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## **PATIENT INFORMATION LEAFLET**

### **TESTOSTERONE CIPLA**

**SCHEDULING STATUS: \$5**

#### **TESTOSTERONE CIPLA (1000 mg/4 mL, solution for injection)**

**Testosterone undecanoate 1000 mg/4 mL.**

**Each mL contains 250 mg of testosterone undecanoate, corresponding to  
157,9 mg of testosterone base form.**

**Each 4 mL vial contains 1000 mg of testosterone undecanoate,  
corresponding to 631,5 mg of testosterone base form.**

**Sugar free.**

**Read all of this leaflet carefully before you are given TESTOSTERONE  
CIPLA**

- 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.

#### **What is in this leaflet**

1. What TESTOSTERONE CIPLA is and what it is used for
2. What you need to know before you take TESTOSTERONE CIPLA
3. How to take TESTOSTERONE CIPLA
4. Possible side effects
5. How to store TESTOSTERONE CIPLA

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## 6. Contents of the pack and other information.

### 1. What TESTOSTERONE CIPLA is and what it is used for

TESTOSTERONE CIPLA is a testosterone which is the most important sex hormone of males and is formed in the testicles and to a small extent in the adrenal cortex (a part of your adrenal gland). Testosterone is responsible for the expression of masculine characteristics during foetal, early childhood and pubertal development and thereafter maintaining masculine characteristics and functions.

TESTOSTERONE CIPLA is used as testosterone replacement therapy in primary and secondary male hypogonadism (a condition where the sex glands called gonads produce too little testosterone).

### 2. What you need to know before you use TESTOSTERONE CIPLA

#### Do not use TESTOSTERONE CIPLA:

- If you are hypersensitive (allergic) to testosterone undecanoate or any of the other ingredients of TESTOSTERONE CIPLA (listed in section 6).
- If you have androgen-dependent (testosterone dependent) carcinoma (type of cancer) of the prostate or of the male mammary gland.
- If you have hypercalcaemia (above normal levels of calcium in the body) accompanying malignant tumours (invasive type of tumour which can spread to other parts of the body via the bloodstream).
- If you have had past or present liver tumours.
- If you are a woman.

## Warnings and precautions

### **Tell your doctor or health care provider before being given the injection:**

- TESTOSTERONE CIPLA can cause accelerated growth, masculinisation, bone maturation and decreased final height.
- Limited data do not suggest the need for a dosage adjustment in elderly patients
- Before starting treatment with TESTOSTERONE CIPLA you will need to undergo a detailed examination in order to exclude a risk of pre-existing prostatic cancer. If you are receiving treatment with TESTOSTERONE CIPLA at least once a year and twice a year you will require regular and careful monitoring of the prostate gland and breast.
- Your testosterone levels should be monitored at baseline and at regular intervals during treatment with TESTOSTERONE CIPLA. If you are receiving long-term treatment with TESTOSTERONE CIPLA you should also be monitored regular for haemoglobin (protein found in your red blood cells which carry oxygen), haematocrit (volume of your red blood cells in comparison to your volume of blood), liver functions tests and lipid profile.
- TESTOSTERONE CIPLA may accelerate the progression of prostate cancer and benign prostatic hyperplasia (enlargement of your prostate gland).
- TESTOSTERONE CIPLA should be used with caution if you have cancer and are at risk of hypercalcaemia (increased calcium levels) due to bone metastases (cancer spreading to your bone).
- If you suffer from severe cardiac (heart), hepatic (liver) or renal (kidney)

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insufficiency or heart disease, TESTOSTERONE CIPLA can cause severe complications characterised by oedema (build up of fluid in the body causing swelling) which can result in heart failure. In such cases treatment with TESTOSTERONE CIPLA must be stopped immediately.

- No formal studies have been performed in patients with liver impairment. The use of TESTOSTERONE CIPLA is contraindicated in men with past or present liver tumors.
- No formal studies have been performed in patients with kidney impairment.
- If you suffer from hypertension (high blood pressure) then TESTOSTERONE CIPLA must be used with caution as TESTOSTERONE CIPLA may cause a rise in blood pressure.
- Please inform your doctor if you suffer from any bleeding disorders as TESTOSTERONE CIPLA is administered into the muscle which may result in bleeding.
- Please inform your doctor if you are at risk of developing blood clots as use of TESTOSTERONE CIPLA has been associated with an increased risk of blood clots.
- If you currently suffer from sleep apnoea (condition whereby your breathing repeatedly starts and stops while sleeping), treatment with TESTOSTERONE CIPLA may increase the likelihood or frequency of your sleep apnoea.
- Please note that TESTOSTERONE CIPLA is a highly abused substance and often used at doses higher than the recommended dose. This can lead to serious cardiovascular, hepatic or psychiatric events. Abuse of TESTOSTERONE CIPLA may also result in dependence and withdrawal

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symptoms when TESTOSTERONE CIPLA is stopped.

