**PACKAGE LEAFLET: INFORMATION FOR THE USER**

3520
03.08.26[2]

# Testosterone undecanoate 1000 mg/4 ml solution for injection

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is available using the above name, but will be referred to as Testosterone undecanoate throughout this leaflet.

**What is in this leaflet:**

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


## 1. What Testosterone undecanoate is and what it is used for

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

**Do not use Testosterone undecanoate**
- If you are allergic to testosterone undecanoate, or any of the other ingredients of this medicine (listed in 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

Testosterone undecanoate is **not** intended for use in women.

**Warnings and precautions**
**Talk to your doctor** before taking Testosterone undecanoate if you have or ever had:
- epilepsy
- heart, kidney or liver problems
- migraine
- temporary interruptions in your breathing during sleep (apnoea), as these 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 treated for high blood pressure, as testosterone may cause a rise in blood pressure.
- 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. Seek urgent medical attention if you experience one of these symptoms.

**If you are suffering from severe heart, liver or kidney disease**, treatment with Testosterone undecanoate may cause severe complications in the form of water retention in your body sometimes accompanied by (congestive) heart failure.
The following blood checks should be carried out by your doctor before and during the treatment: testosterone blood level, full blood count.

**If your liver is not working**
No formal studies have been performed in patients with liver impairment. You will not be prescribed Testosterone undecanoate if you have ever had a liver tumour (see “Do not use Testosterone undecanoate”).

**Children and adolescents**
Testosterone undecanoate is not for use in children and adolescents. There is no data available on the use of Testosterone undecanoate in males under 18 years of age.

**Elderly patients (65 years or older)**
There is no need for your doctor to adjust the dose if you are over 65 (see *“Medical examination/follow up”*).

**Muscle building and drug tests**
Testosterone undecanoate is **not** suitable for building muscles in healthy individuals or for increasing physical strength.
Testosterone undecanoate might lead to positive results in drug tests.

**Drug abuse and dependence**
Always take this medicine exactly as your doctor or pharmacist has told you.
Abuse of testosterone, especially if you take 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. You should not abuse this medicine alone or with other anabolic androgenic steroids because it carries serious health risks. (See "Possible side effects").

**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 undecanoate, he/she will examine you to check that you do not have prostate cancer.
Your doctor will regularly examine your prostate and breast, especially if you are elderly. He/she will also take regular blood samples.
Following the use of hormonal substances such as androgen compounds, cases of benign (non-cancerous) and malignant (cancerous) liver tumours have been observed to occur.

**Other medicines and Testosterone undecanoate**
**Tell your doctor or pharmacist** if you are using or have recently used or might **use any other medicines**, including medicines obtained without a prescription. The doctor may need to adjust the dose if you are using any of the following:
- the hormone ACTH or corticosteroids (used to treat various conditions such as rheumatism, arthritis, allergic conditions and asthma): Testosterone undecanoate may increase the risk of water retention, especially if your heart and liver are not working properly
- blood-thinning tablets (coumarin derived oral anticoagulants) since this can increase the risk of bleeding. Your doctor will check the dose.
- medicines used to treat diabetes. It may be necessary to adjust the dose of your blood sugar reducing medicine. Like other androgens, testosterone may increase the effect of insulin.
  Taking SGLT-2 inhibitors (such as empagliflozin, dapagliflozin or canagliflozin) together with testosterone may increase the number of red blood cells in your blood. Your doctor may need to monitor your blood more regularly.

**Please be sure to inform your doctor if you suffer from a disturbance of blood clotting**, because this is important for your doctor to know before deciding to inject Testosterone undecanoate.

Testosterone undecanoate may also affect the results of some laboratory tests (e.g. thyroid gland). Tell your doctor or the laboratory staff that you are using Testosterone undecanoate.

**Pregnancy and breast-feeding**
Testosterone undecanoate is not for use in women and must not be used in pregnant or breast-feeding women.

**Fertility**
Treatment with high doses of testosterone preparations commonly may reversibly stop or reduce sperm production (see also under “Possible side effects”).

**Driving and using machines**
Testosterone undecanoate has no observed effect on your ability to drive or use machines.

**Testosterone undecanoate contains benzyl benzoate**
Testosterone undecanoate contains 2000 mg benzyl benzoate in each 4 ml vial which is equivalent to 500 mg/ml.

## 3. How to use Testosterone undecanoate

Your doctor will inject Testosterone undecanoate (1 vial) very slowly into a muscle. He/she will give you the injections every 10 to 14 weeks. This is enough to maintain sufficient testosterone levels without leading to a build-up of testosterone in the blood.

Testosterone undecanoate is strictly for intramuscular injection. Special care will be taken to avoid injection into a blood vessel (see “Administration”).

**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 six weeks in order to quickly reach the necessary testosterone level. This will depend on your symptoms and testosterone levels.

---

**The following information is intended for healthcare professionals only:**

At cold storage temperatures the properties of this oil-based solution might temporarily change (e.g. higher viscosity, cloudiness). If stored at cold temperature, the product should be brought to room or body temperature before use.
The solution for intramuscular injection is to be visually inspected prior to use and only clear solutions free from particles should be used.

The contents of a vial are to be injected intramuscularly immediately after opening the vial.
The medicinal product is for single use only and any unused solution should be discarded.

Administration
Special care must be given to avoid intravasal injection.

