

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

DEPO-TESTOSTERONE™ 100 mg injection

Testosterone cypionate

Sugar free

Read all of this leaflet carefully before you start receiving DEPO-TESTOSTERONE

- 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.
- DEPO-TESTOSTERONE 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 DEPO-TESTOSTERONE is and what it is used for
2. What you need to know before you are given DEPO-TESTOSTERONE
3. How to receive DEPO-TESTOSTERONE
4. Possible side effects
5. How to store DEPO-TESTOSTERONE
6. Contents of the pack and other information

1. What DEPO-TESTOSTERONE is and what it is used for

DEPO-TESTOSTERONE is used for replacement therapy in adult males when the body is not producing enough testosterone on its own. The medical term for this condition is hypogonadism.

2. What you need to know before you receive DEPO-TESTOSTERONE

DEPO-TESTOSTERONE should not be administered to you:

- if you are hypersensitive (allergic) to testosterone cypionate or to any of the other ingredients of DEPO-TESTOSTERONE (listed in section 6)
- if you have cancer of the breast
- if you have, or suspect you may have prostate cancer
- if you have heart, liver or kidney disease
- if you have high levels of calcium in your blood
- if your liver is not functioning normally
- if you are younger than 18 years of age
- if you have a reduction in your testosterone (a type of male hormone)
- if you are a woman, especially if you are, or may become pregnant
- If you are pregnant or breastfeeding

Warnings and precautions

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

Special care should be taken with DEPO-TESTOSTERONE:

- if you are immobilised, high levels of calcium in your blood may occur
- if you receive high doses of DEPO-TESTOSTERONE for prolonged periods, you may develop liver cancer or other liver diseases which are all potentially life-threatening complications
- if you are elderly, there is an increased risk of developing prostate cancer
- if you are taking anabolic androgenic steroids
- if you experience pain, swelling, warmth and reddening of the skin in one or both legs, or acute shortness of breath, please talk to your doctor immediately as these may be symptoms of deep vein thrombosis or a blood clot in the lungs
- as there is a possible risk of developing heart problems when using DEPO-TESTOSTERONE, please talk to your doctor before you start receiving DEPO-TESTOSTERONE
- if you have heart, liver or kidney disease, treatment with DEPO-TESTOSTERONE may cause severe complications in the form of water retention in your body sometimes accompanied by (congestive) heart failure
- if you experience visual disturbances

- if you have an enlarged prostate, you may develop problems urinating
- a persistent and usually painful erection that lasts for more than four hours or excessive sexual stimulation may develop
- a low sperm count and reduced ejaculatory volume may occur after prolonged administration or excessive dosage

You should not receive DEPO-TESTOSTERONE for improving athletic performance because of the potential risk of serious adverse health effects.

DEPO-TESTOSTERONE should not to be injected into a vein.

If you experience nausea, vomiting, changes in skin colour, ankle swelling, too frequent or persistent erections of the penis please tell your doctor.

Your doctor will take periodic blood samples to check your blood counts, testosterone and cholesterol if you use DEPO-TESTOSTERONE for long periods.

Children and adolescents

DEPO-TESTOSTERONE should not be given to children under 18 years of age.

Other medicines and DEPO-TESTOSTERONE

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

DEPO-TESTOSTERONE may affect the way in which other medicines work. You should therefore inform your doctor if you are taking any of the following medicines:

- Oral anticoagulants (medicines that prevent your blood from clotting). DEPO-TESTOSTERONE may increase your sensitivity to these medicines, so your doctor may need to adjust your dosage.
- Medicines for the treatment of diabetes. DEPO-TESTOSTERONE may decrease blood glucose and, therefore, insulin requirements.

DEPO-TESTOSTERONE may affect laboratory test results for the levels of thyroid hormone in your blood.

Pregnancy and breastfeeding

DEPO-TESTOSTERONE is intended for use by men only.

DEPO-TESTOSTERONE should never be used in women, pregnancy and breastfeeding.

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 receiving this medicine.

Driving and using machines

It is not always possible to predict to what extent DEPO-TESTOSTERONE 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 DEPO-TESTOSTERONE affects them.

DEPO-TESTOSTERONE contains benzyl alcohol

The preservative benzyl alcohol has been associated with serious adverse events, including the “gasping syndrome”, and death in children. Although normal therapeutic doses of this medicine ordinarily deliver amounts of benzyl alcohol that are substantially lower than those reported in association with the “gasping syndrome”, the minimum amount of benzyl alcohol at which toxicity may occur is not known. The risk of benzyl alcohol toxicity depends on the quantity administered and your liver's capacity to detoxify the chemical. Premature and low-birth weight infants may be more likely to develop toxicity.

