PATIENT INFORMATION LEAFLET

TESTOSTERONE PD

SCHEDULING STATUS

S5

TESTOSTERONE PD 1000 mg/4mL oily solution for injection.

Testosterone undecanoate

TESTOSTERONE PD is sugar free.

Read all of this leaflet carefully before you are given TESTOSTERONE PD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TESTOSTERONE PD 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 TESTOSTERONE PD is and what it is used for
2. What you need to know before you are administered TESTOSTERONE PD
3. How TESTOSTERONE PD is administered
4. Possible side effects
5. How to store TESTOSTERONE PD
6. Contents of the pack and other information

1. What TESTOSTERONE PD is and what it is used for

TESTOSTERONE PD contains testosterone, a male hormone, as the active ingredient. TESTOSTERONE PD is injected into a muscle in your body. There it can be stored and gradually released over a period of time.

TESTOSTERONE PD is used in adult men for testosterone replacement to treat various health problems caused by a lack of testosterone (male hypogonadism). These should be confirmed by two separate blood testosterone measurements and also include clinical symptoms such as:

- impotence
- infertility
- low sex drive
- tiredness
- depressive moods
- bone loss caused by low hormone levels.

2. What you need to know before you are administered TESTOSTERONE PD

TESTOSTERONE PD should not be administered to you:

- if you are hypersensitive (allergic) to testosterone undecanoate, or to any of the ingredients of TESTOSTERONE PD (see section 6)
- if you have androgen-dependent cancer or suspected cancer of the prostate or of the breast
- if you have or had a liver tumour
- if you have cancer-associated hypercalcaemia (calcium levels in your blood that are above normal).

The use of TESTOSTERONE PD in women is not intended.

Warnings and precautions

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

- if you are elderly, you may be at risk of the development of age-associated prostate gland enlargement that can cause difficulty in urinating

- if you have been diagnosed with prostate cancer or an enlarged prostate (benign prostatic hyperplasia)
- if you have cancer, as the level of calcium in your blood may need to be tested regularly
- if you develop severe abdominal pain, during therapy as this may be a symptom of either cancerous or non-cancerous (benign) growths on the liver. Following the use of hormonal substances such as TESTOSTERONE PD, cases of benign (non-cancerous) and malignant (cancerous) liver tumours have been observed to occur
- if you have blood clotting problems, seek urgent medical attention.

Examples of blood clotting problems:

- bleeding disorders (i.e. haemophilia)
- thrombophilia (an abnormality of blood coagulation that increases the risk of thrombosis blood clots in blood vessels)
- factors that increase your risk for blood clots in a vein: previous blood clots in a vein; smoking; obesity; cancer; immobility; if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50); or as you get older.

How to recognise a blood clot:

- painful swelling of one leg or sudden change in colour of the skin e.g. turning pale, red or blue, sudden breathlessness, sudden unexplained cough which may bring up blood; or sudden chest pain, severe light headedness or dizziness, severe pain in your stomach, sudden loss of vision
- if you have epilepsy or suffer from migraines
- if you suffer from temporary interruptions in your breathing during sleep (apnoea), as these may get worse
- if you experience any of the following symptoms: irritability, nervousness, weight gain, prolonged or frequent erection, inform your healthcare provider as your dose of TESTOSTERONE PD may need to be adjusted

- if you have high blood pressure or if you are treated for high blood pressure, as TESTOSTERONE PD may cause a rise in blood pressure.

If you are suffering from severe heart, liver or kidney disease, treatment with TESTOSTERONE PD may cause severe complications in the form of water retention in your body sometimes accompanied by (congestive) heart failure.

Liver or kidney disease

No formal studies have been performed in patients with liver or kidney impairment. You will not be prescribed TESTOSTERONE PD if you have ever had a liver tumour (see TESTOSTERONE PD should not be administered to you).

Laboratory tests

The following blood checks should be carried out by your doctor before and during the treatment: testosterone blood level and full blood count.

Athletes should note that TESTOSTERONE PD might lead to positive results in anti-doping tests.

TESTOSTERONE PD is **not** suitable for building muscles in healthy individuals or for increasing physical strength.

Drug abuse and dependence

Abuse of testosterone, especially if you use too much of this medicine alone or with other anabolic androgenic steroids, can cause serious health problems to your heart and blood vessels (that can lead to death), mental health and/or the liver.

Individuals who have abused testosterone may become dependent and may experience withdrawal symptoms when the dosage changes significantly or is stopped immediately.

Medical examination/follow-up

Male hormones may increase the growth of prostate cancer and enlarged prostate glands (benign prostatic hypertrophy). Before your doctor injects TESTOSTERONE PD, he/she will examine you to check that you do not have prostate cancer.

Your doctor will regularly examine your prostate and breasts, especially if you are elderly. He/she will also take regular blood samples, liver function tests and lipid profile.

Suspected anaphylactic reactions after TESTOSTERONE PD injection have been reported.

Children and adolescents

TESTOSTERONE PD is not for use in children and adolescents. There is no data available on the use of TESTOSTERONE PD in males under 18 years of age.

Other medicines and TESTOSTERONE PD

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

- medicines used to treat diabetes, e.g. metformin, glibenclamide, dapagliflozin, insulin. It may be necessary to adjust the dose of your diabetes medicine. TESTOSTERONE PD) may increase the effect of insulin
- medicines that stimulate liver enzymes (e.g. barbiturates such as phenobarbital, secobarbital-sedative and sleep-inducing medicines)
- medicines that prevent clotting (e.g. warfarin) since this can increase the risk of bleeding. Your doctor will check the dose

- if you are taking oxyphenbutazone, testosterone as in TESTOSTERONE PD has been reported to increase oxyphenbutazone serum levels
- if you are taking the hormone adrenocorticotropic hormone (ACTH) or corticosteroids, e.g. prednisone (used to treat various conditions such as rheumatism, arthritis, allergic conditions and asthma) as TESTOSTERONE PD may increase the risk of water retention, especially if your heart and liver are not working properly
- TESTOSTERONE PD may affect the results of some laboratory tests (e.g. thyroid gland). Tell your doctor or the laboratory staff that you are using TESTOSTERONE PD.

