

AndroFeme® 1

Cream containing 1% w/v (10mg/mL) Testosterone B.P (17- β -Hydroxyandrost-4-en-3-one)

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some of the common questions about ANDROFEME®. 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 possible risks of you using ANDROFEME® against the benefits it can have for you. If you have any concerns about using ANDROFEME® talk to your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What ANDROFEME® is used for?

ANDROFEME® contains the active ingredient testosterone. This form of testosterone is identical to the testosterone produced by the ovaries of women and the testes of men. Testosterone plays an important role in sexual arousal, sexual response, libido, maintenance of bone, energy levels and well-being in men and women. When women suffer from a deficiency of testosterone, one or more of these areas may be affected and ANDROFEME® provides testosterone to address this deficiency.

The skin readily absorbs testosterone and ANDROFEME® is a simple and effective means of getting testosterone into the bloodstream.

Prior to using ANDROFEME®

ANDROFEME® is only for use in women. ANDROFEME® cream should not be used if you are allergic to testosterone, ANDROFEME® or any of the ingredients contained within ANDROFEME®. These are listed at the end of this leaflet. This product contains almond oil. Do not use ANDROFEME® if you have cancer especially breast cancer, kidney disease, are pregnant, lactating or have high calcium levels in the blood. If you have heart disease, high blood pressure or liver disease make sure your doctor is aware of these conditions before use as ANDROFEME® may not be appropriate for you. Check with your doctor or pharmacist if you are unsure about whether you have any of these conditions before starting ANDROFEME®. If you are taking other medications check with your doctor or pharmacist before starting ANDROFEME®. High level athletes need to be aware of the rules governing androgen use if prescribed ANDROFEME® cream. Do not use ANDROFEME® after the expiry date which is printed on the base (crimp) of the tube. If you use this medicine after the expiry date has passed, it may not work as well. Do not use ANDROFEME® if the foil seal at the top of the tube is damaged or broken. ANDROFEME® is not indicated for use in children.

How to use ANDROFEME®

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 printed on the pharmacist label, ask your doctor or pharmacist for help.

How much to use

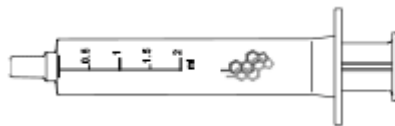
The usual starting dose is 0.5 mL of cream by measured applicator per day. Your doctor or pharmacist will tell you exactly how much to use. You should not use more than 1.5 mL (15 mg testosterone) of cream per day without confirming this dose with your doctor. The dose should not be varied unless directed to do so by your doctor. You will need to return to your doctor at regular intervals so that the dose can be checked via a blood test.

Measuring the correct dose of ANDROFEME®

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® box.

The applicator is marked with 0.5mL graduations for dosing accuracy.



To measure the correct dose of cream, **gently** squeeze the base of the ANDROFEME® tube until cream reaches the open nozzle of the tube. Insert the tip of the applicator into the open nozzle of ANDROFEME® 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® tube and at the same time slowly withdraw the plunger of the applicator. The cream will flow into the barrel of the applicator.

Do not try to squeeze the cream into the syringe.

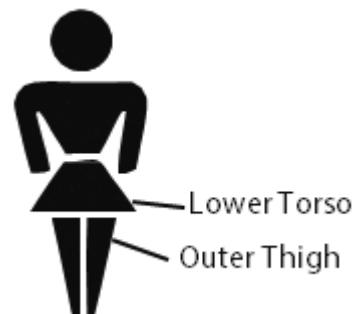
Fill to the required dose. For example: a 0.5 mL dose of ANDROFEME® (50mg testosterone) needs the flat part of the plunger level with the 1.5mL mark. If there are any air bubbles in the measured dose fill slightly past the required dose mark then depress the plunger so that the excess cream flows back into the tube. Stop at the required dose mark.

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

There is a Using the Application Syringe demonstration video at www.lawleydirect.com.au

Where to apply ANDROFEME® cream

Always apply ANDROFEME® directly onto clean, dry, healthy skin of the lower torso or the upper outer thigh.