3. How to receive DEPO-TESTOSTERONE

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

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

DEPO-TESTOSTERONE is given as an injection into your muscle. Special care will be taken to avoid injection into a blood vessel.

Your doctor will decide what dose, how often and for how long you will receive DEPO-TESTOSTERONE.

Before you start receiving DEPO-TESTOSTERONE, your doctor will confirm the diagnosis of hypogonadism by measuring the testosterone concentration in your blood in the morning, on at least two separate days.

Your dosage will vary depending upon your age and your condition. Your doctor will adjust your dose according to your response to DEPO-TESTOSTERONE and the appearance of any side effects.

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

If you receive more DEPO-TESTOSTERONE than you should

Since a health care provider will administer DEPO-TESTOSTERONE, he/she will control the dosage. However, in the event of an overdose, your doctor will manage the overdose.

If you forget to receive a dose of DEPO-TESTOSTERONE

If you miss a dose of DEPO-TESTOSTERONE speak to your doctor or healthcare professional as soon as possible.

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

4. Possible side effects

DEPO-TESTOSTERONE can have side effects.

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

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

- signs of being hypersensitive (allergic) to DEPO-TESTOSTERONE such as skin rash or itching, wheezing and shortness of breath
- pain, swelling, warmth and reddening of the skin in one or both legs or difficulty in breathing, as these may be symptoms of blood clots in the legs or lungs
- yellowing of the skin and eyes, also called jaundice
- heart attack, stroke

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

Other side effects:

- bleeding
- an increase in red blood cell count
- retention of sodium, chloride, water, potassium, calcium, and inorganic phosphates
- high levels of calcium in your blood
- an increased or decreased sex drive
- headache
- anxiety
- depression
- a tingling or pricking sensation ("pins and needles")
- blurred or distorted vision
- nausea
- alterations in liver function tests
- liver cancer

- blood-filled cavities throughout your liver
- excessive growth of facial and body hair
- baldness
- excessively oily skin
- acne
- enlargement of male breasts
- erections that are too frequent or continue for too long, or are painful
- decreased ejaculatory volume
- low sperm count may occur
- swelling from fluid retention in the body
- swelling and pain at the injection site
- psychiatric/mental, mood disorders and behavioural disturbances such as depression, losing contact with reality and aggression

Medicine abuse and dependence

You should only receive DEPO-TESTOSTERONE if it has been prescribed for you by your doctor for your specific medical condition.

Taking high doses of DEPO-TESTOSTERONE that has not been prescribed by your doctor is called 'abuse' and can cause serious health problems.

Serious abuse-related side effects include:

- emotional disorders including feeling depressed, being excitable, feeling anxious or threatened
- 'losing contact with reality'
- hearing or seeing things
- aggressive behavior
- stroke
- heart attack
- heart failure

- liver damage

The following additional side effects have been reported in men:

- elevated mood, being irritable
- small short-lasting strokes (which may cause weakness/paralysis on one side of the body, slurred speech, blurred vision, dizziness)
- fits
- shrinkage of the testicles
- low or no sperm production
- abnormal fat levels in the blood

The following additional side effects have been reported in women:

- development of male physical characteristics
- deepening of the voice
- excessive growth of facial and body hair
- baldness
- enlargement of the clitoris
- reduction in breast size
- irregular periods

The following side-effects have been reported in boys and girls:

- child's body begins changing into that of an adult earlier than usual (development of breasts; facial, underarm and pubic hair; early periods)
- early closure of growth plates in the bones and retarded growth

Individuals who abuse DEPO-TESTOSTERONE may become dependent on/addicted to its effects. If this happens you may find it very difficult to stop using DEPO-TESTOSTERONE, even though you know it is affecting your health.

In cases of abuse, withdrawal symptoms after suddenly stopping or significantly reducing the dose of DEPO TESTOSTERONE may last for weeks or months and include changes in mood, depression, tiredness, craving, restlessness, irritability, loss of appetite, difficulty sleeping, decreased sex drive and loss of function of the testes and ovaries.

Please consult your doctor for advice if you feel you have a dependence on DEPO-TESTOSTERONE.

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **“6.04 Adverse Drug Reaction 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 DEPO-TESTOSTERONE.

5. How to store DEPO-TESTOSTERONE

- Store all medicines out of reach of children
- Store at or below 30 °C
- Protect from light
- 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 DEPO-TESTOSTERONE contains

- Each mL contains 100 mg of the active substance, testosterone cypionate.
- The other ingredients are benzyl alcohol 0,945 % m/v as preservative, benzyl benzoate and cottonseed oil.

What DEPO-TESTOSTERONE looks like and contents of the pack

A pale yellow, oily solution.

DEPO-TESTOSTERONE 100 mg is available in 10 mL vials.

Holder of Certificate of Registration

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