Pregnancy, breastfeeding and fertility

Pregnancy and breastfeeding

TESTOSTERONE PD is not for use in women and must not be used in pregnant or breastfeeding women.

Fertility

Treatment with high doses of testosterone, the active ingredient in TESTOSTERONE PD, may reversibly stop or reduce sperm production (see Possible side effects).

Driving and using machines:

Dizziness has been reported as an uncommon side effect (see Possible side effects). If you are experiencing dizziness, you should avoid driving and the use of machines.

It is not always possible to predict to what extent TESTOSTERONE PD may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which TESTOSTERONE PD affects you.

3. How TESTOSTERONE PD is administered

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

TESTOSTERONE PD is administered as an intra-muscular injection.

Adults:

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

Your doctor will inject TESTOSTERONE PD (1 vial) very slowly into a muscle.

TESTOSTERONE PD will be administered to you every 10 - 14 weeks. This is enough to maintain sufficient testosterone levels without leading to a build-up of testosterone in the blood.

Children:

TESTOSTERONE PD is not indicated for use in children and adolescents under the age of 18 years of age as it has not been clinically evaluated.

Start of treatment

Your doctor will measure your blood testosterone levels before starting treatment and during the early stages of treatment. Your doctor may give you the second injection after only 6 weeks in order to quickly reach the necessary testosterone level. This will depend on your symptoms and testosterone levels.

Maintaining your testosterone levels during treatment

The injection interval should always be within the recommended range of 10 - 14 weeks.

Your doctor will measure your testosterone levels regularly at the end of an injection interval to make sure it is at the right level. If the level is too low, your doctor may decide to give you injections more often. If your testosterone levels are high, your doctor may decide to give you

injections less often. Do not miss your injection appointments, otherwise, your optimum level of testosterone will not be maintained.

Your doctor will tell you how long your treatment with TESTOSTERONE PD will last. If you have the impression that the effect of TESTOSTERONE PD is too strong or too weak, tell your doctor or pharmacist.

If you are receive more TESTOSTERONE PD than you should:

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

If you miss a dose of TESTOSTERONE PD:

Since a health care provider will administer the TESTOSTERONE PD, it is unlikely that a dose will be missed.

4. Possible side effects

TESTOSTERONE PD can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, 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 them, you may have had a serious allergic reaction to TESTOSTERONE PD. 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:

- enlarged prostate and associated problems
- testicular pain, urine flow decreased, inability to completely empty the bladder
- persistent painful erections (priapism)
- brief interruptions in breathing during sleep
- jaundice - yellowing of the skin and whites of the eyes, dark-coloured urine and/or clay-coloured stool, flu-like symptoms (fever, chills).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- blood tests showing abnormally high levels of red blood cells
- weight gain
- hot flushes
- respiratory disorders (such as persistent coughing, wheezing)
- acne
- abnormal prostate examination results
- various reactions where the injection was given (e.g. pain, bruising, or irritation).

Less frequent side effects:

- increased appetite, changes in blood test results (e.g. increased glycosylated

haemoglobin, cholesterol, or blood fats, increased creatine phosphokinase)

- depression, emotional disorder, insomnia, restlessness, aggression, or irritability
- headache, migraine, tremor
- heart and blood vessel disease, high blood pressure, or dizziness
- bronchitis, sinusitis, cough, snoring, hoarse voice
- nausea, diarrhoea
- changes in liver test results
- itchy skin, dry skin, rash
- hair loss, or various skin reactions (e.g. red, itchy rash and white scales, itching, reddening, or dry skin)
- joint pains, pain in limbs (e.g. spasm, cramps, strain, pain or stiffness)
- urinary tract disorders (e.g. urge to pass urine at night, pain or burning sensation when passing urine)
- hardened or enlarged breasts, or increased levels of male hormone (testosterone) and female hormones (estradiol) in the blood, changes in sexual appetite
- fatigue, general feeling of weakness
- excessive sweating, night sweats.

The oily liquid TESTOSTERONE PD may reach the lungs (pulmonary micro-embolism of oily solutions) which can in rare cases lead to signs and symptoms such as cough, shortness of breath, feeling generally unwell, excessive sweating, chest pain, dizziness, pins and needles, or fainting. These reactions may occur during or immediately after the injection and are reversible.

Frequency unknown side effects:

- nervousness, hostile feeling

- itchy red patches and greasy scales on your skin along with white or yellow crusty or powdery flakes
- muscle cramps
- more frequent erections, reduced size of the testicles
- water retention, swelling or puffiness of the tissue directly under your skin, especially in your legs or arms.

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

You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store TESTOSTERONE PD

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Do not use after the expiry date stated on the 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 TESTOSTERONE PD contains:

Each vial contains testosterone undecanoate 1000 mg in a 4 mL solution for injection

(testosterone undecanoate 250 mg/mL, corresponding to 157.9 mg of testosterone base form).

The other ingredients are:

Benzyl benzoate, castor oil.

What TESTOSTERONE PD looks like and contents of the pack

Clear, yellowish oily solution.

TESTOSTERONE PD is available in amber glass vials with a dark grey coated elastomer injection stopper sealed with a grey aluminium flip-off cap with orange plastic button.

Pack size: 1 x 4 mL

Holder of Certificate of Registration

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