

Package leaflet: Information for the user

Testosterone enantate EVER Pharma 250 mg/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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What <Product name> is and what it is used for

<Product name> contains testosterone enantate, a synthetic 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.

<Product name> should be injected deeply into the gluteal muscle. There it can be stored and gradually released to the blood circulation.

2. What you need to know before you use <Product name>

Do not use <Product name>

- 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 benign growth (adenoma) of the prostate

<Product name> **is not** intended for use in women.

Warnings and precautions

Talk to your doctor before using <Product name>, if you have or have ever had

- liver problems including severe upper abdominal complaints
- a tendency to retain fluid causing, for example, swelling of the ankles
- a severe heart, liver or kidney disease; treatment with testosterone may cause severe complications in the form of water retention in your body, sometimes accompanied by (congestive) heart failure
- high blood pressure or if you are being treated for high blood pressure, as testosterone may cause a rise in blood pressure
- blood clotting problems, such as thrombophilia (an abnormality of blood coagulation that increases the risk of thrombosis, i.e. blood clots in blood vessels), since testosterone treatment may increase the risk of thrombosis.

Factors that increase your risk for blood clots in a vein: previous blood clots in a vein; smoking; obesity; cancer; immobility; getting older; 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).

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.
 - suffer from sleep apnoea (interrupted breathing during sleep), as this may get worse
- <Product name> may also affect the results of some laboratory tests (e.g. Thyroid). Tell your doctor or laboratory staff that you are taking <Product name>.

Muscle building and drug test

Male hormones such as testosterone enantate are not suitable for building muscles in healthy people or for increasing physical ability.

<Product name> 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.

Medical examination/consultation

Male hormones may increase the growth of prostate cancer and enlarged prostate glands (benign prostatic hypertrophy). Before your doctor injects <Product name>, 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 <Product name>. 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 4 “Possible side effects”).

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.

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, but 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

<Product name> is **not** for use in children and adolescents. Safety and efficacy have not been adequately established in children and adolescents.

Elderly patients (65 years or older)

Limited data do not suggest the need for a dosage adjustment in elderly patients.

Patients with impaired liver function

No formal studies have been performed in patients with liver impairment. <Product name> will not be prescribed for you if you have ever had a liver tumour (see “Do not use <Product name>”).

Other medicines and <Product name>

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor if you are using any of the following as they may be affected by or may affect <Product name>:

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- Medicines used to treat pain or inflammation (e.g. oxyphenbutazone)
- Anticoagulant tablets which are used to thin the blood, e.g. warfarin
- Medicines for the treatment of diabetes, e.g. metformin. It may be necessary to adjust the dose of your blood sugar reducing medicine.

Pregnancy and breast-feeding

<Product name> 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 may temporarily stop or reduce sperm production (see section 4 “Possible side effects”).

Driving and using machines

<Product name> should not affect your ability to drive or use machinery.

<Product name> contains benzyl benzoate

This medicinal product contains 342 mg benzyl benzoate per ampoule of 1 mL.

3. How to use <Product name>

<Product name> is administered by a health care professional.

It is given by very slow injection into the gluteal 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 forget to use <Product name>

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

If you stop using <Product name>

When the treatment 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 <Product name> 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

Other side effects (frequency cannot be estimated from the available data):

- Liver tumours have been observed. 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
- Acne, hair loss, skin reactions such as rash, urticaria (raised red spots), itching, “pins and needles”, male pattern baldness
- Various kinds of injection site reactions including pain, itching, hardening, swelling and inflammation
- Increase in a prostatic-specific antigen (PSA)
- Increased or decreased interest in sex, abnormal overdevelopment of the breasts in a man, prostate problems, early onset of puberty (<Product name> is not indicated for use in children – see section 2 “Warnings and precautions”)
- 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 erections (if this happens, it is important to tell your doctor as it can injure the penis)
- Headache, weakness, depression, anxiety
- Changes in bone growth (increase or premature stoppage)
- Stomach problems, feeling sick.

Injections of oily liquids such as <Product name> have been associated with reactions such as cough, shortness of breath and chest pain. There may be other signs and symptoms including feeling generally unwell, excessive sweating, dizziness, “pins and needles”, or fainting.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting

system listed in [Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

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 label. The expiry date refers to the last day of that month.

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 <Product name> contains

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

What <Product name> looks like and contents of the pack

<Product name> is a clear, yellowish oily liquid.

Each ampoule is amber glass and contains 1 ml of solution for injection.

They are supplied in packs of 1, 3, 5 or 10 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

< {Name of the Member State} > < {Name of the medicine} >

< {Name of the Member State} > < {Name of the medicine} >

This leaflet was last revised in 17 July 2024.

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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., high 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 an ampoule are to be injected intramuscularly immediately after opening the

ampoule.

The medicinal product is for single use only and any unused solution should be discarded.

Administration

For intramuscular injection only. Care should be taken to inject <Product name> deeply into the gluteal muscle following the usual precautions for intramuscular administration. Special care must be taken to avoid intravascular injection.

As with all oily solutions, <Product name> must be injected strictly intramuscularly and very slowly (over two minutes). 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 <Product name> 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.

Notes on handling the OPC (One-Point-Cut) ampoule:

There is a pre-scored mark beneath the coloured point on the ampoule eliminating the need to file the neck. Prior to opening, ensure that any solution in the upper part of the ampoule flows down to the lower part. Use both hands to open; while holding the lower part of the ampoule in one hand, use the other hand to break off the upper part of the ampoule in the direction away from the coloured point.

