

ANDROFORTE® 2 (And-ro-fort)

Testosterone

Consumer Medicine Information (CMI)

ANDROFORTE 2 is indicated for use in both men and women. It is important to understand that the dosing and site of application is gender specific as stated in *section 4* of this leaflet. To make it easier to understand, this leaflet is written in 3 different colours. Black sections refer to both men and women, green to only women and blue to only men.

This leaflet answers some common questions about ANDROFORTE 2. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ANDROFORTE 2.**

Where to find information in this leaflet:

1. Why am I using ANDROFORTE 2?
2. What should I know before I use ANDROFORTE 2?
3. What if I am taking other medicines?
4. How do I use ANDROFORTE 2?
5. What should I know while using ANDROFORTE 2?
6. Are there any side effects?
7. Product details

1. Why am I using ANDROFORTE 2?

ANDROFORTE 2 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 and the testes of men.

In men, testosterone controls normal sexual development and function. It is essential for the development and maintenance of the male reproductive organs as well as other male characteristics, such as facial and body hair growth, deep voice, sexual drive, muscle mass and body fat distribution.

ANDROFORTE 2 is used to replace the body's natural hormone testosterone when not enough is made by the body.

In women, **ANDROFORTE 2 is used to treat hypoactive sexual desire dysfunction (HSDD) in postmenopausal women.**

Women with this condition often feel distress because they have a very low willingness to have sex. Testosterone can help reduce sexual concerns and distress in postmenopausal women, by improving sexual desire, pleasure, orgasm, responsiveness and self-image.

ANDROFORTE 2 is a simple and effective way of getting testosterone into your body by applying to the skin daily. Your skin absorbs testosterone, which then travels into your bloodstream and throughout your body.

2. What should I know before I use ANDROFORTE 2?

Warnings

Do not use ANDROFORTE 2 if:

- you are allergic to testosterone, tree nuts (almond oil) or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have or have had any of the following:
 - prostate cancer
 - breast cancer (a rare condition in men)
 - any other cancer which your doctor has described as being caused or stimulated by androgen
 - kidney disease known as nephrotic syndrome
 - blockage of a blood vessel by a blood clot (thromboembolism)
 - high calcium levels in the blood (hypercalcaemia)
- if you are pregnant or breastfeeding
- you still menstruate
- you are a child under 18 years of age

Check with your doctor if you:

- have any other medical conditions, especially:
 - allergies to any other medicines, foods, dyes or preservatives
 - a blood clot, or a condition which makes your blood more likely to form a clot
 - high blood calcium levels associated with bone cancer and tumours (hypercalcaemia)
 - high levels of calcium in the urine (hypercalciuria)
 - high blood pressure or heart disease
 - a tendency to retain fluid (signs may include swollen feet or ankles)
 - liver or kidney disease
 - epilepsy (fits)
 - migraines
 - diabetes
 - difficulty in passing water (urinating) due to enlarged prostate gland
 - abnormal pauses in breathing during sleep (sleep apnoea)
- take any medicines for any other condition
- are a high-level athlete. You need to be aware of the rules governing testosterone (an androgen) use if prescribed ANDROFORTE 2 cream, as testosterone may enhance athletic performance and may produce a

positive reaction in anti-doping tests. Misuse of androgens to enhance your physical abilities in sport carries serious health risks and is discouraged.

ANDROFORTE 2 may quicken the growth of existing prostatic tumors and benign prostatic hyperplasia. It may also increase the risk of breast cancer. Before treatment, your doctor should conduct tests to check that you do not have existing prostate or breast cancer and monitor the effects of this medicine during treatment.

Worsening of breathing problems in men during sleep has been reported in people prone to breathing problems during sleep, especially if you have lung problems or are overweight.

In men, if you use ANDROFORTE 2 over long periods of time, you may develop an abnormal increase in the number of red blood cells in the blood (polycythaemia). Your doctor may organise regular blood counts to monitor this.

If you have not told your doctor about any of the above, tell them before you start using ANDROFORTE 2.

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 under [Section 6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use this medicine if you are pregnant or breastfeeding. It may cause harm to the unborn child when administered to pregnant women. Pregnant women must also avoid any contact with the ANDROFORTE 2 treated skin. Testosterone passes into breast milk and there is a possibility that your baby may be affected.