As with all oily solutions, Testosterone undecanoate must be injected strictly intramuscularly and very slowly. Pulmonary micro embolism of oily solutions can in rare cases lead to signs and symptoms such as cough, dyspnoea, malaise, hyperhidrosis, chest pain, dizziness, paraesthesia, or syncope. These reactions may occur during or immediately after the injection and are reversible. Treatment is usually supportive, e.g. by administration of supplemental oxygen.

Suspected anaphylactic reactions after Testosterone undecanoate injection have been reported.

Warnings
Careful and regular monitoring of the prostate gland and breast must be performed in accordance with recommended methods (digital rectal examination and estimation of serum PSA) in patients receiving testosterone therapy at least once yearly and twice yearly in elderly patients and at-risk patients (those with clinical or familial factors).

Besides laboratory tests of the testosterone concentrations in patients on long-term androgen therapy the following laboratory parameters should be checked periodically: haemoglobin, haematocrit, and liver function tests and lipid profile.

In patients suffering from severe cardiac, hepatic or renal insufficiency or ischemic heart disease, treatment with testosterone may cause severe complications characterised by oedema with or without congestive cardiac failure. In such case, treatment must be stopped immediately.

**Maintaining your Testosterone undecanoate 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 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.

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

**If you use more Testosterone undecanoate than you should**
Symptoms of having too much Testosterone undecanoate include:
- irritability
- nervousness
- weight gain
- long-lasting or frequent erections

Tell your doctor if you have any of these. Your doctor will inject it less often or will stop treatment.

**4. Possible side effects**
Like all medicines, this medicine can cause side effects, although not everybody gets them.
The **most common side effects** are acne and pain where the injection is given.

**Common side effects** (may affect up to 1 in 10 patients):
- abnormally high levels of red blood cells
- weight gain
- hot flushes
- acne
- enlarged prostate and associated problems
- various reactions where the injection was given (e.g. pain, bruising or irritation)

**Uncommon side effects** (may affect up to 1 in 100 patients):
- allergic reaction
- increased appetite, changes in blood test results (e.g. increased blood sugars or fats)
- depression, emotional disorder, insomnia, restlessness, aggression, or irritability
- headache, migraine, or tremor
- cardiovascular disorder, high blood pressure, or dizziness
- bronchitis, sinusitis, cough, shortness of breath, snoring, or voice problems
- diarrhoea, or nausea
- changes in liver test results
- hair loss, or various skin reactions (e.g. itching, reddening or dry skin)
- joint pain, pain in limbs, muscle problems (e.g. spasm, pain or stiffness), or an increased creatine phosphokinase in the blood
- urinary tract disorders (e.g. decreased flow of urine, urinary retention, urge to pass urine at night)
- prostatic disorders (e.g. prostatic dysplasia, or hardening or inflammation of the prostate), changes in sexual appetite, painful testicles, painful, hardened or enlarged breasts, or increased levels of male and female hormones
- tiredness, general feeling of weakness, excessive sweating, or night sweat

**Rare side effects** (may affect up to 1 in 1000 patients):
- The oily liquid Testosterone undecanoate may reach the lungs (pulmonary microembolism 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. The patient should therefore be observed during and immediately after each injection in order to allow for early recognition of possible signs and symptoms of pulmonary oily microembolism.

Suspected anaphylactic reactions after Testosterone undecanoate injection have been reported.

In addition to the side effects listed above the following have been reported following treatment with preparations containing testosterone: 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 eyes (jaundice).

Treatment with high doses of testosterone preparations commonly stops or reduces sperm production, although this returns to normal after treatment ceases. Testosterone replacement therapy of poorly functioning testicles (hypogonadism) can in rare cases cause persistent, painful erections (priapism). High-dosed or long-term administration of testosterone occasionally increases the occurrences of water retention and oedema (swelling due to fluid retention).

For testosterone products in general a common risk of increased red blood cell count, haematocrit (percentage of red blood cells in blood) and haemoglobin (the component of red blood cells that carries oxygen), were observed by periodic blood tests.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Testosterone undecanoate**
Keep this medicine out of the sight and reach of children.
This medicinal product does not require any special storage conditions.

**Do not** use this medicine after the expiry date which is stated on the carton and the label after "EXP". The expiry date refers to the last day of that month.

If the solution becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.

**Do not** throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

**6. Contents of the pack and other information**
**What Testosterone undecanoate contains**
Each ml solution for injection contains 250 mg testosterone undecanoate corresponding to 157.9 mg testosterone.
Each vial with 4 ml solution for injection contains 1000 mg testosterone undecanoate corresponding to 631.5 mg testosterone.

The other ingredients are benzyl benzoate and refined castor oil.

**What Testosterone undecanoate looks like and contents of the pack**
Testosterone undecanoate is a clear, yellowish oily liquid. The contents of the packs are:
1 brown glass vial with 4 ml solution for injection.

**Manufacturer and Product Licence holder**
Manufactured by Laboratorios Farmalan, S.A., Calle La Vallina, s/n, Poligono Industrial Navatejera, 24193- Villaquilambre, Leon, Spain.

Procured from within the EU by Product Licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex HA1 1XD.
Repackaged by Servipharm Ltd.

| POM | PL 20636/3520 |
|---|---|

Leaflet revision and issue date (Ref) 03.08.26[2]

Blind or partially sighted?
Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the leaflet in a format suitable for you.

**Notes on handling the vial:**
The vial is for single use only. The content of a vial is to be injected intramuscularly immediately after drawing up into the syringe. After removal of the plastic cap (A) do not remove the metal ring (B) or the crimp cap (C).

