

ANDROFORTE® 5

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ANDROFORTE 5?

ANDROFORTE 5 contains the active ingredient testosterone. ANDROFORTE 5 is used to replace the body's natural hormone testosterone when not enough is made by the body. For more information, see Section 1. [Why am I using ANDROFORTE 5?](#) in the full CMI.

2. What should I know before I use ANDROFORTE 5?

Do not use if you have ever had an allergic reaction to testosterone, tree nuts (almond oil), or any of the ingredient listed at the end of the CMI. Do not use ANDROFORTE 5 if you have or are suspected to have prostate cancer or breast cancer. ANDROFORTE 5 must not be used by children or women, particularly if they are pregnant or anticipate becoming pregnant, or breastfeeding. **Talk to your doctor if you have any other medical conditions.** For more information, see Section 2. [What should I know before I use ANDROFORTE 5?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ANDROFORTE 5 and affect how it works. A list of these medicines is in Section 3. [What if I am taking other medicines?](#) in the full CMI.

4. How do I use ANDROFORTE 5?

Your doctor or pharmacist will explain how and where on the body to apply ANDROFORTE 5. Your doctor or pharmacist will tell you exactly how much to use. It is **very important** to use the correct dose of cream on the correct part of the body. Detailed instructions can be found in Section 4. [How do I use ANDROFORTE 5?](#) in the full CMI.

5. What should I know while using ANDROFORTE 5?

Things you should do	<ul style="list-style-type: none">• Tell any doctors, dentists, and pharmacists who treat you that you are using this medicine.• Keep all of your doctor's appointments so that your progress can be checked.• Contact your doctor immediately if you think someone has come into regular contact with the cream on your skin. Avoid unwanted transfer to another by wearing clothes which cover the application area and/or by showering before contact.
Things you should not do	<ul style="list-style-type: none">• Do not stop using ANDROFORTE 5, or change the dosage, without checking first with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how ANDROFORTE 5 affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep ANDROFORTE 5 in a cool, dry place where the temperature stays below 25°C. Do not freeze.

For more information, see Section 5. [What should I know while using ANDROFORTE 5?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include skin reactions, headaches or migraines, prostatic disorders, changes in sexual drive, breast changes, dizziness, difficulty in breathing or worsening of sleep apnoea, memory loss, changes in sense of smell or taste, mood changes, blood pressure changes, flushing, increased appetite, weight gain, hair changes, muscle cramps or pain, unusual weakness, generally feeling unwell, blood glucose (sugar) changes, swollen feet or ankles, reduction in the size of the testicles, changes in heartbeat, feeling tired, nausea, and vomiting. Serious side effects include symptoms of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, or itching or hives on the skin. Other serious side effects include unwanted frequent or prolonged and painful erections, yellowing of the skin and eyes, and numbness, heat or swelling in your arms or legs, which could indicate a blood clot. For more information, see Section 6. [Are there any side effects?](#) in the full CMI.

ANDROFORTE® 5 (And-ro-fort)

testosterone

Consumer Medicine Information (CMI)

This leaflet provides important information about using ANDROFORTE 5. **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 5.**

Where to find information in this leaflet:

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

1. Why am I using ANDROFORTE 5?

ANDROFORTE 5 contains the active ingredient testosterone.

Testosterone is a natural hormone, known as an androgen, which controls normal sexual development and function in men.

Testosterone 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 5 is used to replace the body's natural hormone testosterone when not enough is made by the body.

ANDROFORTE 5 is a testosterone containing cream that is applied by the patient daily to the skin. It is a simple and effective way of getting testosterone into your body. Your skin absorbs testosterone, which then travels into your bloodstream and throughout your body.

2. What should I know before I use ANDROFORTE 5?

Warnings

Do not use ANDROFORTE 5 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)
- you are a woman, especially if you are pregnant or breastfeeding
- you are a child

Check with your doctor if you:

- have any other medical conditions, especially:
 - 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 5 cream, as testosterone may enhance athletic performance. Misuse of androgens to enhance your physical abilities in sport carries serious health risks and is discouraged. Athletes should note that the active substance, testosterone, may produce a positive reaction in anti-doping tests.

ANDROFORTE 5 may quicken the growth of existing prostatic tumours and benign prostatic hyperplasia (enlargement of the prostate gland). It may also increase the risk of breast cancer in males. Before treatment, your doctor should conduct tests to check that you do not have existing prostate or breast cancer. During treatment, your doctor may monitor the effects of this medicine.

Worsening of breathing problems during sleep has been reported during treatment with testosterone replacement in people prone to breathing problems during sleep. This is especially true if you are overweight or have lung problems.

If you use ANDROFORTE 5 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 5.

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.

ANDROFORTE 5 may cause harm to the unborn child when administered to pregnant women.

Pregnant women must also avoid any contact with the ANDROFORTE 5 treated skin. ANDROFORTE 5 may cause serious reactions in nursing infants

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 5 and affect how it works. These include:

- oral anticoagulants, medicines used to thin blood and to treat or prevent blood clots
- corticosteroids or adrenocorticotropic hormone (ACTH), hormones used to control inflammation
- oxypfenbutazone, 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 5.