ANDROFORTE 2 should only be used by women who no longer have their menstrual periods, either naturally or because they have had a total hysterectomy.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ANDROFORTE 2 and affect how it works. These include:

- oral oestrogens, medicines contained in oral contraceptives and hormone replacement therapy
- tibolone, a medicine used for hormone replacement
- oral anticoagulants, medicines used to thin blood and to treat or prevent blood clots
- corticosteroids or adrenocorticotrophic hormone (ACTH), hormones used to control inflammation
- oxyphenbutazone, a medicine used to treat pain and inflammation
- insulin, a medicine used to control blood sugar levels
- bupropion, a medicine used to aid in smoking cessation

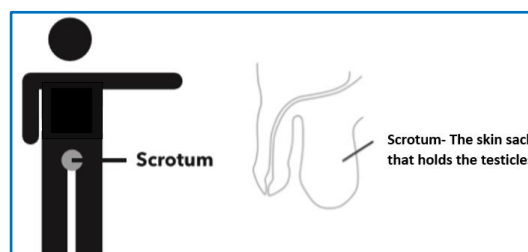
- ciclosporin, a medicine used to suppress the immune system
- some herbal products such as ancreamica dahurica, chapparal, comfrey, eucalyptus, germander tea, Jin Bu Huan, kava, penny royal oil, skullcap, and valerian.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ANDROFORTE 2.

4. How do I use ANDROFORTE 2?

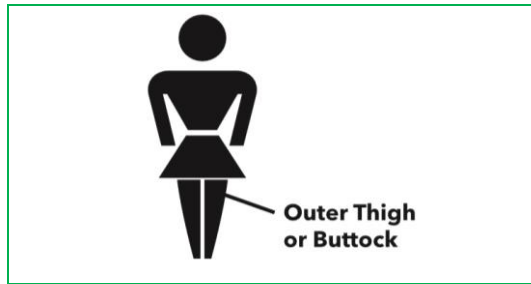
How much to use

- Follow the instructions provided and use ANDROFORTE 2 until your doctor tells you to stop.
- When you have finished a tube, start the next tube on the following day. Never leave a break between tubes.
- Your doctor or pharmacist will explain how and where on the body to apply ANDROFORTE 2.
- The dose should not be varied unless directed to do so by your doctor.
- It is very important to use the correct dose of cream on the correct part of the body because the two sites of application absorb testosterone very differently.
- ANDROFORTE 2 helps control the symptoms of your condition, but does not cure it. Therefore, you must use it every day. Applying at the same time each day will have the best effect and it will also help you remember when to apply it.
- **For men (18 years old and above): application to the scrotum:**



- The usual starting dose is 1.25 mL (25mg) of cream applied to the **entire scrotum** (the skin sack that holds the testicles) **once per day** at approximately the same time each day, preferably in the morning.
- The scrotum does not need to be shaved prior to application of the cream.
- Do not shower or swim for at least **two hours** after applying the cream to the scrotum.
- You should not use more than 2.5 mL (50 mg testosterone) of cream per day.
- You will need to return to your doctor at regular intervals so that the dose can be checked via a blood test.

- **For women (18 years old and above):
application to the upper outer thigh or buttock:**



- The usual starting dose is 0.25mL (5mg) of cream to the **outer thigh or buttock once per day** at approximately the same time each day.
- Avoid swimming or showering until at least **four hours** after application of ANDROFORTE 2 cream.
- You should not use more than 0.5 mL (10 mg testosterone) of cream per day unless directed by your doctor.
- You will need to return to your doctor **three to six weeks** after starting treatment so that the dose can be checked via a blood test and adjusted if required.
- If you take the wrong dose, ANDROFORTE 2 may not work as well and your problem may not improve.
- You should ideally attend the same laboratory for blood testing.
- It may take 1-2 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.
- ANDROFORTE 2 is usually used for a minimum of 3 months to see if the medicine works for you.
- There is currently limited safety information on the use of ANDROFORTE 2 beyond two years. Your doctor will discuss the benefits and risks of longer use with you.

How to use ANDROFORTE 2

- 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 ANDROFORTE 2 box. The applicator is marked with 0.5 mL graduations for dosing accuracy.



