

PATIENT INFORMATION LEAFLET

Testosterone Enantate 250mg/ ml Solution for Injection Testosterone Enantate

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 Enantate is and what it is used for
2. What you need to know before you use Testosterone Enantate
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1. What Testosterone Enantate is and what it is used for

Testosterone Enantate is a manufactured version of the naturally occurring male sex hormone, testosterone.

It is used in adult men for testosterone replacement to treat various health problems caused by a lack of testosterone (male hypogonadism). This 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 use Testosterone Enantate

Do not use Testosterone Enantate:

- if you are allergic to Testosterone Enantate or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from androgen (steroid hormone) dependent prostate cancer or breast cancer
- if you have high calcium levels in your blood
- if you have or have had tumours of the liver
- if you have kidney disease (nephrosis)

Warnings and precautions

Talk to your doctor before using Testosterone Enantate if you:

- have liver problems including severe upper abdominal complaints
- have a tendency to retain fluid causing, for example, swelling of the ankles
- suffer from sleep apnoea (interrupted breathing during sleep), as this may get worse
- are suffering from severe heart, liver or kidney disease; treatment with Testosterone Enantate may cause severe complications in the form of water retention in your body sometimes accompanied by (congestive) heart failure
- have high blood pressure or if you are being treated for high blood pressure as testosterone may cause a rise in blood pressure
- have or have ever had blood clotting problems; 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.

- have epilepsy, migraine, diabetes mellitus or cancerous bone disease.

Testosterone Enantate should not be used in women because they may develop signs of virilisation, e.g. acne, increased hair growth on the face or body and voice changes.

Male hormones such as Testosterone Enantate are not suitable for increasing muscular development in healthy people or for increasing physical ability.

Medical examination/consultation

Male hormones may increase the growth of prostate cancer and enlarged prostate glands (benign prostatic hypertrophy). Before your doctor injects Testosterone Enantate, s/he will examine you to check that you do not have prostate cancer. If you are older, you may be at an increased risk for the development of prostate enlargement when using Testosterone Enantate. Although there is no clear evidence that sex hormones such as Testosterone Enantate actually generate cancer of the prostate, they can enhance the growth of any existing cancer of the prostate.

As a precaution, regular examinations of the prostate are recommended in men, especially if you are elderly.

If you are on long-term androgen therapy blood tests should be carried out periodically (see section "Possible side effects").

The following blood checks should be carried out by your doctor before and during the treatment:

- testosterone blood level and
- full blood count

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. Although it is improbable that a tumour will occur, these would present a health concern. In isolated cases, internal bleeding could occur from these tumours, which might endanger life. Thus you should always seek the immediate emergency attention of a doctor when you suffer severe abdominal pains. Not all unusual sensations you might feel in your upper abdomen can be counted as a possible sign of tumour or bleeding. Those that do not disappear within a short time should however better be brought to your doctor's attention.

Additional information on special populations

Children and adolescents

Testosterone Enantate is not indicated for use in children and adolescents (see "Warnings and precautions").

In children and adolescents, earlier development of male secondary sex characteristics (masculinisation) may occur. Testosterone can affect bone growth and in some cases reduce final height.

Safety and efficacy have not been adequately determined in children and adolescents.

Elderly patients (65 years or older)

Limited data do not suggest the need for a dosage adjustment in elderly patients (see "Warnings and precautions").

Patients with impaired liver function

No formal studies have been performed in patients with liver impairment. The use of Testosterone Enantate is contraindicated in men with past or present liver tumours (see “Do not use Testosterone Enantate”).

Patients with impaired kidney function

No formal studies have been performed in patients with kidney impairment.

Other medicines and Testosterone Enantate

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 having any of the following as they may be affected or affect Testosterone Enantate:

- Medicines used to treat nervousness and sleep problems (barbiturates or other enzyme inducers)
- Medicines used to treat pain or inflammation (oxyphenbutazone)
- Anticoagulants which are used to thin the blood, e.g. warfarin
- Medicines for the treatment of diabetes, e.g. metformin. 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.

Pregnancy and breast-feeding

Testosterone Enantate is intended for use by men only. It is not indicated in pregnant or breast-feeding women. Testosterone Enantate should not be used during pregnancy due to the possibility of virilisation (development of male sex characteristics) of the female foetus.

Fertility

Treatment with high doses of testosterone preparations may reversibly reduce sperm production (see “Possible side effects”).

Driving and using machines

Testosterone Enantate should not affect your ability to drive or use machinery.

Testosterone Enantate contains benzyl benzoate

Testosterone Enantate contains 342 mg benzyl benzoate per ampoule. Benzyl benzoate can be metabolised into benzyl alcohol and benzoic acid once the medicine is administered. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

Testosterone Enantate must not be given to premature babies or neonates.