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® from being absorbed. Never apply the cream to broken or damaged skin.

Do not use ANDROFEME® on the genital area, unless specifically directed to do so by your doctor.

ANDROFEME® cream should be applied at approximately the same time each day.

It is recommended that patients do not swim or shower until at least one hour after application of ANDROFEME® cream. Close skin contact with the area of application within an hour of application, by a partner or children should be avoided. This may result in the partner or child absorbing some testosterone through the skin contact.

Cover the application area with clothing once applied.

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

Wash your hands thoroughly with soap and water after applying the cream.

If you miss a dose

If you forget to apply your cream, you should apply it as soon as you remember provided this is within 9 hours of your usual time of application.

Otherwise do not apply the cream until the next application is due. Missing a dose will not create an undue disruption to your treatment.

If you use too much (overdose)

Because of the way ANDROFEME® is used, an unintentional overdose is unlikely.

If you think that you or anyone else may have used too much ANDROFEME®, immediately telephone your doctor or the local Poisons Information Centre for advice or go to the Accident and Emergency Department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

If ANDROFEME® is accidentally swallowed or eaten contact a doctor.

During ANDROFEME® use

Do's

Inform your doctor or pharmacist that you are using ANDROFEME® before starting any other prescribed medicine. Some medicines interact with other medications. Tell all doctors, dentists and pharmacists who are treating you that you are using ANDROFEME®. It is very important that you have a follow-up blood test to measure your testosterone levels within three weeks of starting ANDROFEME®. This is to confirm that your starting dose is correct and ensure your testosterone levels are within the normal range for women.

Do Not's

Do not give ANDROFEME® to anyone else, even if they have the same symptoms or condition as you.

Observe care when driving or operating machinery at the start of treatment using ANDROFEME® until you know how ANDROFEME® affects you. There is no evidence that ANDROFEME® will affect your ability to drive or to operate machinery.

Side-effects

Tell your doctor as soon as possible if you do not feel well while you are using ANDROFEME®.

All medicines can have side effects in some people. Sometimes they are serious, most of the time they are not. Some side effects may need medical treatment.

Tell your doctor if you notice any of the following that are troublesome or ongoing:

- Skin irritation, for example rash or slight redness and itching of the skin where the cream has been applied. Any irritation will usually disappear within a few days. If it persists contact your doctor or pharmacist.
- Acne
- Loss of head hair (male pattern baldness)
- Headache
- Nausea, sickness
- Swelling of the ankles
- Yellowing of the skin
- Increased body hair
- Weight gain
- Deepening of the voice

ANDROFEME® may stop you ovulating and affect your periods. Rarely-reported events associated with testosterone supplementation include:

- Electrolyte imbalances in the blood
- Changes to the tissue of the breast and endometrium (uterus)

Tell your doctor if you observe any other effects not listed above.

Do not be alarmed by this list of possible side-effects. You most likely will not experience any of them.

ANDROFEME® has not been associated with these effects however because it contains testosterone there is a potential for side effects.

After using ANDROFEME®

Storage

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. Keep the tube 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 12 weeks. Keep medicines out of reach of children.

Disposal

If your doctor tells you to stop using ANDROFEME® ask your pharmacist how to dispose of any cream that is left over.

Product description

ANDROFEME® cream is a white, opaque odorless cream in a sealed laminated 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 consumer information sheet and a graduated measuring applicator.

Ingredients

Each 50 ml tube contains 500 milligrams (500mg) of testosterone. Each 1 ml dose delivers 10 mg of testosterone.

Other ingredients in the cream include

- cetomacrogol 1000,
- cetostearyl alcohol,
- almond oil,
- dl- α -tocopherol acetate (Vitamin E acetate),
- butylated hydroxytoluene,
- anhydrous citric acid,
- triethanolamine,
- Carbomer 940,
- B&J Phenonip® and purified water.

ANDROFEME® is available in a 50 ml sealed laminated tube.

Name and Address of Supplier

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