- **To measure the correct dose of cream:**
 - gently squeeze the base of the ANDROFORTE 2 tube until cream reaches the open nozzle of the tube.
 - insert the tip of the applicator into the open nozzle of ANDROFORTE 2 cream so that 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 2 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 the applicator to the required dose. For example: a 0.5 mL dose of ANDROFORTE 2 needs the flat part of the plunger level with the 0.5 mL mark.
- 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.
- remove the applicator from the nozzle of the tube and replace the cap firmly on the tube.

To view a demonstration video of how to use syringe applicator see:

<https://www.lawleypharm.com.au/products>

• To apply the cream:

- depress the plunger of the applicator containing the dose of ANDROFORTE 2 directly onto clean, dry and healthy skin on the part of your body as directed by your doctor.
- massage the cream into the area until absorbed. Typically, this takes 30 seconds or so.
- avoid using perfume, deodorant or moisturising creams/gels on the area because this may interfere with ANDROFORTE 2 being absorbed.
- cover the application area with clothing once applied.
- never apply the cream to broken or damaged skin.
- Do not use on **female genitalia** or other areas.

• Following application:

- wash your hands thoroughly with soap and water after applying the cream.
- be careful to avoid potential transfer to children, pregnant or breastfeeding women.
- rinse the applicator in hot water after use and replace in box with ANDROFORTE 2 cream ready for the next day's application.

For contacts:

- if someone you know 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 forget to use your ANDROFORTE 2 dose at the usual time, apply it 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 the dose you missed.

If you use too much ANDROFORTE 2

Wash the skin with soap and water. If you think that you may have used too much ANDROFORTE 2, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ANDROFORTE 2?

Things you must do

- If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with some of the results.
- Keep all of your doctor's appointments so that your progress can be checked. Your doctor may monitor your blood pressure, [examine your prostate](#) or conduct other tests from time to time to make sure the medicine is working and to check for unwanted side effects.
- If you are about to be started on any new medicine, remind your doctor, dentist and pharmacist that you are using ANDROFORTE 2.
- [If you become pregnant while taking this medicine, tell your doctor immediately.](#)
- [For women over 50 years it is recommended that a mammogram is performed every 2 years, unless otherwise advised by your doctor.](#)

Call your doctor straight away if you see any signs of increased levels of testosterone in a child or partner that may have occurred through accidental exposure to ANDROFORTE 2.

ANDROFORTE 2 may be transferred to another person during close skin contact with the area where the cream has been applied.

If close contact occurs repeatedly or for long periods of time, especially with children, this could cause signs of increased testosterone (virilisation), such as more hair on the face or the body and a deepened voice. [In women, this may also cause changes in the menstrual cycle.](#) Signs of increased testosterone in children include:

- enlarged [penis](#) or [clitoris](#)
- early development of pubic hair
- increased [erections](#) or sex drive
- aggressive behaviour

Avoid unwanted transfer to another by wearing clothes which cover the application area and/or by showering before contact. You need to ensure that your partner is not put at risk of receiving testosterone by accident.

To avoid unwanted transfer to another person, you should:

- [leave a gap of 6 hours between applying ANDROFORTE 2 to the outer thigh or buttock and having intimate physical contact. You should also wear clothing to cover the application area and/or have a shower or bath beforehand](#)
- [leave a gap of at least 2 hours between applying ANDROFORTE 2 to the scrotum and having intimate physical contact, and/or wash the genital area with a damp warm flannel beforehand.](#)

If a child comes into contact with ANDROFORTE 2, thoroughly wash the area of skin exposed to the cream with soap and water immediately.

Things you should not do

- Do not use ANDROFORTE 2 to treat any other complaints unless your doctor tells you to.
- Do not give ANDROFORTE 2 to anyone else, even if they have the same condition as you.
- Do not stop using ANDROFORTE 2, or change the dosage, without checking first with your doctor. If you stop using it suddenly, your condition may worsen or you may have unwanted side effects.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ANDROFORTE 2 affects you.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

- 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
- Rinse the applicator in hot water after use and replace in box with ANDROFORTE 2 cream ready for the next day's application.

