SCHEDULING STATUS

S5

TestaForte (5 % *w/v* cream)

Testosterone

Read all of this leaflet carefully before you start TestaForte

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TestaForte has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TestaForte is and what it is used for
2. What you need to know before you use TestaForte
3. How to use TestaForte
4. Possible side effects
5. How to store TestaForte
6. Contents of the pack and other information

1. What TestaForte is and what it is used for

TestaForte 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.

TestaForte 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.

2. What you need to know before you take TestaForte

Do not use TestaForte:

- if you are hypersensitive (allergic) to testosterone or any of the other ingredients of TestaForte (listed in section 6).

  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.
- if you have prostate cancer.
- if you have breast cancer (a rare condition in men).

TestaForte must not be used by children. The safety of TestaForte in children under 18 years of age has not been established.

Warnings and precautions

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 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)
- heart, liver or kidney disease
- have ore had blood clotting problems
- epilepsy (fits)
- migraines
- diabetes
- difficulty in passing water (urinating) due to enlarged prostate gland
- abnormal pauses in breathing during sleep (sleep apnoea).

TestaForte 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 will 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 TestaForte 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.

Athletes should note that the active substance, testosterone, may produce a positive reaction in antidoping tests.
Misuse of androgens to enhance your physical ability in sport carries serious health risks and is discouraged.

Your doctor may need to monitor your blood pressure and conduct blood tests, as TestaForte may increase your blood pressure and affect your liver, kidney or heart- function. You may not experience any specific symptoms.

Other medicines and TestaForte

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines and TestaForte may interfere with each other. These include:

- oral anticoagulants, medicines used to treat or prevent blood clots;
- corticosteroids or adrenocorticotropic hormone (ACTH), hormones used to control 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;

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

TestaForte must not be used by women, particularly if they are or anticipate becoming pregnant. TestaForte may cause harm to the unborn child when administered to pregnant women.

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

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

3. How to use TestaForte

Do not share medicines prescribed for you with any other person.

Your doctor or pharmacist will explain how and where on the body to apply TestaForte.

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, ask your doctor or pharmacist for help.

How much to use

Your doctor or pharmacist will explain how and where on the body to apply TestaForte.

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 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 a maximum of 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 adjusted, if necessary.

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.

How to use it

Follow these steps when applying TestaForte:

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 TestaForte box. The applicator is marked with 0,25 ml graduations for dosing accuracy.

To measure the correct dose of cream, gently squeeze the base of the TestaForte tube until cream reaches the open nozzle of the tube. Insert the tip of the applicator into the open nozzle of TestaForte 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 TestaForte 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 2 ml dose of TestaForte (100 mg testosterone) needs the flat part of the plunger to be level with the 2 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.

Depress the plunger of the applicator containing the dose of TestaForte directly onto clean, dry and healthy skin on the part of the body as directed by your doctor:

- 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.
- on the scrotum (the skin sack that holds the testicles). The scrotum does not need to be shaved prior to application of the cream.

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 TestaForte 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 the cream to the upper body or two (2) hours after applying the cream to the scrotum.

If you have the impression that the effect of TestaForte is too strong or too weak, tell your doctor or pharmacist.

When to use it

Apply TestaForte 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

TestaForte helps control the symptoms of your condition, but does not cure it. Therefore, you must use TestaForte every day.

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

If you use more TestaForte than you should

Wash the skin with soap and water. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you missed a dose of TestaForte

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.

WHILE YOU ARE USING TestaForte

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using TestaForte.

Tell any other 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.

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 TestaForte 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 TestaForte to treat any other complaints unless your doctor tells you to.

Do not give TestaForte to anyone else, even if they have the same condition as you.

Do not stop using TestaForte, 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 to prevent transfer of TestaForte to another person

TestaForte may be transferred to another person during close skin contact with the cream application area. Transfer can also happen through contact with clothes or implements that were in contact with the area that is being treated. For this reason, keep all clothes or implements that were in contact with the treatment area away from others, especially children and pregnant women. Wash your clothes sepearately.

If contact occurs 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 TestaForte.

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 TestaForte to the upper body 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 applying TestaForte to the scrotum leave a gap of at least 2 hours after application before intimate contact and/or have a shower or bath beforehand.

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

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

4. Possible side effects

TestaForte can have side effects.

Not all side effects reported for TestaForte are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using TestaForte, please consult your health care provider for advice.

If any of the following happens, stop taking TestaForte and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have any of them, you may have had a serious reaction to TestaForte. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- yellowing of the skin and eyes, also called jaundice.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency unknown

- skin reactions such as irritation, redness, dry or stinging skin, acne and/or hives, oily skin,
- headaches or migraines,
- prostatic disorders such as difficulty or pain while urinating, frequent urination,
- changes in sexual drive,
- painful, tender or enlarged breasts,
- dizziness, difficulty in breathing or worsening of sleep apnoea,
- increased feeling or sensitivity of skin,
- memory loss,
- changes in the sense of smell or taste,
- mood changes, nervousness, anger,
- increased or decreased blood pressure, flushing,
- increased appetite,
- hair loss, discoloured hair, excessive hairiness,
- muscle cramps or pain,
- unusual weakness, generally feeling unwell,
- changes in the levels of blood glucose~~.~~,
- yellowing of the skin,
- weight gain,
- diarrhoea

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

- increased tendency to retain fluid (signs may include swollen feet or ankles) and changes in electrolytes,
- decreased sperm count, which may affect fertility,
- reduction in the size of the testicles,
- unwanted, frequent or prolonged and painful erections.

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:

- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions & Quality Problem Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of TestaForte.

5. How to store TestaForte

Store all medicines out of reach of children.

- Store below 25 °C. Do not freeze.
- Do not store it in the bathroom, near a sink, or on a windowsill.
- The tube should not be opened until immediately prior to application of the cream.
- TestaForte should be used within 12 weeks of opening.
- Do not use after the expiry date stated on the label / carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What TestaForte contains

Active ingredient per tube:

- TestaForte – 50 mg testosterone per 1 ml of cream

Inactive ingredients:

- almond oil, butylated hydroxytoluene, carbomer 940, cetomacrogol 1000, cetostearyl alcohol, citric acid, dl-α-tocopheryl acetate (Vitamin E acetate), Phenonip (PI 10352) which contains methyl-, ethyl-, propyl-, iso-butyl- and butylhydroxybenzoates, purified water, trolamine.

What TestaForte looks like and contents of the pack

TestaForte is a white, opaque, oil-in-water cream.

TestaForte is supplied in a 50 ml sealed tube and contains 50 mg testosterone per 1 ml of cream.

TestaForte is presented as single boxed tube with a graduated syringe-style measuring device.

Holder of Certificate of Registration

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