

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS’ REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor’s prescription only

Testosterone Teva Solution for injection

One vial contains:

Testosterone undecanoate 1,000 mg.

(1 ml solution for injection contains 250 mg testosterone undecanoate, equivalent to 157.9 mg testosterone).

Inactive ingredients and allergens: see section 6 “Additional information”.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Testosterone Teva is intended for use in adult men as a replacement for the hormone testosterone, for treatment of problems caused by testosterone deficiency (male hypogonadism).

Testosterone deficiency will be confirmed by two separate measurements of testosterone in the blood and will also include medical symptoms such as:

- Impotence
- Infertility
- Low libido
- Tiredness
- Depressive moods
- Loss of bone mass caused by low levels of hormones

Testosterone Teva is slowly injected into the muscle, where it is stored and gradually released over a period of time.

Therapeutic class: Testosterone Teva is a replacement for the male hormone (androgen) testosterone and belongs to a group of medicines called androgens.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to testosterone undecanoate or to any of the other ingredients the medicine contains. For a list of inactive ingredients, see section 6 “Additional information”.
- You have an androgen-dependent cancer or suspected prostate gland or breast cancer.
- You have or have had a tumor in the liver.
- You are a woman.

Special warnings regarding the use of the medicine

Before using Testosterone Teva, tell the doctor if you suffer or have suffered in the past from:

- Epilepsy
- Problems in the heart, kidneys or liver
- Migraine
- Temporary interruptions in your breathing during sleep (apnea), as they may get worse
- Cancer, as the level of calcium in your blood may need to be tested regularly
- High blood pressure or if you are receiving treatment for high blood pressure, since testosterone may cause a rise in blood pressure
- Blood clotting problems
 - Bleeding disorders (hemophilia)
 - Thrombophilia (blood clotting abnormality that increases the risk of thrombosis – blood clots in blood vessels).
 - Factors that increase your risk of blood clots in a vein: previous blood clots in a vein; smoking; obesity; cancer; lack of movement; if one of your immediate family members had a blood clot in the leg, lung or another organ at a young age (for example, below the age of 50); or as you get older.

How to recognize a blood clot: painful swelling in one leg or a sudden change in the color of the skin, e.g., it turns pale, red or blue, sudden shortness of breath, sudden, unexplained cough, which may be accompanied by blood spitting; or sudden pain in the chest, severe light-headedness or dizziness, severe abdominal pain, sudden loss of vision. Seek urgent medical assistance if you experience any of these symptoms.

In thrombophilia patients, there have been reports of thrombotic events during treatment with testosterone (for example deep vein thrombosis, pulmonary embolism, ocular thrombosis). In thrombophilia patients, there have been reports of blood clots even under anticoagulant treatment; therefore, continuing treatment with testosterone should be carefully evaluated after the first thrombotic event. In case of continuing treatment, further measures should be taken to minimize the risk of blood clot formation.

Testosterone Teva is not intended for use in children and adolescents under the age of 18.

Tumors

Androgens may accelerate the progression of prostate cancer and benign prostatic hyperplasia.

Testosterone Teva should be used with caution in cancer patients who are at high risk of hypercalcemia (associated with excessive calcium in the urine), due to bone metastases. Regular monitoring of serum calcium concentrations is recommended in these patients.

There have been reports of cases of benign and malignant liver tumors in users of hormonal substances such as androgens.

In case of complaints of severe pain in the upper abdomen, liver enlargement or signs of intra-abdominal bleeding in men using Testosterone Teva, a liver tumor should be included in the diagnostic consideration.

If you suffer from a severe heart, liver or kidney disease, treatment with Testosterone Teva may cause severe complications manifested by water retention in your body, sometimes accompanied by heart failure. Your doctor will refer you to the following tests before and during treatment: blood testosterone level, full blood count.

If your liver is not functioning properly

There have been no formal studies in patients with impaired liver function. You will not be prescribed Testosterone Teva if you have ever had a liver tumor (see section 2 “Do not use the medicine if”).

Elderly patients (65 years or older)

There is no need for your doctor to adjust the dosage if you are above the age of 65 (see below “Medical tests and follow-up”).

There is limited experience on the safety and efficacy of using Testosterone Teva in patients above the age of 65. It should be taken into account that physiological testosterone blood levels decrease with age.

Muscle building and drug tests

Testosterone Teva is **not** suitable for building muscles in healthy people or for increasing physical strength.

Testosterone Teva may lead to positive results in drug tests.

The effects of abuse of the preparation as a drug and developing dependence on it

Always take the medicine exactly as instructed by the doctor or pharmacist.

Abuse of testosterone, especially when taking more than the recommended dose, alone or in combination with another anabolic androgenic steroid medicine, can cause serious medical problems in your heart and blood vessels (which can lead to death), mental problems and/or liver problems. People who have abused testosterone may develop dependence and may experience withdrawal syndrome symptoms upon significant dosage reduction or if the administration of the medicine is abruptly discontinued.

