

ANDROFORTE[®] 5

(And-ro-fort)

testosterone

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some 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 risks of you using AndroForte[®] 5 against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask 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 is used to replace the body's natural hormone testosterone when not enough is made by the body.

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 a testosterone containing cream that is applied by the patient daily to the skin. The testosterone passes from the cream through the skin and into the bloodstream. Absorption can be variable between individuals.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU USE ANDROFORTE[®] 5

When you must not use it

Do not use AndroForte[®] 5 if you have an allergy to:

- testosterone, the active ingredient in AndroForte[®] 5
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- 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

Do not use AndroForte[®] 5 if you have or are suspected to have:

- prostate cancer
- breast cancer (a rare condition in men)

AndroForte[®] 5 must not be used by children.

The safety of AndroForte[®] 5 in children under 18 years of age has not been established.

AndroForte[®] 5 must not be used by women, particularly if they are or anticipate becoming pregnant.

AndroForte[®] 5 may cause harm to the unborn child when administered to pregnant women. AndroForte[®] 5 may cause serious reactions in nursing infants. Pregnant women must avoid any contact with the AndroForte[®] 5 treated skin.

Do not use this medicine after the expiry date which is printed on the crimp of the tube and the carton.

For example "EXP" (e.g. 11 13 refers to November 2013). The expiry date refers to the last day of that month.

If it has expired return it to your pharmacist for disposal.

Do not use this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any of the following medical conditions:

- high blood calcium levels associated with tumours (hypercalcaemia)

- high levels of calcium in the urine (hypercalciuria)
- high blood pressure, diabetes or heart disease
- a tendency to retain fluid (signs may include swollen feet or ankles)
- liver or kidney disease
- epilepsy (fits)
- migraines
- difficulty in passing water (urinating) due to enlarged prostate gland
- bone cancer
- breathing problems during your sleep

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.

Sportsmen.

Athletes should note that the active substance, testosterone, may produce a positive reaction in anti-doping tests.

Misuse of androgens to enhance your physical ability in sport carries serious health risks and is discouraged.

Taking other medicines

Tell your doctor 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 and AndroForte® 5 may interfere with each other. These include:

- 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
- cyclosporin, a medicine used to suppress the immune system
- some herbal products

These medicines may be affected by AndroForte® 5 or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

HOW TO USE ANDROFORTE® 5

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 pharmacist label, ask your doctor or pharmacist for help.

How much to use

The usual starting dose is 2 mL 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 4 mL (200mg 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.

How to use it

Follow these steps when applying 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 0.5mL 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 to the required dose. For example: a 2mL dose of AndroForte® 5 (100mg testosterone) needs the flat part of the plunger level with the 2mL 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. Depress the plunger of the applicator containing the dose of AndroForte® 5 directly onto clean, dry, healthy skin of the torso which includes the abdomen and the sides of the body from the waist to just below the arm pits. It is preferable to apply to areas with minimal hair and body fat. Massage the cream into the area until absorbed. Typically this takes 30 seconds or so. Rinse the applicator in hot water after use and replace in box with AndroForte® 5 cream ready for the next day's application.



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

Cover the application area with clothing once applied.

Do not shower or swim for at least six (6) hours after applying AndroForte® 5.

When to use it

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 helps maintain a steady level of testosterone in the blood. It will also help you remember when to apply it.

How long to use it

AndroForte® 5 helps control the symptoms of your condition, but

does not cure it. Therefore you must use AndroForte® 5 every day.

When you have finished a tube, start the next tube on the following day. Never leave a break between tubes. Continue using AndroForte® 5 for as long as your doctor tells you to.

If you forget to use it

If you forget to apply a dose, apply it as soon as you remember.

If you do not remember to apply the dose until the next dose is due, then just apply one dose.

Do not apply a double dose to make up for a forgotten individual dose.

Continue as normal the following day.

If you use too much (overdose)

Wash the skin with soap and water.

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much AndroForte® 5. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE USING ANDROFORTE® 5

Things you must do

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.

