

CONSUMER MEDICINE INFORMATION

What is in this leaflet

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

If you have any concerns about using ANDROMEN[®] FORTE talk to your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What ANDROMEN[®] FORTE is used for?

ANDROMEN[®] FORTE 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 and ANDROMEN[®] FORTE can provide testosterone to address this deficiency. The skin readily absorbs testosterone and ANDROMEN[®] FORTE is a simple and effective means of getting testosterone into the bloodstream.

Prior to using ANDROMEN[®] FORTE

ANDROMEN[®] FORTE cream is only for use in men. ANDROMEN[®] FORTE cream should not be used if you are allergic to testosterone or any of the ingredients contained within ANDROMEN[®] FORTE. These are listed at the end of this leaflet. This product contains almond oil and macadamia nut oil. If you have used ANDROMEN[®] FORTE 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[®], Primodion[®] depot and Primoteston[®] depot. Do not use ANDROMEN[®] FORTE if you have cancer especially prostatic cancer, breast cancer, kidney disease 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 ANDROMEN[®] FORTE 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 ANDROMEN[®] FORTE. If you are taking other medications check with your doctor or pharmacist before starting ANDROMEN[®] FORTE. High level athletes need to be aware of the rules governing androgen use if prescribed ANDROMEN[®] FORTE cream. Do not use ANDROMEN[®] FORTE 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 ANDROMEN[®] FORTE if the tamper proof seal at the top of the tube is damaged or broken. ANDROMEN[®] FORTE is not indicated for use in children or women.

How to use ANDROMEN[®] FORTE

Your doctor or pharmacist will explain how to apply ANDROMEN[®] FORTE. Follow all directions exactly as they are explained. If you are unclear talk to your doctor. The dose of ANDROMEN[®] FORTE 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. Fit 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 ANDROMEN[®] FORTE cream

A small plastic applicator with 1 unit graduations is provided inside the ANDROMEN[®] FORTE 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 ANDROMEN[®] FORTE measure are covered by cream. The principle is exactly the same as applying toothpaste to a toothbrush. Each 1 unit of ANDROMEN[®] FORTE cream provides 25mg of testosterone.

Where to apply ANDROMEN[®] FORTE cream

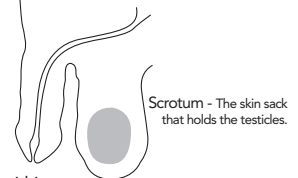
Always apply ANDROMEN[®] FORTE cream to clean dry skin. The best area to use ANDROMEN[®] FORTE FORTE is the scrotum (the skin sack that holds the testicles). This is the recommended site of application because absorption of testosterone is greatest from this part of the body. Past users of ANDROMEN[®] FORTE may have applied the cream to the lower area of the torso (the sides of the body above the hips). If changing from truncal application to scrotal application the dose of ANDROMEN[®] FORTE needs to be lowered due to the increase receptivity of scrotal skin to the absorption of ANDROMEN[®] FORTE. It is recommended that a dose of no greater than 2 units (50mg testosterone) once daily be applied when initiating scrotal application. Many men experience a warming sensation of the scrotal skin for a few minutes after applying ANDROMEN[®] FORTE – this is normal and quickly subsides.

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

Never apply the cream to broken or damaged skin.

ANDROMEN[®] FORTE 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 ANDROMEN[®] FORTE 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.



Scrotum - The skin sack that holds the testicles.

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 ANDROMEN[®] FORTE is used, an unintentional overdose is unlikely. If you think that you or anyone else may have used too much ANDROMEN[®] FORTE, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 Australian callers only) 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 ANDROMEN[®] FORTE is accidentally swallowed or eaten contact a doctor.

CONSUMER MEDICINE INFORMATION

During ANDROMEN[®] FORTE use

DO'S: Inform your doctor or pharmacist that you are using ANDROMEN[®] FORTE 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 ANDROMEN[®] FORTE. Have your testosterone blood levels measured regularly by your doctor. This is especially important in the first few weeks of starting ANDROMEN[®] FORTE to ensure testosterone levels are within the normal levels for men.

DON'TS: Do not give ANDROMEN[®] FORTE 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 ANDROMEN[®] FORTE until you know how ANDROMEN[®] FORTE affects you. There is no evidence that ANDROMEN[®] FORTE 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 ANDROMEN[®] FORTE. 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 ANDROMEN[®] FORTE – 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. ANDROMEN[®] FORTE has not been associated with these effects but because it contains testosterone there is a potential for side effects.

After using ANDROMEN[®] FORTE

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 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 ANDROMEN[®] FORTE ask your pharmacist what to do with any cream that is left over.

Product description

What it looks like

ANDROMEN[®] FORTE 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 2500 milligrams (2500mg) of testosterone. Each 2 unit (1 gram) dose delivers approximately 50mg 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, phenoxyethanol and purified water. ANDROMEN[®] FORTE is available in a 50 gram sealed laminated tube.

Sponsor

Lawley Pharmaceuticals
ABN 33 890 156 936
61 Walcott Street
Mt Lawley, Perth
Western Australia 6050
Australia

ANDROMEN[®] FORTE is a registered trademark.
Consumer Hotline Australia: 1800 627 506 (freephone)
or Perth, Australia : +61 8 9228 9033
Facsimile: +61 8 9228 9455
Email: info@lawleypharm.com.au
Website: www.lawleypharm.com.au
Date of leaflet preparation: January 2008
AUST L 95334