**PACKAGE LEAFLET**

**Package leaflet: Information for the user**

**Testosterone Enanthate/Norma 250 mg/ml solution for injection**
testosterone enanthate

**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.

**What is in this leaflet**

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


## 1. What Testosterone Enanthate/Norma is and what it is used for

**Testosterone Enanthate/Norma** is used to replace testosterone in adult men for the treatment of various health problems caused by testosterone deficiency (male hypogonadism). This condition must be confirmed by two separate testosterone blood counts and also include clinical symptoms, such as:
- impotence
- infertility
- low sex drive
- fatigue
- depressive mood
- bone loss due to low hormone levels

## 2. What you need to know before you use Testosterone Enanthate/Norma

**Do not use Testosterone Enanthate/Norma**
- if you are allergic to testosterone enanthate or any of the other ingredients of this medicine (listed in section 6),
- if you have an androgen-dependent carcinoma (tumour) of the prostate or male mammary gland,
- if you have hypercalcemia (excess calcium in the blood) secondary to malignant tumours,
- if you have or have had a liver tumour,
- if you suffer from kidney disease,
- if you have high blood pressure,
- if you suffer from severe liver dysfunction.

**Warnings and precautions**

**Testosterone Enanthate/Norma** is not indicated for increasing muscle growth in healthy individuals or for enhancing physical performance.

**Consult your doctor before using Testosterone Enanthate/Norma if you have or you ever had:**
- fluid retention that causes swollen legs (oedema),

- temporary pauses in breathing during sleep (apnoea), as these may get worse,
- blood clotting problems:
  - bleeding disorders (i.e. haemophilia),
  - thrombophilia (a blood clotting abnormality that increases the risk of thrombosis - blood clots in the blood vessels),
  - factors that increase your risk for blood clots in a vein: previous blood clots in a vein; smoking; obesity; cancer; physical inactivity; if any of your close family members 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 with aging.

How to recognise a blood clot: painful swelling of a leg or sudden change in skin colour, e.g. turning pale, red or blue; sudden breathlessness, sudden unexplained cough which may bring up blood; or sudden chest pain; severe lightheadedness or dizziness; severe stomach pain; sudden loss of vision. Seek urgent medical attention if you experience any of these symptoms.

Tell your doctor if you have high blood pressure or if you are treated for high blood pressure, as testosterone may cause rise in blood pressure.

If you suffer from a severe heart, liver, or kidney disease, treatment with **Testosterone Enanthate/Norma** may lead to serious complications, such as fluid retention in the body, sometimes accompanied by (congestive) heart failure.

**Drug Abuse and addiction**
Always take this medicine exactly as your doctor or pharmacist has told you.
Testosterone abuse, 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 be fatal), mental health and/or liver.

Individuals who have abused testosterone may become dependent and may experience withdrawal symptoms when the dosage changes significantly or is stopped abruptly. You should not abuse this medicine alone or with other anabolic androgenic steroids because it poses serious health risks (see section “Possible side effects”.)

**Medical examinations/consultations**
As a precaution, you should regularly take andrological check-ups, including a digital rectal examination of the prostate.
Before and during treatment, your doctor should perform the following blood tests: blood testosterone levels, complete blood count.

Following the use of testosterone enanthate, benign (non-cancerous) and malignant (cancerous) liver tumours have been observed, which may cause life-threatening intra-abdominal bleeding.
If you experience upper abdominal discomfort, contact your doctor who will carry out examinations to rule out liver tumour.

Elderly patients treated with androgens may be at increased risk of developing prostatic hyperplasia (enlargement of the prostate). Although there is no clear evidence that androgens cause prostate carcinoma (prostate tumour), they may promote its growth if it is already present. Therefore, before prescribing testosterone-based therapy, your doctor will rule out the prostate cancer.

**Testosterone Enanthate/Norma** may cause excessive sexual stimulation. If this occurs, contact your doctor.

If you are elderly, your doctor will closely monitor this medicine to ensure it does not cause excessive undesirable physical, nervous, or mental stimulation.

