PACKAGE LEAFLET: INFORMATION FOR THE USER

ANDROFEME® 10 mg/ml cream
testosterone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

1. What AndroFeme is and what it is used for
2. What you need to know before you use AndroFeme
3. How to use AndroFeme
4. Possible side effects
5. How to store AndroFeme
6. Contents of the pack and other information

1. WHAT ANDROFEME IS AND WHAT IT IS USED FOR
AndroFeme 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. AndroFeme is used to treat hypoactive sexual desire dysfunction (HSDD) in postmenopausal women on optimised hormone replacement therapy (HRT). Women with this condition often feel distress because they have a very low sexual desire / interest to have sex. Testosterone can help reduce sexual concerns and distress in postmenopausal women, by improving:
- Sexual desire
- Pleasure
- Orgasm

AndroFeme is a cream you apply to your skin. The skin absorbs testosterone, which then travels to your bloodstream and throughout your body.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ANDROFEME
Do not use AndroFeme
- If you are allergic to testosterone, tree nuts (almond oil) or any of the other ingredients of this medicine (listed in section 6)
- If you are taking AndroFeme with an oestrogen hormone supplement and have breast cancer now or had it in the past, or other cancers and conditions which your doctor has described as being caused by or worsened by oestrogens

Warnings and precautions
Talk to your doctor or pharmacist before using AndroFeme if you have any other medical conditions, especially:
- If you have allergies to any other medicines, foods, preservatives or dyes
- If you have heart disease or high blood pressure
- If you have liver disease
- If you have kidney disease
- If you are at risk of breast, endometrial or ovarian cancer
- If you have diabetes

The efficacy of this medicine is reduced if your oestrogen therapy is of a certain type ('conjugated equine oestrogens'). Therefore, you need to discuss your type of oestrogen with your doctor, who could advise you which type of oestrogen is suitable together with AndroFeme.
If you are a high-level athlete; you need to be aware of the rules governing testosterone (an androgen) use if prescribed AndroFeme cream, as testosterone may enhance athletic performance.

Be aware that this product may produce a positive reaction in anti-doping tests.
You should avoid close skin contact with others, of the area where AndroFeme has been applied, as it may be transferred to them. This risk can be reduced if you wear clothes that cover the application area.
Testosterone does not affect your thyroid gland. However, tell your doctor if you are having a blood test to see how your thyroid gland is working, as testosterone may affect the test results.
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 in section 4.

Children and adolescents
AndroFeme is not for use in children or adolescents.

Other medicines and AndroFeme
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.
Some medicines may interfere with AndroFeme and affect how it works. These include:
- Oral oestrogens, including oral contraceptives (the Pill), tibolone and medicines contained in hormone replacement therapy
- Anticoagulants, medicines used to thin blood and to treat or prevent blood clots
- Corticosteroids, hormones used to control inflammation
- Adrenocorticotropic hormone (ACTH) used to test how your adrenal glands are working
- Insulin, a medicine used to control blood sugar levels

Pregnancy and breast-feeding
AndroFeme is only indicated for postmenopausal women, who no longer have their menstrual periods, either naturally or because they have had a hysterectomy. Do not use AndroFeme if you are, or suspect that you may be pregnant or are able to become pregnant, because it may cause harm to the unborn child. Do not use AndroFeme if you are breast-feeding because it may cause harm to the child.

Driving and using machines
Be careful before you drive or use any machines or tools until you know how AndroFeme affects you

AndroFeme contains cetostearyl alcohol, butylhydroxytoluene and paraben esters
AndroFeme contains cetostearyl alcohol and butylhydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis). Butylhydroxytoluene may also cause irritation to the eyes and mucous membranes. AndroFeme contains various parahydroxybenzoate (paraben) esters as preservatives, which may cause allergic reactions (possibly delayed).

3. HOW TO USE ANDROFEME
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The usual starting dose is 0.5 ml (5 mg) of cream by measured applicator per day.
You should not use more than 1.0 ml (10 mg testosterone) of cream per day.
If you take the wrong dose, AndroFeme may not work as well, and your problem may not improve.
You will need to return to your doctor after starting treatment so that the dose can be checked via a blood test and adjusted if required. It may take up to 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. Continue taking your medicine for as long as your doctor tells you.