Do not abuse this medicine or its combination with another anabolic androgenic steroid medicine, since such use is very dangerous to your health (see section 4 “Side effects”).

Children and adolescents

This medicine is not intended for use in children and adolescents under the age of 18. There is no information regarding the use of Testosterone Teva in males under the age of 18.

Medical tests and follow-up

Male hormones may increase the development of prostate cancer and cause prostate gland enlargement (benign prostatic enlargement). Before using Testosterone Teva, you will be examined in order to make sure that you do not suffer from prostate cancer. Your doctor will regularly examine your prostate and breast, especially if you are elderly. He will also refer you for periodic blood tests.

Following the use of hormonal substances such as androgenic substances, cases of benign (non-cancerous) and malignant (cancerous) tumors in the liver have been observed.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. You should also tell the doctor or pharmacist if you might take any other medicines. Especially if you are taking:

- The hormone ACTH or corticosteroids (used for treatment of various conditions such as rheumatism, arthritis, allergy conditions and asthma), since Testosterone Teva may increase the risk of water retention, especially if your heart or liver are not functioning properly.
- Blood thinning tablets (coumarin derived oral anticoagulants), since they may increase the risk of bleeding. Your doctor will check the dosage.
- Medicines for treatment of diabetes. The dosage of the blood sugar-reducing medicine may need to be adjusted. Like other androgens, testosterone may increase the effect of insulin.

The doctor may adjust the dosage of Testosterone Teva if you are taking any of these medicines.

Make sure to inform your doctor if you suffer from a blood clotting disorder, since it is important for your doctor to know this before deciding to inject Testosterone Teva.

Testosterone Teva may also affect the results of several laboratory tests (for example, thyroid gland). Tell your doctor that you are using Testosterone Teva.

Pregnancy, breastfeeding and fertility

Pregnancy and breastfeeding

Testosterone Teva is not intended for use in women and must not be used in pregnant and breastfeeding women.

Fertility

Treatment with high dosages of testosterone preparations may commonly reversibly stop or reduce sperm production (see also section 4 “Side effects”).

Driving and operating machinery

No effect of Testosterone Teva on your ability to drive or operate machinery has been observed.

Important information about some of the ingredients of the medicine

Testosterone Teva contains benzyl benzoate.

This medicine contains 2,000 mg benzyl benzoate in each 4 ml vial, that is, equivalent to 500 mg/ml.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor’s instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined only by the doctor.

The generally accepted dosage is: one injection (1 vial) every 10 to 14 weeks.

This dosage is enough to maintain an adequate testosterone level without causing a build-up of testosterone in the blood.

Do not exceed the recommended dose.

How to take the medicine

Testosterone Teva (1 vial) will be injected very slowly into your muscle. Testosterone Teva is intended for intramuscular injection only. Special care should be taken to avoid injection into a blood vessel (see “Administration of the injection”).

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 attain the required testosterone level.

This will depend on your symptoms and testosterone levels.

Maintaining Testosterone Teva levels during treatment

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

Your doctor will measure your testosterone levels regularly at the end of the injection interval in order to make sure they are at the appropriate 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 optimal testosterone level will not be maintained.

If you think that the effect of Testosterone Teva is too strong or too weak, tell that to your doctor.

If you accidentally took a higher dosage than recommended, the following symptoms may appear:

- Restlessness
- Nervousness
- Weight gain
- Persistent or frequent erections

Tell your doctor if you suffer from one or more of the conditions mentioned above. The doctor will instruct you to receive the injection less often or will stop the treatment.

If you took an overdose or if a child accidentally swallowed this medicine, go to the doctor or to a hospital emergency room immediately and take the package of the medicine with you.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Testosterone Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

The most common side effects are acne and pain at the injection site.

Common side effects (may affect up to 1 in 10 users):

- Abnormally high levels of red blood cells
- Weight gain
- Hot flashes
- Acne
- Enlarged prostate and related problems, elevated level of prostate-specific antigen, abnormal prostate examination, benign prostatic hyperplasia
- Various reactions at the injection site (such as pain, bruising or irritation)

Uncommon side effects (may affect up to 1 in 100 users):

- An allergic reaction
- Increased appetite, changes in the results of blood tests (such as high levels of sugars or fats in the blood)
- Depression, emotional disorder, insomnia, restlessness, aggressiveness or irritability
- Headache, migraine or tremor
- Heart and blood vessel (cardiovascular) disorder, high blood pressure or dizziness
- Bronchitis, sinusitis, cough, shortness of breath, snoring or voice problems
- Diarrhea or nausea
- Changes in liver test results, increased aspartate aminotransferase levels
- Hair loss or various skin reactions (such as rash, itch, redness or dry skin)
- Arthralgia (joint pain), pain in the limbs, muscle problems (such as cramps, pain or stiffness) or increased creatine phosphokinase in the blood
- Urinary tract disorders (such as decreased urine flow, urinary retention, urge to urinate at night, discomfort during urination (dysuria))
- Prostate disorders (such as prostatic dysplasia, hardening or inflammation of the prostate), changes in sexual drive, painful testicles, painful, hardened or enlarged breasts or elevated levels of male and female hormones
- Tiredness, general feeling of weakness, increased sweating or night sweating

Rare side effects (may affect up to 1 in 1,000 users):

The oily liquid of Testosterone Teva may reach the lungs (pulmonary microembolism of oily solutions), which in rare cases can lead to signs and symptoms such as cough, shortness of breath, general malaise, excessive sweating, chest pain, dizziness, sensation of numbness (“pins and needles” sensation) or fainting. These reactions may occur during or immediately after the injection, and are reversible.