Like all oily solutions, **Testosterone Enanthate/Norma** should be injected only intramuscularly and very slowly. Pulmonary microembolism of oily solutions (small oil droplets in the arteries of the

lungs) may cause signs and symptoms such as coughing, breathing difficulty, and chest pain. Other signs and symptoms may also appear, including discomfort, sweating, dizziness, paresthesia (altered sensation, such as tingling), or fainting. These reactions may occur during or shortly after the injection and are reversible. Treatment consists of supportive measures, such as oxygen administration.

**Testosterone Enanthate/Norma** should not be used in women, as it can cause jaundice (yellowing of the skin and the whites of the eyes) and signs of virilization, e.g. acne, abnormal hair growth in areas of the body typical of males, voice changes.

**For those who engage in sports activities**
Use of the medication without therapeutic need constitutes doping and can still result in a positive anti-doping test.

**Additional information on special populations**

***Children and adolescents***
**Testosterone Enanthate/Norma** is not indicated in children and adolescents.
In children, testosterone, other than its masculinizing effects, it may also affect bone maturation, leading to reduced height growth.

***Elderly patients (65 years or older)***
No dose adjustment is required for elderly patients (see section "Medical examination/consultations").

***Patients with impaired liver function***
The use of **Testosterone Enanthate/Norma** is contraindicated in patients who have or have had liver tumours (see section "Do not use **Testosterone Enanthate/Norma**").

**Other medicines and Testosterone Enanthate/Norma**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking any of the following medicines:
- medicines used to treat neurological conditions and sleep problems (barbiturates, e.g. phenobarbital or other enzyme inducers) as they may reduce the effectiveness of **Testosterone Enanthate/Norma**,
- medicines used to treat pain and inflammation (oxyphenbutazone),
- medicines used to thin the blood (oral anticoagulants, coumarin derivatives) as they may increase the risk of bleeding. Your doctor will check the dosage. Your doctor will also monitor closely your coagulation parameters,
- medicines used to treat diabetes. The dose of medicines that lower blood sugar may need to be adjusted. Like other androgens, testosterone may enhance the effect of insulin.

Remember to tell your doctor if you suffer from a blood coagulation disorder, because it is important for your doctor to know this before deciding to give you a **Testosterone Enanthate/Norma** injection.

**Fertility**
Testosterone replacement therapy may reversibly reduce spermatogenesis (sperm production – see section 4).

**Driving and using machines**
**Testosterone Enanthate/Norma** has no effect on the ability to drive or use machines.

**Testosterone Enanthate/Norma contains benzyl benzoate**.
This medicine contains 342.0 mg of benzyl benzoate in each 1 ml ampoule.

**Testosterone Enanthate/Norma contains castor oil**.

It may cause severe allergic reactions.

## 3. How to use Testosterone Enanthate/Norma

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This medicine is for intramuscular use only.
The oily solution should be injected very slowly (see section "Warnings and precautions" and "Possible side effects") immediately after being drawn into the syringe.

**The recommended dose is:**

- for the development and stimulation of androgen-dependent target organs and for the initial treatment of deficiency symptoms: one ampoule of 250 mg intramuscularly every 2-3 weeks.
- for the maintenance of an adequate androgenic effect, one ampoule of 250 mg intramuscularly every 3-4 weeks.

Depending on the individual needs, your doctor may decide to shorter intervals between injections, while in many cases longer intervals of up to 6 weeks between injections may also suffice.

Before starting treatment, and from time to time at the end of an interval between injections, your doctor will measure your blood testosterone levels. Lower-than-normal testosterone levels indicate the need to shorten the interval between injections, while the interval should be extended in case of elevated levels.

**If you use more Testosterone Enanthate/Norma than you should:**
**If you accidentally ingest/take too much Testosterone Enanthate/Norma, contact your doctor immediately or go to the nearest hospital.**
No special treatment is necessary; your doctor will decide whether you should discontinue treatment or reduce the dose.

If you have any doubts on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

For side effects associated with the use of androgens, please also refer to section "Warnings and precautions".

The **most common** side effects of **Testosterone Enanthate/Norma** are pain at the injection site, itching (erythema) at the injection site, cough and/or breathing difficulty (dyspnea) during or immediately after the injection.

**Common** side effects are: increased red blood cell count, haematocrit (percentage of red blood cells in the blood) and haemoglobin (the oxygen-carrying red blood cell component), as detected in periodic blood tests, and weight gain.

