® 1 When you must not use it

Do not take this medicine if you have an allergy to:

- testosterone, the active ingredient, tree nuts (almond oil) or to any of the other ingredients listed at the end of this leaflet under Product Description.

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.

Do not take this medicine if you have or have had any of the following medical conditions:

- any cancer which your doctor has described as being caused or stimulated by hormones
- kidney disease known as nephrotic syndrome
- blockage of a blood vessel by a blood clot formed elsewhere in the body (thromboembolism)
- high calcium levels in the blood (hypercalcaemia)

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine. The active ingredient in ANDROFEME® 1 passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to children. Safety and effectiveness in children have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- heart disease or high blood pressure
- liver disease
- kidney disease

High level athletes need to be aware of the rules governing testosterone (an androgen) use if prescribed ANDROFEME® 1 cream as testosterone may enhance athletic performance.

If you have not told your doctor about any of the above, tell him/her before you start taking ANDROFEME® 1.

Taking other medicines

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

Some medicines and ANDROFEME® 1 may interfere with each other. These include:

- oral oestrogens, medicines contained in oral contraceptives and hormone replacement therapy
- tibolone, a medicine used for hormone replacement
- oral anticoagulants, medicines used to thin blood and to treat or prevent blood clots
- corticosteroids or adrenocorticotropic hormone (ACTH), hormones used to control inflammation
- oxyphenbutazone, a medicine used to treat pain and inflammation
- insulin, a medicine used to control blood sugar levels
- bupropion, a medicine used to aid in smoking cessation
- ciclosporin, a medicine used to suppress the immune system.

These medicines may be affected by ANDROFEME® 1 or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use ANDROFEME® 1

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. **If you do not understand the instructions, ask your doctor or pharmacist for help.**

How much to use

The usual starting dose is 0.5mL (5mg) of cream by measured applicator per day. You should not use more than 1.0mL (10mg testosterone) of cream per day unless directed to do so by your doctor. The dose should not be varied unless directed to do so by your doctor.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

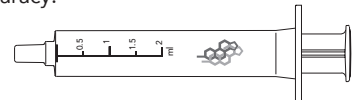
Follow the instructions they give you.

If you take the wrong dose, ANDROFEME® 1 may not work as well and your problem may not improve.

You will need to return to your doctor **three to six weeks** after starting treatment so that the dose can be checked via a blood test and adjusted if required. It may take 1-2 months for you to notice an improvement. If symptoms do not improve after 6 months, you should discuss an alternative treatment with your doctor.

How to use it

To open the tube remove the cap and peel off the foil seal. A measuring applicator (syringe style) in a sealed sleeve is enclosed in the ANDROFEME® 1 box. The applicator is marked with 0.25mL graduations for dosing accuracy.



To measure the correct dose of cream, **gently** squeeze the base of the ANDROFEME® 1 tube until cream reaches the open nozzle of the tube. Insert the tip of the applicator into the open nozzle of ANDROFEME® 1 cream so that the nozzle and the shoulder of the applicator are in contact.

Invert the tube and the applicator so the cream will flow with gravity when squeezed. Carefully squeeze the base of the ANDROFEME® 1 tube and **at the same time** slowly withdraw the red plunger of the applicator. The cream will flow into the barrel of the applicator.

Do not try to squeeze the cream into the syringe.

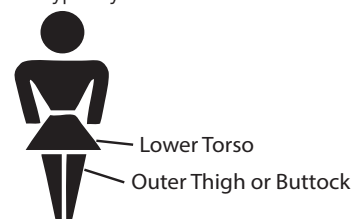
Fill the applicator to the required dose. For example: a 0.5mL dose of ANDROFEME® 1 (5mg testosterone) needs the flat part of the plunger level with the 0.5mL mark. If there are any air bubbles in the measured dose, fill slightly past the required dose mark then depress the plunger so that the excess cream flows back into the tube.

Stop at the required dose mark.

Remove the applicator from the nozzle and replace the cap firmly on the tube.

Where to apply ANDROFEME® 1 cream

Always apply ANDROFEME® 1 directly onto clean, dry, healthy skin of either the lower abdomen, the upper outer thigh or buttock. Massage the cream into the area until absorbed. Typically this takes about 30 seconds.