Store it in a cool dry place where the temperature stays below 25°C. Store away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in a car or on window sills.

Do not freeze.

Keep it where young children cannot reach it.

When to discard your medicine

Once opened, the contents of the tube should be used within 125 days.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below, and if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

These are the possible side effects of ANDROFORTE 2.

Less serious side effects in men	What to do
Hormone-related: <ul style="list-style-type: none"> • changes in sexual drive • painful, tender, or enlarged breasts • mood changes, nervousness, anger • increased appetite and weight gain • hair loss, discoloured hair, excessive hairiness • reduction in the size of the testicles • changes in the levels of blood glucose (sugar) • oily skin, acne • prostatic disorders such as difficulty or pain while urinating, frequent urination Cardiovascular or heart-related: <ul style="list-style-type: none"> • increased or decreased blood pressure, flushing • changes in heartbeat, feeling tired, nausea and vomiting which may be a sign of changes in your electrolytes Skin-related: <ul style="list-style-type: none"> • skin reactions such as irritation, redness, dry or stinging skin, hives • increased feeling or sensitivity of skin Breathing-related: <ul style="list-style-type: none"> • difficulty in breathing or worsening of sleep apnoea Neurological or brain-related: <ul style="list-style-type: none"> • headaches or migraines • dizziness • memory loss • changes in the sense of smell or taste Other side effects: <ul style="list-style-type: none"> • muscle cramps or pain • unusual weakness, generally feeling unwell • swollen feet or ankles (signs of increased tendency to retain fluid) 	<p>Speak to your doctor if you notice any of the following and they worry you.</p>

Less serious side effects in women	What to do
Hormone-related: <ul style="list-style-type: none"> • acne and oily skin • increased body hair particularly on the face • loss of head hair (male pattern baldness) or thinning • headache Stomach-related: <ul style="list-style-type: none"> • abdominal bloating • constipation. 	<p>Speak to your doctor if you notice any of the following and they worry you.</p>

Serious side effects

Serious side effects in men	What to do
Hormone-related: <ul style="list-style-type: none"> • yellowing of the skin and eyes, also called jaundice • sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness, heat or swelling in your arm or leg, which could indicate a blood clot • unwanted, frequent or prolonged and painful erections Allergic reaction-related: <ul style="list-style-type: none"> • shortness of breath • wheezing or difficulty breathing • swelling of the face, lips, tongue, or other parts of the body • rash, itching or hives on the skin. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice this serious side effect.</p> <p>You may need urgent medical attention or hospitalisation.</p>

Serious side effects in women	What to do
Hormone-related: <ul style="list-style-type: none"> • nausea and vomiting • yellowing of the skin and/or eyes, also called jaundice • swelling of the ankles • weight gain • persistent headaches • deepening of the voice • changes in tissue of the breast • vaginal bleeding • ovulation and menstrual periods may stop in premenopausal women. • enlargement of the clitoris Allergic reaction-related: <ul style="list-style-type: none"> • shortness of breath • wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • rash, itching or hives on the skin. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice this serious side effect.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed above may also occur in some patients. In men, some of these side effects can only be found when your doctor does tests from time to time to check your progress, including:

- increases in blood cholesterol, increased haematocrit, haemoglobin and red blood cell count
- increased creatinine
- increased Prostate Specific Antigen (PSA).
- reduction in your sperm count, which may affect your fertility

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ANDROFORTE 2 contains

Active ingredient (main ingredient)	ANDROFORTE 2 – 20 mg testosterone per 1 mL of cream
Other ingredients (inactive ingredients)	dl-alpha-tocopheryl acetate (Vitamin E acetate) almond oil cetomacrogol 1000 cetostearyl alcohol carbomer 940 trolamine butylated hydroxytoluene citric acid purified water
Potential allergens	almond oil phenonip (PI 10352) contains hydroxybenzoates

Do not take this medicine if you are allergic to any of these ingredients.

What ANDROFORTE 2 looks like

ANDROFORTE 2 is a white, opaque 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.

To tube is boxed together with a sealed syringe-style measuring applicator marked in 0.5 mL graduations.

Who distributes ANDROFORTE 2

Lawley Pharmaceuticals Pty Ltd
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Fax: +61 8 9388 0098

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