The side effects listed below are derived from spontaneous reports and scientific literature; therefore, it is not possible to estimate their frequency from the available data.

- benign and malignant liver tumours
- allergic reaction
- increased number of red blood cells in the blood (polycythaemia)
- increased or decreased sexual desire (increased or decreased libido)
- depression

- difficulty sleeping (insomnia)
- restlessness
- aggression
- emotional disturbance
- irritability
- headache, migraine or tremor
- dizziness
- redness of the skin and sudden feeling of fever throughout the body (hot flush)
- high blood pressure (hypertension)
- cough, bronchitis, sinusitis, snoring
- difficulty breathing (dyspnoea)
- changes in voice sound and tone (dysphonia)
- frequent or loose bowel movements (diarrhoea)
- feeling sick (nausea)
- yellowing of the skin and whites of the eyes (jaundice)
- skin reactions such as:
    - acne
    - hair loss (alopecia)
    - skin rash
    - itching and small spots on the skin (urticaria)
    - itching
    - redness of the skin (erythema)
    - dry skin
- excessive sweating (hyperhidrosis)
- pain in the joints (arthralgia), arms and legs (pain in the extremities), or muscles (myalgia)
- various types of reactions at the injection site (pain, itching, redness, hardness, swelling, inflammation)
- tiredness (fatigue)
- weakness (asthenia)
- increased prostate-specific antigen (PSA) (increased immune response)
- abnormal liver function tests (e.g. increased aspartate aminotransferase)
- increased glycosylated haemoglobin
- increased testosterone in the blood
- increased estradiol in the blood
- hardening or abnormal growth of the breasts in males (gynaecomastia)
- breast pain
- testicular pain
- enlarged prostate and associated disorders
- increased appetite, changes in certain blood tests (e.g. increased blood sugar or fat)
- muscle problems (e.g. spasm or stiffness, muscle strain)
- increased creatine phosphokinase in the blood
- urinary tract disorders (e.g. decreased urinary flow, urinary retention, need to urinate at night, difficulty urinating)
- prostate disorders (e.g. prostate dysplasia or hardening or inflammation of the prostate).

In **rare** cases, injections of oily solutions such as **Testosterone Enanthate/Norma,** can lead to a clot in a blood vessel in the lungs (pulmonary microembolism). This can lead to the following symptoms:
- cough
- difficulty in breathing (dyspnea)
- feeling unwell and/or dizzy
- excessive sweating (hyperhidrosis)
- chest pain
- abnormal skin sensations, such as burning, tingling, itching, or prickling (paresthesia)
- fainting

These reactions may occur during or immediately after the injection and they are reversible.

High-dose or prolonged testosterone administration can induce anxiety, hypercalcemia (increased blood calcium levels), and may increase the tendency to fluid retention (accumulation of fluid in tissues), and edema (swelling). Your doctor will monitor you closely if you show such tendency, particularly if you suffer from severe kidney or heart problems, asthma, or epilepsy.

High doses of testosterone or its derivatives inhibit the secretion of gonadotropins (the hormones that stimulate the testes), resulting in testicular atrophy.
Prolonged, high-dose treatment with **Testosterone Enanthate/Norma** reversibly inhibits or reduces spermatogenesis.

If, in individual cases, frequent or persistent erections (priapism) occur, your doctor will decide whether to reduce the dosage or discontinue treatment to avoid injury of the penis.

Hostility/aggressiveness and increased hair growth have been reported during treatment with testosterone-containing medicines.

**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 ADR Reporting Website: https://medicinesauthority.gov.mt/adrportal
By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Testosterone Enanthate/Norma

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Protect it from light.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. The expiry date applies to the product in its unopened packaging, stored correctly.

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 protect the environment.

## 6. Contents of the pack and other information

**What Testosterone Enanthate/Norma contains:**
- The active substance is testosterone enanthate.
  1 ampoule contains 250 mg of testosterone enanthate (equivalent to 180 mg of testosterone) in oily solution.
- The other ingredients are: Benzyl benzoate, Castor oil.

**What Testosterone Enanthate/Norma looks like and contents of the pack**
**Testosterone Enanthate/Norma** is a clear, yellowish, oily solution.

Available in a cardboard box containing a brown glass ampoule and a package leaflet.

**Marketing Authorisation Holder and Manufacturer**

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