No perfume, deodorant or moisturising creams/gels should be used on the area because this may interfere with ANDROFEME® 1 from being absorbed. Cover the application area with clothing once applied. Never apply the cream to broken or damaged skin. Do not use ANDROFEME® 1 on the genital or other areas, unless specifically directed to do so by your doctor. Wash your hands thoroughly with soap and water after applying the cream. Rinse the applicator in hot water after use and replace in the box with the cream.

When to use it

Apply ANDROFEME® 1 once a day at approximately the same time each day. Applying the cream at the same time each day will have the best effect. It will also help you remember when to apply it. It is recommended that patients do not swim or shower until at least four hours after application of ANDROFEME® 1 cream.

How long to use ANDROFEME® 1

Continue taking your medicine for as long as your doctor tells you.

ANDROFEME® 1 is usually used for a minimum of 3 months to see if the medicine works for you. Your doctor will also check testosterone levels in the blood at regular intervals. If your symptoms do not improve after 6 months, your doctor may discontinue ANDROFEME® 1 and discuss an alternative treatment with you. There is currently limited safety information on the use of ANDROFEME® 1 beyond two years. Your doctor will discuss the benefits and risks of longer use with you.

If you forget to take it

Take your dose as soon as you remember and continue to apply it as you would normally. If it is almost time for your next dose, skip the dose you missed and apply your next dose when you are meant to.

Do not apply a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect. If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 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 ANDROFEME® 1. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using ANDROFEME® 1 **Things you must do**

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ANDROFEME® 1.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some blood tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take ANDROFEME® 1 to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using ANDROFEME® 1, or change the dosage, without checking first with your doctor.

If you stop using it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

ANDROFEME® 1 may be transferred to another person during close skin contact with the area where the cream has been applied. If close contact occurs repeatedly or for long periods of time, especially with children, this could cause signs of virilisation. Signs of increased testosterone in children include enlarged penis or clitoris, early development of pubic hair, increased erections or sex drive, aggressive behaviour.

Call your doctor right away if you see any signs in a child or partner that may have occurred through accidental exposure to ANDROFEME® 1.

Unwanted transfer to another person can be avoided by wearing clothes which cover the application area and/or by showering before contact. You need to ensure that your partner is not put at risk of receiving testosterone by accident.

Be careful driving or operating machinery until you know how ANDROFEME® 1 affects you.

Side-effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ANDROFEME® 1.

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.

Do not be alarmed by the following lists of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

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

- acne and oily skin
- increased body hair particularly on the face
- loss of head hair (male pattern baldness) or thinning
- headache
- abdominal bloating
- constipation.

The above list includes some more common side effects.

Tell your doctor as soon as possible if you notice any of the following:

- nausea and vomiting
- yellowing of the skin and/or eyes, also called jaundice
- swelling of the ankles
- weight gain
- persistent headaches
- deepening of the voice
- changes in tissue of the breast and endometrium (uterus)
- ovulation and menstrual periods may stop in premenopausal women.

The above list includes more serious side effects which may occur if your dose is too high and may require medical attention.

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.

Some of these side effects such as electrolyte disturbances and increased red blood cells can only be found when your doctor does tests from time to time to check your progress.

After using ANDROFEME® 1

Keep the tube sealed until time for use. Replace cap firmly on the tube once opened.

Do not transfer the cream out of the original tube into another container.

Rinse the applicator in hot water after use and replace in box with ANDROFEME® 1 cream ready for the next day's application.

Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well. Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not freeze. Once opened, the contents of the tube should be used within 4 months.

Do not store ANDROFEME® 1 or any other medicines in the bathroom or near the sink.

Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ANDROFEME® 1 cream is a white, opaque odourless cream in a sealed laminated 50mL tube. The crimp at the base of the tube has the batch number and expiry date imprinted on it. The tube is boxed together with a graduated measuring applicator.

Ingredients

Active ingredients:

ANDROFEME® 1 contains 10mg testosterone per 1mL of cream (1% w/v).

Inactive ingredients:

- dl- α -tocopheryl acetate (Vitamin E acetate)
- almond oil • cetomacrogol 1000
- cetostearyl alcohol • carbomer 940
- trolamine • butylated hydroxytoluene
- Phenonip (PI 10352) contains hydroxybenzoates
- citric acid • purified water.

Supplier

Lawley Pharmaceuticals Pty Ltd
Unit 2/15A Harrogate Street
West Leederville WA 6007

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This leaflet was revised in March 2020.
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