

AndroForte® 5

Cream containing 5% w/v (50mg/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 ANDROFORTE® 5. 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 ANDROFORTE® 5 against the benefits it can have for you.

If you have any concerns about using ANDROFORTE® 5, talk to your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What ANDROFORTE® 5 is used for

ANDROFORTE® 5 contains the active ingredient testosterone. This form of testosterone is identical to the testosterone produced by the testes of men and the ovaries of women. Testosterone plays an important role in physical and sexual development, sexual arousal, sexual response, libido, maintenance of bone, energy levels and well-being in men and women. When men suffer from a deficiency of testosterone one or more of these areas may be affected. ANDROFORTE® 5 provides testosterone to address this deficiency. The skin readily absorbs testosterone and ANDROFORTE® 5 is a simple and effective means of getting testosterone into the bloodstream.

Prior to using ANDROFORTE® 5

ANDROFORTE® 5 cream is only for use in men.

ANDROFORTE® 5 cream should not be used if you are allergic to testosterone or any of the ingredients contained within ANDROFORTE® 5. These are listed at the end of this leaflet. This product contains almond oil.

If you have used ANDROFORTE® 5 or any other testosterone preparation before and became unwell, tell your doctor or pharmacist before using the cream. Other testosterone containing preparations include Testogel® (AndroGel® and Testim® USA only), Reandron®, Sustanon®, Andriol®, Primodian® depot and Primoteston® depot.

Do not use ANDROFORTE® 5 if you have cancer, especially prostatic or breast cancer; kidney disease; or liver disease. Make sure your doctor is aware of these conditions before using ANDROFORTE® 5 because it 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 ANDROFORTE® 5. If you are taking other medications check with your doctor or pharmacist before starting ANDROFORTE® 5. High level athletes need to be aware of the rules governing androgen use if prescribed ANDROFORTE® 5 cream. Do not use ANDROFORTE® 5 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 ANDROFORTE® 5 if the foil seal at the top of the tube is damaged or broken.

ANDROFORTE® 5 is not indicated for use in children or women.

How to use ANDROFORTE® 5

Your doctor or pharmacist will explain how to apply ANDROFORTE® 5. Follow all directions exactly as they are explained. If you are unclear, talk to your doctor. The dose of ANDROFORTE® 5 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 the dose can be checked via a blood test.

Opening the tube

To open the tube, remove the cap and peel off the foil seal. Dispose of the foil seal and replace the cap firmly after using the cream.

Measuring the correct dose of ANDROFORTE® 5 cream

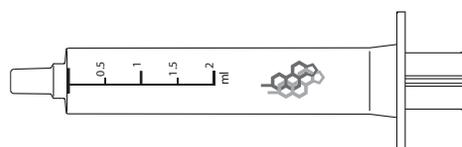
To measure the correct dose of cream, **gently** squeeze the base of the ANDROFORTE® 5 tube until cream reaches the open nozzle of the tube. Insert the tip of the applicator into the open nozzle of ANDROFORTE® 5 cream so the nozzle and the shoulder of the applicator are in contact. **Invert the tube and the applicator so the cream will flow with gravity when squeezed.**

Carefully squeeze the base of the ANDROFORTE® 5 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 1.0 mL dose of ANDROFORTE® 5 (50mg of testosterone) needs the flat part of the plunger level with the 1.0 mL mark. If there are any air bubbles in the measured dose, fill slightly past the required dose mark then depress the plunger so 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.



Where to apply ANDROFORTE® 5 cream

Always apply ANDROFORTE® 5 cream to clean, dry skin. The best area to use ANDROFORTE® 5 is the scrotum (the skin sack that holds the testicles). This is the recommended site of application because absorption of testosterone is greatest from this part of the body. It is recommended

that a dose of no greater than 1ml (50mg testosterone) once daily be applied when initiating scrotal application. Many men experience a warming sensation of the scrotal



Scrotum - The skin sack that holds the testicles

skin for a few minutes after applying ANDROFORTE® 5 – this is normal and quickly subsides. No perfume, deodorant or moisturizing creams or gels should be used on the area because this may interfere with ANDROFORTE® 5 from being absorbed. Never apply the cream to broken or damaged skin. ANDROFORTE® 5 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 ANDROFORTE® 5 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 via skin contact.



CONSUMER MEDICINE INFORMATION (cont'd)

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 nine 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 ANDROFORTE® 5 is used, an unintentional overdose is unlikely. If you think that you or anyone else may have used too much ANDROFORTE® 5, immediately telephone your doctor or your 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 ANDROFORTE® 5 is accidentally swallowed or eaten, contact a doctor.

During ANDROFORTE® 5 use

Do's

Inform your doctor or pharmacist that you are using ANDROFORTE® 5 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 ANDROFORTE® 5. Have your testosterone blood levels measured regularly by your doctor. This is especially important in the first few weeks of starting ANDROFORTE® 5 to ensure testosterone levels are within the normal levels for men.

Do Not's

Do not give ANDROFORTE® 5 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 ANDROFORTE® 5 until you know how ANDROFORTE® 5 affects you. There is no evidence that ANDROFORTE® 5 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 ANDROFORTE® 5. 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. Many men experience a warm sensation of the scrotal skin for a few minutes after applying ANDROFORTE® 5 – this is normal.
- 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
- Frequent or persistent erections

Rarely-reported events associated with testosterone supplementation include:

- Electrolyte imbalances in the blood
- A reduction in the number of sperm produced

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. ANDROFORTE® 5 has not been associated with these effects but because it contains testosterone there is a potential for side effects.

After using ANDROFORTE® 5

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 ANDROFORTE® 5 ask your pharmacist how to dispose of any cream that is left over.

Product description

ANDROFORTE® 5 cream is a white, opaque and odorless cream in a 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 graduated measuring applicator.

Ingredients

Each 50 ml tube contains 2500 milligrams (2500mg) of testosterone. Each 1ml dose delivers 50mg 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.

ANDROFORTE® 5 is available in a 50 ml sealed laminated tube.

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Date of Preparation: April 2014.

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