- TESTOSTERONE CIPLA is administered into the muscle and may result in microembolism (small blood clot) which is rare but may cause symptoms such as cough, shortness of breath, malaise (general feeling of discomfort), excessive sweating, chest pain, dizziness, paraesthesia (tingling sensation typically in the hands and feet commonly known as 'pins and needles') and syncope (passing out). These reactions usually occur during or immediately after administration of TESTOSTERONE CIPLA. Treatment usually occurs with administration of oxygen.

### **Other medicines and TESTOSTERONE CIPLA**

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

- Testosterone and its derivatives, as contained in TESTOSTERONE CIPLA have been reported to increase the activity of coumarin derived from oral anti-coagulants. If you are currently taking oral anti-coagulants, you will require close monitoring especially at the beginning and end of treatment with TESTOSTERONE CIPLA.
- Concurrent administration of testosterone, as contained in TESTOSTERONE CIPLA with adrenocorticotrophic hormone (ACTH) (a hormone that is normally released from your brain) or corticosteroids may enhance oedema formation, therefore these medicines should be administered cautiously to you especially if you suffer from heart or liver disease and are at risk of oedema formation.

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- TESTOSTERONE CIPLA may affect the results of thyroid tests.
- TESTOSTERONE CIPLA may enhance the blood-sugar lowering effects of insulin and therefore the dose of insulin used to manage diabetes may need to be reduced.
- Interactions can occur with drugs that induce microsomal enzymes, which can result in increase clearance of TESTOSTERONE CIPLA e.g., barbiturates.
- TESTOSTERONE CIPLA may interfere with the metabolism of other medicines.

### **Pregnancy, breastfeeding and fertility**

#### *Pregnancy*

TESTOSTERONE CIPLA is not indicated for use in women and must not be used in pregnant women.

#### *Breastfeeding*

TESTOSTERONE CIPLA is not indicated for use in women and must not be used in breastfeeding women.

#### *Fertility*

Treatment with TESTOSTERONE CIPLA may reversibly reduce spermatogenesis (development of sperm cells).

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**Driving and using machines**

Dizziness has been reported as less frequent side effect. Avoid driving and use of machines when feeling dizzy.

It is not always possible to predict to what extent TESTOSTERONE CIPLA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TESTOSTERONE CIPLA affects them.

**3. How to use TESTOSTERONE CIPLA**

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

Check with your doctor or pharmacist if you are not sure.

Your doctor or pharmacist will inject 1 vial of TESTOSTERONE CIPLA every 10 to 14 weeks. Injections with this frequency are capable of maintaining sufficient testosterone levels without leading to a build-up of testosterone in the blood.

Your doctor will tell you how long your treatment with TESTOSTERONE CIPLA will last.

Do not miss your injection appointments. Otherwise, your optimum level of testosterone will not be maintained.

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

***Start of treatment***

Serum testosterone levels should be measured before start of treatment. The first injection interval may be reduced to a minimum of 6 weeks. With this loading dose, appropriate levels of testosterone in your body will be reached quickly.

*Individualisation of treatment*

It is advisable to occasionally measure testosterone blood levels at the end of an injection interval. Blood levels below normal range would indicate the need for a shorter injection interval. In the case of high blood levels, an extension of the injection interval may be considered. The injection interval should remain within the recommended range of 10 to 14 weeks.

TESTOSTERONE CIPLA is strictly for intramuscular injection. Special care must be given to avoid intravascular injection. The injections must be administered very slowly.

You will not be expected to give yourself TESTOSTERONE CIPLA. It will be given to you by a person who is qualified to do so.

**If you use more TESTOSTERONE CIPLA than you should**

No special therapeutic measure apart from termination of therapy with the medicine or dose reduction is necessary after overdose.

Since a health care provider will administer TESTOSTERONE CIPLA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

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**If you forget to use TESTOSTERONE CIPLA**

Please adhere to the timelines on the injection intervals agreed with your doctor for optimal efficacy of the treatment. If you missed your appointment, consult your doctor.

