

ANDRO-FEME[®] Cream

Testosterone (tes-TOS-te-rone)



Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about ANDRO-FEME[®]. 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 ANDRO-FEME[®] against the benefits it can have for you.

If you have any concerns about using ANDRO-FEME[®] talk to your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What ANDRO-FEME[®] is used for?

ANDRO-FEME[®] 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 ANDRO-FEME[®] can provide testosterone to address this deficiency.

The skin is very good at absorbing testosterone and ANDRO-FEME[®] is a simple and effective means of getting testosterone into the bloodstream.

Prior to using ANDRO-FEME[®]

ANDRO-FEME[®] is only for use in women.

ANDRO-FEME[®] cream should not be used if you are allergic to testosterone, ANDRO-FEME[®] or any of the ingredients contained within ANDRO-FEME[®]. These are listed at the end of this leaflet.

This product contains *almond oil* and *macadamia nut oil*.

Do not use ANDRO-FEME[®] if you have cancer especially breast cancer, kidney disease, are pregnant or 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 ANDRO-FEME[®] 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 ANDRO-FEME[®].

If you are taking other medications check with your doctor or pharmacist before starting ANDRO-FEME[®].

High level athletes need to be aware of the rules governing androgen use if prescribed ANDRO-FEME[®] cream.

Do not use ANDRO-FEME[®] 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 ANDRO-FEME[®] if the tamper proof seal at the top of the tube is damaged or broken.

ANDRO-FEME[®] is not indicated for use in children.

How to use ANDRO-FEME[®]

Your doctor or pharmacist will explain how to apply ANDRO-FEME[®].

Follow all directions exactly as they are explained. If you are unclear talk to your doctor.

The dose of ANDRO-FEME[®] will be determined for you by your doctor. This dose is specific to your condition and 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 to make sure it is right for you.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Opening the tube

To open the tube remove the cap and turn it upside down. Flip the triangle onto the top of the tube.

Twist to open. Dispose of the broken seal and replace the cap firmly after using the cream.

Measuring the correct dose of ANDRO-FEME[®] Cream

A small plastic applicator with 1 unit graduations is provided inside the ANDRO-FEME[®] box.

Your doctor will have determined what dose is appropriate for you.

Squeeze the tube so that the prescribed dose of cream covers the applicators graduated guidelines.

Use immediately.

For example: if the dose required is 2 units squeeze the tube so that two 1 unit graduations on the ANDRO-FEME[®] measure are covered by cream. The principle is exactly the same as applying toothpaste to a toothbrush.

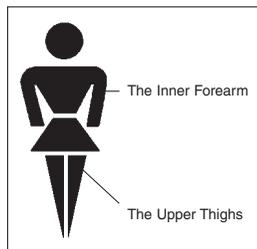
Each 1 unit of ANDRO-FEME[®] cream provides 5mg of testosterone.

Where to apply ANDRO-FEME[®] cream

Always apply ANDRO-FEME[®] cream to clean dry flat areas of skin.

The best area to use ANDRO-FEME[®] is the inner aspects of the forearms or the upper thighs of the legs.

No perfume, deodorant or moisturising creams or gels should be used on the area because this may interfere with ANDRO-FEME[®] from being absorbed.



Never apply the cream to broken or damaged skin.

Do not use ANDRO-FEME[®] on the genital area.

ANDRO-FEME[®] 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 ANDRO-FEME[®] cream.

Close skin contact with the area of application within an hour of application by a partner should be avoided. This may result in the partner absorbing some testosterone through the skin contact.

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 time. Missing a dose will not create an undue disruption to your treatment.

If you use too much (overdose)

Because of the way ANDRO-FEME® is used, an unintentional overdose is unlikely.

If you think that you or anyone else may have used too much ANDRO-FEME®, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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 ANDRO-FEME® is accidentally swallowed or eaten contact a doctor.

During ANDRO-FEME® use

Do's

Inform your doctor or pharmacist that you are using ANDRO-FEME® 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 ANDRO-FEME®.

Have your testosterone blood levels measured regularly by you doctor.

This is especially important in the first few weeks of starting ANDRO-FEME® to ensure testosterone levels are within the normal levels for women.

Dont's

Do not give ANDRO-FEME® 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 ANDRO-FEME® until you know how ANDRO-FEME® affects you. There is no evidence that ANDRO-FEME® will affect your ability to driving or to operate machinery.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ANDRO-FEME®.

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

ANDRO-FEME® 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. ANDRO-FEME® has not been associated with these effects but because it contains testosterone there is a potential for side effects.

After using ANDRO-FEME®

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 30°C.

Do not leave it in the car on a hot day or on window sills.

DO NOT FREEZE.

Once opened, the content 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 ANDRO-FEME® ask your pharmacist what to do with any cream that is left over.

Product description

What it looks like

ANDRO-FEME® cream is a white opaque odourless cream in a white laminated tube. The crimp at the base of the tube has the batch number and expiry date imprinted on it.

The tube is boxed and in the box is a consumer information sheet and graduated measure.

Ingredients

Each 50 gram tube contains 500 milligram (500mg) of testosterone. Each 2 unit (1 gram) dose delivers approximately 10mg of testosterone.

Other ingredients in the cream include cetomacrogol 1000, cetostearyl alcohol, almond oil, macadamia nut oil, dl- α -tocopherol acetate (Vitamin E acetate), butylated hydroxytoluene, anhydrous citric acid, triethanolamine, Carbomer 940, B&J Phenonip®, hydroxybenzoates, phenoxethanol and purified water.

ANDRO-FEME® is available in a 50 gram sealed laminated tube.

Sponsor

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ANDRO-FEME® is a registered trademark.
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