There is currently limited safety information on the use of AndroFeme beyond 2 years. Your doctor will discuss the benefits and risks of longer use with you.

When to use AndroFeme:

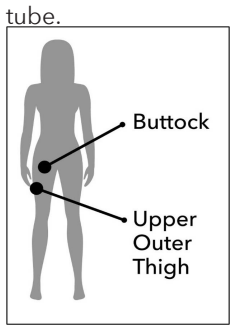
Apply once per day at approximately the same time each day.

- Applying the cream at the same time each day will have the best effect. It will also help you remember when to apply it.
- Avoid swimming or showering for at least 4 hours after application.
- Avoid using cosmetics or sunscreen on the area of application. Contact between condoms and the product should also be avoided.



How to use 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 0.5 ml graduations for dosing accuracy.
  The usual starting dose is 0.5 ml and you should not use more than 1.0 ml of cream per day.
- To measure the correct dose of cream:
  - o Gently squeeze the base of the AndroFeme tube until cream reaches the open nozzle of the tube.
  - o 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.
  - o Invert the tube and the applicator so the cream will flow with gravity when squeezed.
  - o Carefully squeeze the base of the AndroFeme 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.
  - o Fill the applicator to the required dose. For example: a 0.5 ml dose of AndroFeme (5 mg testosterone) needs the flat part of the plunger level with the 0.5 ml mark.
  - o 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.
  - o Remove the applicator from the nozzle of the tube and replace the cap firmly on the tube.
- To apply the cream:
  - o Always apply AndroFeme directly onto clean, dry, healthy skin of either the upper outer thigh or buttock.
  - o Massage the cream into the area until absorbed. Typically, this takes about 30 seconds.
  - o Cover the application area with clothing once applied.
  - o Never apply the cream to broken or damaged skin. Do not use AndroFeme on the genitals or other areas.
- Following application:
  - o Wash your hands thoroughly with soap and water after applying the cream.
  - o Be careful to avoid potential transfer to others.
  - o Rinse the applicator in hot water after use and replace in the box with the AndroFeme cream.
- For contacts:
  - o If someone comes into regular contact with the skin where you have applied the cream, advise them to wash the affected area on their body with warm, soapy water as soon as possible.



If you use more AndroFeme than you should

If you think that you have used too much AndroFeme, wash the area with soap and water.

If you forget to use AndroFeme

AndroFeme should be used regularly at the same time each day. If you miss your dose at the usual time, apply 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 a forgotten dose.

If you stop using AndroFeme

If you stop using AndroFeme suddenly, your condition may worsen.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Common side effects may affect up to 1 in 10 people. The following common, hormone-related side effects were reported in relevant clinical trials. If you get any of these side-effects, talk to your doctor as soon as possible.

- acne
- increased hair growth
- hair loss
- voice changes

The following side effects have also been reported but their frequency is not known:

- thinning of hair
- dizziness

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE ANDROFEME

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and tube. The expiry date stated after EXP refers to the last day of that month.
Store below 30°C. Do not freeze. After first opening, use within 4 months.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What AndroFeme contains

- The active substance is testosterone. One millilitre (1 ml) of cream contains 10 mg testosterone.
- The other ingredients are macrogol cetostearyl ether, cetostearyl alcohol, butylhydroxytoluene (E321), almond oil, phenoxyethanol, methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216), isobutyl parahydroxybenzoate, butyl parahydroxybenzoate, citric acid, trolamine, carbomer, all-rac-alpha-tocopheryl acetate, purified water.

What AndroFeme looks like and contents of the pack

AndroFeme is a white, opaque, odourless cream in a sealed laminated 50 ml 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.

Marketing Authorisation Holder

Andro Pharmaceuticals Ltd, Winton Priors, Priorsfield Road, Compton, Guildford, Surrey, GU3 1DW, United Kingdom

Manufacturer

McGregor Cory Limited (trading as DHL Supply Chain), Cherwell Site 1, Middleton Close, Banbury, Oxfordshire, OX16 4RS, United Kingdom

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