**ANDROFEM® 1**

Cream containing 160 mg/L (5mg/g) Testosterone BP (17-β-Hydroxyandrost-4-en-3-one)

**Consumer Medicine Information**

**What is in this leaflet?**

This leaflet answers some of the common questions about ANDROFEM®. It does not contain all the available information. It should 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 ANDROFEM® against the benefits it can have for you. If you have any concerns about using ANDROFEM®, talk to your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

**What ANDROFEM® is used for?**

ANDROFEM® 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 performance, libido, maintenance of bone, energy levels and well-being in men and women. When oestrogens fail to produce sufficient testosterone, part of the female body may experience changes.

**How to use ANDROFEM®**

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 pharmacy label, ask your doctor or pharmacist for help.

**How much to use**

The usual starting dose is 0.5ml 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 1.5ml (150mg) of testosterone per day, without confirming this dose with your doctor. The dose should not be varied unless directed 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.

Clinical trials have shown that there is a four to eight week time lag between starting testosterone treatment and an improvement in sexual motivation. If there is no improvement in symptoms after 6 months of continuous therapy then alternative treatments should be considered.

**Measuring the correct dose of ANDROFEM®**

To open the tube remove the cap and peel off the foil seal. A measuring applicator (squeezer) is enclosed in a sealed sleeve is enclosed in the ANDROFEM® 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 ANDROFEM® tube until cream reaches the open nozzle of the tube. Insert the tip of the applicator into the open nozzle of ANDROFEM® cream, so that no cream is lost before the applicator of the cream in and place the applicator in hot water after use and replace in the base of the container. The cream will flow with gravity once the applicator is in hot water after use and replace in the base of the container.**

Also you do not risk squeezing the cream into the syringe. Fill the required dose. For example: a 0.5ml dose of ANDROFEM® (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, I’ll slightly past the required 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. There is a Clinical Application Syringes demonstration video at www.llewellypharm.com.au

**Where to apply ANDROFEM® cream**

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

Absorbing some testosterone through the skin contact. Cover the application area with dressing. Do not put a dressing over the application site. The cream will flow into the barrel of the applicator.

Do not try to squeeze the cream into the syringe.

**Disposing**

If you find that you are left with any unused cream, you should apply it as you now you have been informed within your usual time of medication. Otherwise do not apply the cream until the next application is due. Exposing a dose will create an undue disruption to your treatment.

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 you now you have been informed within your usual time of medication. Otherwise do not apply the cream until the next application is due. Exposing a dose will create an undue disruption to your treatment.

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

If you use too much (overdose)

Because of the way ANDROFEM® is used, an overdose of testosterone is usually well tolerated. If you think that you or anyone else may have used too much ANDROFEM®, 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 ANDROFEM® is accidentally swallowed or eaten, contact a doctor.

During ANDROFEM® use

Do’s

Inform your doctor or pharmacist that you are taking ANDROFEM® before starting any other prescribed medicine. Some medicines may be affected by ANDROFEM® or may also affect its effects.

Tell all doctors, dentists and pharmacists who are likely to treat you that you are using ANDROFEM®. It is very important that you have a follow-up blood test to measure your testosterone levels within three weeks of starting ANDROFEM®. This is to confirm that your starting dose is correct and ensure no side effects have occurred in women.

If you observe any of the other effects not listed above.

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

You may experience some or none of these side effects, but in the majority of cases, these effects are not severe. Side effects may include:

- Headache
- Swelling of the ankles
- Yellowing of the skin
- Increased blood pressure
- Weight gain
- Deepening of the voice
- Breast tenderness
- Changes to the texture of the breast and areola
- Changes to the performance of the luteinising hormone

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

**Ingredients**

Each 50ml tube contains 500mg testosterone. Each 1ml dose delivers 10mg of testosterone. Other ingredients in the cream include crotamiton 1000, cetearyl alcohol, glycerol, propylene glycol, parabens, Colour Tartronic acid, Sodium lauroyl sarcosine.

**Androgene® is available in a 50ml sealed laminated tube.

**Name and Address of Supplier**

Llewelly Pharmaceuticals Pty Ltd Unit 1, 74-84 High Street, Leederville, WA 6007

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**Date of Preparation: Dec 2016. ANDROFEM® is a registered trademark.**