Suspected anaphylactic reactions after the injection of Testosterone Teva have been reported.

Androgens may accelerate the progression of prostate cancer and benign prostatic hyperplasia.

In addition to the side effects listed above, the following effects have been reported following treatment with testosterone-containing preparations:

Nervousness, hostility, brief interruptions in breathing during sleep, various skin reactions including dandruff and oily skin, increased hair growth, more frequent erections, and very rare cases of yellowing of the skin and the eyes (jaundice).

Treatment with high dosages of testosterone preparations commonly stops or reduces sperm production, thereby reducing the size of the testicles, although this returns to normal after stopping the treatment. Testosterone replacement therapy in cases of low functioning testicles (hypogonadism) may, in rare cases, cause persistent, painful erections (priapism). High-dosage or long-term administration of testosterone sometimes increases cases of water retention and edema (swelling due to fluid retention).

For testosterone preparations in general, a common risk of increased red blood cell count, increased hematocrit (percentage of red blood cells in the blood) and hemoglobin (the component of red blood cells that carries oxygen), has been observed in periodic blood tests.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature lower than 25°C.
- The vial should be used immediately after opening.
- The medicine should be used only if it is clear and particle-free.
- Do not discard medicines in the wastewater or domestic trash. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient testosterone undecanoate, the medicine also contains: Benzyl benzoate, castor oil refined.
- What does the medicine look like and what are the contents of the package? A clear, colorless to yellowish oily solution. The preparation comes in a package of one vial made of brown glass containing 4 ml of solution for injection.
- License holder and address: Teva Israel Ltd., 124 Dvora HaNevi’a St., Tel Aviv 6944020.
- Name and address of the manufacturer: Laboratories Farmalan, Spain.
- Revised in January 2025.**
- Registration number of the medicine in the national drug registry of the Ministry of Health: 178-40-37442.

The following information is intended for the medical staff only:

At low storage temperatures, the properties of this oil-based solution may temporarily change (e.g., higher viscosity, cloudiness). If the preparation is stored at a cold temperature, it should be brought to room temperature or body temperature before use.

Before use, the solution for intramuscular injection should be visually inspected, and only clear and particle-free solutions should be used.

The content of the vial should be injected into the muscle immediately after opening the vial.

The medical preparation is for single use only and any remaining unused solution should be discarded.

Administration of the injection

Extra caution should be exercised to avoid injection into a blood vessel.

As with all oily solutions, Testosterone Teva should be injected directly into the muscle only and very slowly. Pulmonary microembolism of oily solutions may, in rare cases, lead to signs and symptoms such as cough, shortness of breath, feeling generally unwell, excessive sweating, chest pain, dizziness, sensation of numbness or fainting. These reactions can occur during or immediately after the injection, and are reversible. The treatment is usually supportive, for example by administration of supplemental oxygen.

Suspected anaphylactic reactions after the injection of Testosterone Teva have been reported.

Warnings

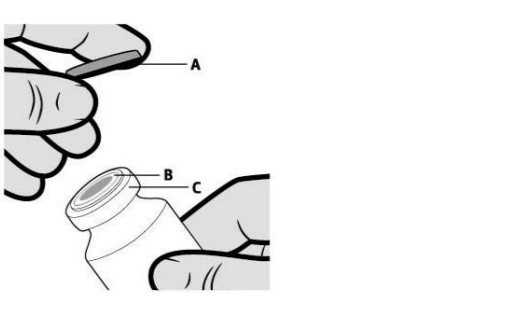
Careful and regular monitoring of the prostate gland and the breasts should be performed according to the recommended methods at least once a year (digital rectal examination and serum PSA evaluation) in patients receiving testosterone treatment, and twice a year in elderly patients and patients at risk (those with clinical or familial factors).

Besides laboratory tests for testosterone concentration in patients receiving long-term treatment with androgens, the following laboratory parameters should be tested periodically: hemoglobin, hematocrit, liver function tests and fat profile.

In patients suffering from severe heart, liver or kidney insufficiency or from ischemic heart disease, testosterone treatment may cause severe complications characterized by edema with or without heart failure. If this happens, the treatment should be stopped immediately.

Notes on handling the vial

The vial is for single use only. The content of the vial should be injected into the muscle immediately after drawing it into the syringe. After removing the plastic cap (A) do not remove the metal ring (B) or the aluminum cap (C).



TESTOSTERONE INJ PIL MWL0125