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 “Side effects”).

3. How to use Testosterone Enantate

Testosterone Enantate may cause toxic reactions and allergic reactions in infants and children up to 3 years old.

Testosterone Enantate is administered by a doctor or nurse.

It is given by very slow injection into a muscle, usually every 2 to 3 weeks. The injections are continued for as long as your doctor considers necessary, depending on your individual circumstances. Men receiving long term treatment may later be given injections at 3 to 6 week intervals.

Your doctor will measure your blood testosterone levels before starting treatment and occasionally during the treatment at the end of an injection interval and adjust your dose as necessary.

During treatment, it is advisable for men to have a regular prostate check by a doctor.

If you use more Testosterone Enantate than you should

As Testosterone Enantate is administered in hospital by a healthcare professional it is most unlikely that you will be given the wrong dose. If you have any concerns about your dose or the use of this product speak to your doctor.

If you forget to use Testosterone Enantate

Please adhere to the timelines on the injection intervals agreed with your doctor for optimal efficacy of the treatment.

If you stop using Testosterone Enantate

When Testosterone Enantate is stopped, symptoms of testosterone deficiency may reoccur.

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

4. Possible side effects

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

Some people may be allergic to Testosterone Enantate. If you experience an allergic reaction you should stop using Testosterone Enantate and tell your doctor straight away or contact the accident and emergency department of your nearest hospital. Signs of an allergic reaction may include:

- severe rash
- swallowing or breathing problems
- swelling of your lips, face, throat or tongue
- weakness, feeling dizzy or faint
- nausea

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

- Increase in red blood cell count, haematocrit (percentage of red blood cells in blood) and haemoglobin (the component of red blood cells that carries oxygen); these are identified by periodic blood tests
- Weight gain

Rare side effects (may affect up to 1 in 1000 patients):

The oily liquid (Testosterone Enantate) 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 oil microembolism.

Not known (frequency cannot be estimated from the available data):

- Liver tumours have been observed which can cause serious internal bleeding. Tell your doctor if you notice any new pain in the stomach that is severe or persists
- High levels of red blood cells (polycythaemia), blood circulation problems, high levels of calcium in the blood
- Abnormal liver function test results, yellowing of the skin and eyes (jaundice), enlarged liver
- Increased blood testosterone levels
- Increase in blood estradiol
- High blood pressure
- Coughing, bronchitis, sinusitis, snoring
- Shortness of breath
- Feeling dizzy
- Acne, hair loss, skin reactions such as redness, rash, urticaria (raised red spots), itching, dryness of the skin, “pins and needles”, male pattern baldness
- Various kinds of injection site reactions including pain, itching, hardening, swelling, bruising and inflammation
- Increase in a prostatic-specific antigen (increased immune response)

- Increased or decreased interest in sex, abnormal overdevelopment of the breasts in a man, early onset of puberty (Testosterone Enantate is not indicated for use in children – see section 2 “Warnings and precautions”)
- Feeling pain in the breast
- In high doses or over a long period of time, retention of too much water, and even swelling of the ankles may occur
- Men may develop reduced sperm count, and frequent or persistent painful erections (if this happens, it is important to tell your doctor as it can injure the penis)
- Enlarged prostate and associated problems
- Increased appetite, changes in blood test results (e.g. increased blood sugars or fats)
- Increase in 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), painful testicles, painful, hardened or enlarged breasts
- Headache, migraine, tremor, weakness, depression, anxiety, sleeplessness, restlessness, aggression, irritability
- Emotional disorder
- Changes in bone growth (increase or premature stoppage), joint pain, pain in limbs, muscle problems (e.g. spasm, pain or stiffness)
- Stomach problems, feeling sick, diarrhoea
- Tiredness
- Excessive sweating
- Hot flush
- Changes in the sound or tone of the voice.

Hostility, nervousness and increased hair growth have been reported under treatment with testosterone containing preparations.

Reporting of side effects:

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the internet 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 Enantate

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

The information in Sections 5 and 6 is primarily for healthcare professionals.

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

Testosterone Enantate ampoules should be stored away from light.

Testosterone Enantate should be inspected visually prior to administration and only clear solution free from particles should be used.

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 Enantate contains

The active substance is Testosterone Enantate. Each 1 ml ampoule contains 250 mg testosterone enantate (the equivalent of about 180mg testosterone) in oily solution. The other ingredients are: benzyl benzoate and castor oil refined.

What Testosterone Enantate looks like and contents of pack

Testosterone Enantate is a clear, yellowish oily liquid. Each ampoule is clear glass and contains 1 ml of solution for injection. They are supplied in packs of 3 ampoules.

Marketing Authorisation Holder

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Bayer AG, Berlin, Germany.

This leaflet was last revised in November 2025

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