4. How do I use ANDROFORTE 5?

How much to use

- Follow the instructions provided and use ANDROFORTE 5 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.
- ANDROFORTE 5 helps control the symptoms of your condition, but does not cure it. Therefore you must use ANDROFORTE 5 every day.
- Your doctor or pharmacist will explain how and where on the body to apply ANDROFORTE 5.
- 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.
- **Application to the scrotum:**
 - The usual starting dose is 0.5 mL of cream by measured applicator per day applied to the entire scrotum (the skin sack that holds the testicles).
 - Your doctor or pharmacist will tell you exactly how much to use.
 - You should not use more than 1 mL (50 mg testosterone) of cream per day.
 - The dose 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 via a blood test.
- **Application to the upper body:**
 - The usual starting dose is 2 mL of cream by measured applicator per day applied to the upper body (torso, abdomen and sides of the body).
 - Your doctor or pharmacist will tell you exactly how much to use.
 - You should not use more than 4 mL (200 mg testosterone) of cream per day.
 - The dose 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 via a blood test.

When to use ANDROFORTE 5

- Apply ANDROFORTE 5 once per day at approximately the same time each day, preferably in the morning.
- Using it at the same time each day will have the best effect. It will also help you remember when to apply it.
- Do not shower or swim for at least six (6) hours after applying the cream to the upper body or two (2) hours after applying the cream to the scrotum.

How to use ANDROFORTE 5

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



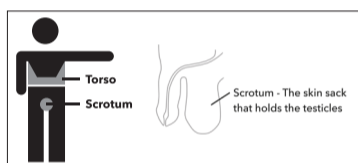
To measure the correct dose of cream:

- gently squeeze the base of the ANDROFORTE 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 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 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 the applicator to the required dose. For example: a 0.5 mL dose of ANDROFORTE 5 (25 mg testosterone) for scrotal application 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 5 directly onto clean, dry and healthy skin on the part of your body as directed by your doctor:
 - on the scrotum** (the skin sack that holds the testicles). The scrotum does not need to be shaved prior to application of the cream.
 - on the upper body** including the torso, abdomen and the sides of the body from the waist to just below the arm pits. It is preferable to apply to areas on the upper body with minimal hair and body fat.



- 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 5 being absorbed.
- cover the application area with clothing once applied.
- never apply the cream to broken or damaged skin.
- Following application:**
 - wash your hands thoroughly with soap and water after applying the cream.
 - be careful to avoid potential transfer to women, particularly pregnant or breastfeeding women.
 - rinse the applicator in hot water after use and replace in box with ANDROFORTE 5 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 ANDROFORTE 5

ANDROFORTE 5 should be used regularly at the same time each day. If you forget to apply your 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 5

Wash the skin with soap and water. If you think that you may have used too much ANDROFORTE 5, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 5?

Things you must do

- If you are about to have any blood tests, tell your doctor that you are taking this medicine. The use of ANDROFORTE 5 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 and conduct other tests (including blood tests) from time to time, particularly if you are elderly. This is to make sure the medicine is

working and to check for unwanted side effects. ANDROFORTE 5 may increase your blood pressure and affect your liver function.

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using ANDROFORTE 5.
- Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.

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 5.

ANDROFORTE 5 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. If your partner is pregnant, it is extra important that you take care to protect her from testosterone.

To avoid unwanted transfer to another person, you should:

- leave a gap of 6 hours between applying ANDROFORTE 5 to the upper body and having intimate physical contact. You need also wear clothing such as a T-shirt to cover the application area and/or have a shower or bath beforehand
- leave a gap of at least 2 hours between applying ANDROFORTE 5 to the scrotum and having intimate physical contact, and/or wash the genital area with a damp warm flannel beforehand.

If a woman or child comes into contact with ANDROFORTE 5, thoroughly wash the area of skin exposed to the cream with soap and water immediately.

Things you should not do

- Do not use ANDROFORTE 5 to treat any other complaints unless your doctor tells you to.
- Do not give ANDROFORTE 5 to anyone else, even if they have the same condition as you.
- Do not stop using ANDROFORTE 5, 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 5 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 5 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 5.

Less serious side effects	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 	Speak to your doctor if you notice any of the following and they worry you.
Cardiovascular or heart-related: <ul style="list-style-type: none"> increased or decreased blood pressure, flushing changes in heart beat, feeling tired, nausea and 	

Less serious side effects	What to do
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) 	Speak to your doctor if you notice any of the following and they worry you.

Serious side effects

Serious side effects	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. 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice this serious side effect. You may need urgent medical attention or hospitalisation.

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. 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 (percentage of red blood cells in the blood), haemoglobin and red blood cell count
- increased creatinine
- increased Prostate Specific Antigen (PSA). PSA is a protein produced by the prostate which can be used to detect prostate disease
- 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 5 contains

Active ingredient (main ingredient)	ANDROFORTE 5 – 50mg testosterone per 1 mL of cream
Other ingredients (inactive ingredients)	dl- α -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 5 looks like

ANDROFORTE 5 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. (AUST R 123764)

Who distributes ANDROFORTE 5

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