**If you stop using TESTOSTERONE CIPLA**

When TESTOSTERONE CIPLA is stopped, symptoms of testosterone deficiency may reoccur. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

TESTOSTERONE CIPLA can have side effects.

Not all side effects reported for TESTOSTERONE CIPLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TESTOSTERONE CIPLA, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Anaphylaxis (a severe, potentially life-threatening allergic reaction).

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

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

- Cardiovascular disorder (heart problems)
- Respiratory disorder (lung problems).

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

Tell your doctor if you notice the following:

Frequent side effects:

- Polycythaemia (a type of blood cancer)
- Increased haematocrit (ratio of red blood cells to blood volume)
- Increased red blood cell count
- Increased haemoglobin (protein in the blood responsible for carrying oxygen)
- Weight gain
- Hot flushes
- Diarrhoea
- Acne
- Leg pain
- Arthralgia
- Increased prostate specific antigen (foreign body)
- Abnormal prostate examination
- Benign prostatic hyperplasia (increase in size of prostate gland)
- Injection site reactions, injection site pain and bruising at injection site.

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## Less frequent side effects:

- Increased appetite
- Increased cholesterol and fats in the blood
- Depression and emotional disorder
- Insomnia (difficulty or inability to sleep)
- Restlessness
- Aggression
- Irritability
- Headache
- Migraine
- Tremor (shaking movement of the body)
- Increased sweating
- Dizziness
- Nervousness and hostility
- Increased blood pressure
- Bronchitis (a bacterial chest infection)
- Sinusitis (swelling or inflammation of the sinus cavity)
- Cough
- Shortness of breath
- Snoring
- Dysphonia (hoarse voice)
- Nausea
- Abnormal liver function test and aspartate aminotransferase (liver enzyme)  
increased
- Alopecia (balding)

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- Rash, red and dry skin
- Seborrhoea (oily skin)
- Pain in extremities (hands and feet)
- Muscle disorders and stiff muscles
- Blood creatinine phosphokinase increased (indicative of muscle injury)
- Decreased urine flow, urinary retention, urinary tract disorder, nocturia (waking up at night to urinate) and dysuria (burning sensation when urinating).
- Inflammation of the prostate gland
- Libido changes (changes in sex drive)
- Pain in the testicles
- Breast enlargement
- Breast pain
- Increased oestradiol (hormone) levels
- Increased testosterone levels
- Increased frequency of erections
- Interruption or reduction in sperm cell formation
- Reduction in size of testicles
- Painful erections.
- Fatigue
- Weakness
- Water retention or swelling
- Abnormal heart sounds
- Increased alkaline phosphatase (enzyme)
- Pulmonary microembolism (tiny blood clot).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: [drugsafety@cipla.com](mailto:drugsafety@cipla.com) or telephone: 080 222 6662 (toll free)

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

## **5. How to store TESTOSTERONE CIPLA**

Store all medicines out of reach of children.

Store TESTOSTERONE CIPLA at or below 30 °C.

- Do not use after the expiry date stated on the label.
- The medicine is for single use only and any unused solution should be discarded in accordance with local requirements.

## **6. Contents of the pack and other information**

### **What TESTOSTERONE CIPLA contains**

The active substance is Testosterone undecanoate 1000 mg/4 mL.

The other ingredients are benzyl benzoate and castor oil (refined).

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### **What TESTOSTERONE CIPLA looks like and contents of the pack**

TESTOSTERONE CIPLA solution for injection, is a clear yellowish oily solution in a vial containing 1000 mg/4 mL (250 mg/mL) of testosterone undecanoate.

TESTOSTERONE CIPLA 1000 mg/4 mL solution for injection is contained in 6R (amber glass) vials with a rubber stopper and aluminium flip-off cap. Pack size is 1 x 4 mL vial.

### **Holder of Certificate of Registration**

#### **CIPLA MEDPRO (PTY) LTD.**

Building 9

Parc du Cap

Mispel Street

Bellville

7530

RSA

Customer care: 080 222 6662

### **This leaflet was last revised in**

First authorization: 09 September 2025

Date of Revision: Not applicable

### **Registration number**

57/21.7/0491

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### **Access to the corresponding Professional Information**

To access corresponding Professional Information, scan the QR code below.

PLACE HOLDER:  
The QR code to be  
generated and  
included after  
approval