Keep all of your doctor's appointments.

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.

The use of AndroForte® 5 may affect the results of certain laboratory tests.

If you are about to have any tests, tell your doctor that you are using this medicine.

Things you must 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 their symptoms seem similar to yours.

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.

Things to be careful of

Testosterone may be transferred to another person during close and relatively prolonged skin contact with the cream application area.

If contact occurs a number of times or for long periods of time this could cause the other person to show signs of increased testosterone such as more hair on the face and 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.

Call your doctor right away if you see any signs in a child or a woman that may have occurred through accidental exposure to AndroForte® 5.

Unwanted transfer of testosterone to another person can be avoided 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.

You should leave a gap of 6 hours between applying AndroForte® 5 and having intimate physical contact.

You should also wear clothing such as a T-shirt to cover the application area and/or have a shower or bath beforehand.

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

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

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using AndroForte® 5.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- skin reactions such as irritation, redness, dry or stinging skin, acne and/or hives
- headaches or migraines
- prostatic disorders such as difficulty or pain while urinating, frequent urination
- painful, tender or enlarged breasts
- dizziness or difficulty in sleeping

- feeling of "pins and needles" or tingling sensation
- memory loss
- heightened senses
- mood changes, anger, anxiety
- increased blood pressure
- diarrhoea, nausea or vomiting
- hair loss
- increased blood cholesterol
- increased haematocrit (percentage of red blood cells in the blood), haemoglobin and red blood cell count.
- changes in the levels of blood glucose
- increased Prostate Specific Antigen (PSA). PSA is a protein produced by the prostate which can be used to detect prostate disease.

These are the possible side effects of AndroForte® 5.

Tell your doctor immediately, or go to Accident and Emergency department at your nearest hospital if you notice any yellowing of the skin and eyes, also called jaundice.

This is a very serious side effect. You may need urgent medical attention or hospitalisation.

Your doctor may need to monitor your blood pressure and conduct blood tests, as AndroForte® 5 may increase your blood pressure and affect your liver function. You may not experience any specific symptoms.

Side effects associated with high doses or long term treatment include:

- increased tendency to retain fluid (signs may include swollen feet or ankles)
- decreased sperm count, which may affect fertility
- unwanted, frequent or prolonged and painful erections

- severe stomach pain or tenderness, which does not disappear within a short time.
- blood clots

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

AFTER USING ANDROFORTE® 5

Storage

Keep AndroForte® 5 in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

AndroForte® 5 is a white, opaque cream presented in a boxed laminated tube together with a sealed syringe-style measuring applicator marked in 0.5mL graduations.

AndroForte® 5 is supplied in a 50mL sealed tube.

Ingredients

Active ingredient per tube:

- AndroForte® 5 - 50 mg testosterone per 1mL of cream

Inactive ingredients:

- cetomacrogol 1000
- cetostearyl alcohol
- carbopol 940
- almond oil
- dl- α -tocopheryl acetate (Vitamin E acetate)
- triethanolamine
- Phenonip®
- butylated hydroxytoluene
- anhydrous citric acid
- purified water

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ABN 12095973523

Australian Registration Numbers

AndroForte® 5 - AUST R 123764

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See TGA website (www.tga.gov.au) for latest Australian Consumer Medicine Information.

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PRESENTATION AND STORAGE CONDITIONS

AndroForte® 5 is presented as single boxed tube with a graduated syringe-style measuring device. AndroForte® 5 is supplied in a 50mL sealed tube and contains 50mg testosterone per 1mL of cream.

The tube should not be opened until immediately prior to application of the cream.

Store below 25°C. Do not freeze.

In-use storage:

AndroForte® 5 should be used within 12 weeks of opening.

Shelf Life:

AndroForte® 5 has a 36 month shelf-life from the date of manufacture.

For the expiry date and batch number please see the crimp of the tube.

Supplier

Made in Australia for:

Lawley Pharmaceuticals Pty Ltd